



The Silbione[®] Difference
Silicones for Healthcare Applications

Bluestar Silicones. Delivering Your Potential.

BLUESTAR
SILICONES

Silbione® Silicones Designed Specifically for Healthcare Applications

Dental & Audiology



Dental and Audiology silicone materials are designed for high fidelity, reliable reproduction and impressions made in a very short period of time.

Bluestar Silicones, with 20 years of experience in Dental and Audiology materials, continuously develops tin-free innovation and provides tailor-made solutions, manufactured in a state-of-the-art ISO 13485 environment.

Orthotics, Prosthetics & Comfort Care



Comfort is the priority in healthcare applications. Silbione® LSRs, RTVs, Gels and Foams deliver outstanding performance to enable the production of comfort care devices. The cushioning effects, form definition and life-like feel of Silbione® silicones, make them ideal materials for prosthetic devices such as liners, artificial limbs and pressure relief cushions.

Bluestar Silicones offers a complete range of Silbione® soft silicone technologies that combine comfort with high mechanical properties for producing a variety of devices for the prosthetic market.

Medical Devices



Bluestar Silicones offers a range of Silbione® silicones designed specifically for medical devices including liquid silicone rubber (LSR), high-consistency rubber (HCR), Room Temperature Vulcanized (RTV) elastomers, adhesives, gels and specialty fluids. Silbione® LSRs offer the distinctive advantages of easy processing, easy release and high performance physical properties.

The excellent mechanical characteristics of Silbione® HCRs make them ideal for a variety of applications including balloon catheters and medical tubing.

Skin Care & Wound Management



For wound management, Silbione® Skin Adhesives gels gently adhere to dry skin and are easily removed without damaging new skin formation.

Silbione® Skin Adhesives silicone technology can be used in conjunction with other wound treatment technologies to optimize the final dressing performance.

Bluestar Silicones is one of the world's leading fully integrated silicone manufacturers with applications and research laboratories, production sites and sales offices located around the globe.

We focus on developing state-of-the-art application expertise to help our customers challenge their boundaries.

At Bluestar Silicones, we're more than just high quality silicone products. We are dedicated people located around the globe committed to your success. From technical support, to customized formulations, to biocompatibility support, Bluestar Silicones has the people in place when and where you need them.

Bluestar Silicones is dedicated to serving the Healthcare market by improving the quality of medical and healthcare devices and building a lasting partnership you can rely upon. A basic silicone producer for more than 50 years, Bluestar Silicones is committed to serving its customers by living to standards of product stewardship, offering you extensive service and material expertise.

Why silicones?

As one of the most tested biomaterials, silicones are increasingly used in healthcare and medical applications for their biocompatibility and high performance physical properties.

- Biocompatibility
- Hypoallergenic
- Strength and Durability
- Flexibility
- Bacterial resistance
- Sterilisability
- Realistic skin feel
- Stability
- Lubricity
- Phthalate-free

Bluestar Silicones updated in 2012 their Healthcare Product Guidelines, supporting the sales of its healthcare grade Silbione® silicone products to customers involved in manufacturing of medical devices and healthcare products for use on or in the body for less than 30 days.

Biocompatibility



Bluestar Silicones believes in the safety and efficacy of its silicone products for healthcare and medical applications. Many of our products have been tested to meet US FDA, USP Class VI and ISO 10993 requirements and select products are supported by a Master File (MAF) on file with the FDA Center for Devices and Radiological Health (CDRH). For specific biocompatibility data, please contact your Bluestar Silicones representative.

Technical Support & Customization



Bluestar Silicones can help create new opportunities to improve your product performance and productivity, as well as achieving cost savings and efficiencies. Our technical representatives are happy to help... put our team to the test!

Value-based Innovation



Silicones satisfy new market needs day after day. Bluestar Silicones' mindset is to contribute to the future of healthcare by promoting innovation at an affordable price. A complete team of experts is dedicated to develop new solutions and provide formulation modification and improvements.

Quality & Certification



You can rest assured that our Silbione® brand silicones are manufactured in a clean environment to ensure we meet the appropriate healthcare grade levels for purity, quality, and lot-to-lot consistency.

Explore the Silbione[®] Difference

- With enhanced final product performance (durability, purity, transparency, consistency, low weight, mechanical properties, special application performance).

Satisfy your customers

Delivering
Your Potential
with a partner
you can trust

Improve your competitiveness

- Through improved productivity, with fine tuned products for your tailor-made process.
- By working hand-in-hand with our application chemists in our laboratories near you or on your manufacturing process.
- Through increased efficiency with very reactive built-in polymer chemistry.

Differentiate your offering

- Our customized solutions can help your products stand out.
- Personalized service, rapid response.

Peace of mind

- On-staff board certified PhD toxicologist.
- Regulatory and biocompatibility support.
- Readily available biocompatibility data.
- Purity & Quality achieved in a clean and dedicated manufacturing environment with experienced professionals.



A quality system certified to NF EN ISO 9001: 2008 and NF EN / AS 9100 standard

- Regulatory assistance
- Quality assurance throughout the world
- Dynamic innovation based on partnership
- The assurance of an ecological solution



An ongoing commitment to safety, protection of health and the environment

Having signed its name to the U.I.C. (Chemical Industry's Union) commitment to progress, Bluestar Silicones is committed to manufacturing its products and carrying out its operations with a continuous focus on improving safety and protecting health and the environment.

Bluestar Silicones throughout the world

Commonwealth of Independent States (CIS), Middle East, Eastern Europe, Africa

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Customer Service

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Italy

Caronno, in Italy, is ISO 13485 certified and specializes in RTV-2 silicone elastomers for dental and other healthcare applications, including advanced woundcare with products manufactured in an ISO Class clean room.

Bluestar Siliconi Italia SpA

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Germany, Switzerland, Austria

Lübeck, in Germany, specializes in healthcare grade RTV-2s and gels for a variety of healthcare applications including skin adhesives, wound care and external breast prostheses applications.

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USA - Canada

York, in South Carolina, USA, is the new US site of Bluestar Silicones, including specific workshops and an R&D team dedicated to the healthcare market. The York site produces a full range of silicone technologies including LSRs, HCRs, RTVs, adhesives and specialty fluids for a wide variety of healthcare applications

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China

Shanghai, in China, comprises a new workshop including a clean room dedicated to healthcare regulatory market products. It manufactures RTV-2s and gels material for dental impression and duplication, orthotics and prosthetics. Along with a dedicated R&D team, it supports local and global customers that manufacture healthcare products in Asia.

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Dental & Audiology

The best in class tailor-made technology

Dental and Audiology Silicone materials are designed for high fidelity, reliable reproduction and impressions made in a very short period of time. Bluestar Silicones, with 30 years of experience in Dental and Audiology materials, develops constant innovation, and provides tailor-made solutions, manufactured in a state-of-the-art environment.

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The best in class tailor-made technology

Silbione® VPS Impression Materials

Silbione® VPS range is composed of putties (pastes for first impression) and bodies (fluids for second impression) of addition cure silicones which are at the forefront of silicone dental impression materials.

Our large range of impression materials, with a very high level of hydrophilicity, high thixotropy but very fluid under shear, are easy to handle during use.

PH: Putty Hard, PS: Putty Soft, PHQ: Putty Hard Quick
 PSQ: Putty Soft Quick, LB: Light Body, RB: Regular Body
 LBQ: Light Body Quick, HB: Heavy Body, BR: Bite Registration

→ These products can be customised upon request.

SILBIONE®

	Products	Color	Taste	Classification		Mix Ratio	Hardness Shore A	Specific Gravity (g/cm³)	Maximum Working Time	Total Setting Time
				ISO 4823	ADA19					
Putty	RTV 4370 A/B PH	reddish purple	-	type 0	type 1 very high	1:1	70	1.55	2'00"	3'00"
	RTV 4371 A/B PHQ	military green	-						1'15"	2'00"
	RTV 4770 A/B PHQ	blue	-						1'15"	2'15"
	RTV 4360 A/B PS	yellow	-				60		2'00"	3'00"
	RTV 4361 A/B PSQ	dark blue	-						1'15"	2'00"
Body	RTV 4353 A/B LB	bright green	-	type 3	type 1 low	1:1	53	1.37	2'15"	3'30"
	RTV 4348 A/B LBQ	pumpkin orange	-				48		1'30"	2'00"
	RTV 4358 A/B RB	purple	-				58		1.42	2'15"
	RTV 4760 A/B RB	purple blue	mint	type 2	type 1 medium viscosity	5:1	60	1.46	2'30"	4'30"
	RTV 4760 A/B RBQ	purple blue							1'15"	2'15"
	RTV 4362 A/B HB	antical pink	-	type 1	type 1 high viscosity	1:1	62	1.45	2'30"	4'00"
	RTV 4765 A/B HB	purple	-						5:1	65
	EF	RTV 4388 A/B BRQ	blue	mint	-	-	1:1	88	1.7	20"

Silbione® Laboratory Reproduction Materials

Putty Lab products are high hardness addition cure silicone pastes that can be used for insulating and repairing or making molds of palate contours. Duplication materials are flowable addition cure silicone with hardness between 8 and 30 ShA and a fast setting time (<30min).



These products can be customised upon request.

BLUESIL™

Products	Type	Color	Viscosity (mPa.s) at 23°C	Mix Ratio	Hardness Shore A	Specific Gravity (g/cm ³)	Mixing Time	Maximum Working Time	Total Setting Time
RTV 4382 A/B	Addition Cure	pink	paste	1:1	82	1.85	30"	1'30"	2'15"
RTV 4390 A/B		blue	paste	1:1	90	1.9	30"	2'00"	3'00"
RTV 4010 A/B		blue	2,000	1:1	10	1.05	-	5'	< 30'
RTV 4015 A/B		colorless	2,000	1:1	15	1.05	-	5'	< 30'
RTV 4018 A/B		white	4,000	1:1	18	1.1	-	5'	< 30'
RTV 4022 A/B		blue	8,000	1:1	22	1.05	-	5'	< 30'
RTV 4028 A/B		green	5,000	1:1	28	1.2	-	5"	< 30'
RTV 4619 A/B		trans.	12,000	1:1	19	1	-	4'	< 30'

Duplication material



Bluesil™ duplication - a technology of hydrophilic duplication materials.

Along with the same mechanical properties as the regular range, hydrophilic properties eliminate the need for (contact angle of less than 40°) a wetting agent before pouring the refractory plaster, which allows time saving, increased accuracy and cost effectiveness.

Products	Type	Color	Viscosity (mPa.s) at 23°C	Mix Ratio - Aspect	Hardness Shore A	Specific Gravity (g/cm ³)	Contact Angle	Maximum Working Time	Total Setting Time
RTV 4123 A/B	AC	blue	6,000	1:1 - liquid	23	1.2	40°	5'	<30'

Silbione® Audiology Materials

Silbione® RTVs are designed for ear canal impression taken at audiology laboratories for the production of personalized hearing devices.

Products	Color	Aspect / Viscosity	Mix ratio	Hardness Shore A	Specific Gravity (g/cm ³)	Mixing Time	Maximum Working Time	Total Setting Time
RTV 4330 A/B	yellow	paste	1:1	30	1.4	30"	2'00"	5'00"
RTV 4329 A/B	green	thixotropic fluid	1:1	30	1.3	not applicable	1'15"	2'30"
RTV 4340 A/B	blue	paste	1:1	40	1.5	30"	2'00"	5'00"

Addition cure

Bluestar Silicones supports the sales of these Silbione® silicone products to customers involved in manufacturing and assembling approved medical devices for less than 30-day implantation.



- Enhanced final product performance, based on patented technology.
- Large range of flavors on demand.
- The best of both worlds: high thixotropy and excellent flowability.
- Effortless extrusion from cartridges (ease of handling).

- 20% lower density materials - more for less - best value for the money.



- High fidelity impression.
- Fast setting time.
- Highly consistent quality and batch-to-batch consistency.
- Outstanding shelf life, stability of key performances even in harsh conditions (elevated temperature).
- Very high purity products manufactured in a clean room.
- Silbione® is non-toxic and biocompatible.
- On-staff Board Certified PhD toxicologist, dedicated, experienced professionals for registration files.

- With our customized formulations to achieve your desired performance (hardness, consistency, setting time, etc).
- Large range of colors.
- Large choice of packaging (containers, pots, tubes, kits, cartridges, etc.).

For detailed commercial contacts please visit our website:
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Medical Device Manufacturing

Trouble-Free Molding and Easy Release
With High Performance Properties

Bluestar Silicones products are designed specifically to meet the diverse and demanding needs of the medical device market. Combining the expertise of its designers, engineers and production experts, Bluestar Silicones continuously innovates and improves products to better match with the healthcare market requirements.

From balloon catheters to wound drains, needle-less valves, peristaltic pump tubing, respiratory masks, and device coatings, Bluestar Silicones has the silicone solution to meet your need.

Bluestar offers a complete range of Silbione® silicone technologies for medical devices including Liquid Silicone Rubber (LSR), Heat Cured Rubber (HCR), RTV Adhesives, Specialty Fluids and Dispersions.

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SILICONES



Medical Device Manufacturing

The best in class tailor-made technology

SILBIONE® LSR

Silbione® Product	Typical Applications	Typical properties							Appearance	Extracti FDA 21CFR 177.2600
		Durometer ShA	Tensile MPa	Elongation %	Tear Strength kN/m	Specific Gravity	Extrusion Rate g/min	Viscosity		
LSR 4301 A/B	Orthopedic insoles and cushioning; prosthetic liners	1	1.8	1090	8	1.07	(Viscosity = 55,000 mPa.s)	clear		
LSR 4305 A/B	Orthopedic insoles and cushioning; prosthetic liners	5	3.0	1100	10	1.07	(Viscosity = 60,000 mPa.s)	clear	Water extraction only	
LSR 4310 A/B	Cushioning	10	5.5	1100	20	1.09	270	clear		
LSR 4325 A/B	Balloons	23	8.5	950	30	1.11	130	clear		
LSR 4330 A/B	Molded healthcare & medical parts <30 days	30	9.5	800	35	1.11	105	clear		
LSR 4340 A/B	Molded healthcare & medical parts <30 days	40	9	615	40	1.12	90	clear	●	
LSR 4340 FC A/B	Fast Cure for large, thick parts	40	9	615	40	1.12	90	clear	○	
LSR 4340 SL A/B	Self-lubricating	34	6.5	580	38	1.10	100	opaque		
LSR 4350 A/B	Molded medical parts <30 days	50	8.5	570	43	1.12	80	clear	● ⁽²⁾	
LSR 4360 A/B	Molded medical parts <30 days	60	9.5	480	43	1.13	75	clear	○	
LSR 4360 SP A/B	Self lubricating, precision molded parts	54	8.4	500	37	1.11	115	clear		
LSR 60 A/B	Self bonding	59	9.5	415	33	1.11	100	clear	see note ⁽²⁾	
LSR 4370 A/B	Molded healthcare & medical parts <30 days	68	9	450	41	1.14	70	clear	○	

Liquid Silicone Rubber (LSR)

For injection molding medical device precision components, **Silbione® LSRs** offer the distinctive advantages of easy processing, easy release and high performance physical properties to improve part appearance and functionality, and reduce rejection rates. Typical applications include o-rings, stoppers, drains and intricate parts.

Biocompatibility											
on Testing	Biocompatibility Tests ⁽¹⁾										
FDA 7117.11 Nitrosamines	Cytotoxicity	Skin Sensitization	Intracutaneous Tox	Systemic Toxicity	Mutagenicity	Hemolysis	Mucosal Irritation	Pyrogenicity (USP)	7-Day Implant	28-Day implant	USP Class VI
	●	●	●								●
●	●	●	●								●
	●	●	●	●			●	●			●
	●	○	○	○	○				○		○
	●	●	●	●	●				●		●
●	●	●	●	●	●	●		●		●	●
○	●	○	○	○	○	○		○		○	○
	○	○	○	○	○					○	○
●	●	○	●	●	●			○	●		●
	●	●	●	○	○			○	○		●
	●	●	●								○
	○	○	○	○	●				○	● ⁽²⁾	●
○	●	●	●	●	●			●	●		●

- Indicates test performed on the material; successfully passed.
- Indicates test not performed on the material; however, it is substantially equivalent to another tested Silbione® product.

Note: The typical properties listed above are not intended for use in preparing specifications for any particular application of Bluestar Silicone materials.

Silbione® is a registered trademark of Bluestar Silicones.

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

(2) - Supported by testing meeting European Pharmacopoeia section 3.1.9 hexane extraction.

(3) - 90-day study

Bluestar Silicones supports the sales of these Silbione® silicone products to customers involved in manufacturing and assembling approved medical devices for less than 30-day implantation.

Heat Cured Rubber (HCR)

The excellent mechanical characteristics of Silbione® HCRs make them ideal for a variety of medical device applications including molded medical device parts, balloon catheters and extruded tubing.

SILBIONE® HCR

	Silbione® Product	Typical Applications	Typical properties					
			Durometer ShA	Tensile MPa	Elongation %	Tear Strength kN/m	Specific Gravity	Appearance
Catalysed HCR	HCRA 4120 A/B*	Extruding and molding parts for healthcare and medical devices, including tubing, catheter balloons, needle entry ports.	25	9.9	1,260	38	1.12	clear
	HCRA 4130 A/B*		29	10.3	1,100	38	1.12	clear
	HCRA 4150 A/B*		50	11	700	40	1.15	clear
	HCRA 4165 A/B*		65	10.2	740	42	1.18	clear
	HCRA 4170 A/B**		70	8,9	550	39	1.18	clear
	HCRA 4360 A/B**		64	10	550	35	1.16	transparent
	HCRA 4375 A/B**		75	9.3	490	26	1.19	transparent
Uncatalysed HCR	HCRU ⁽²⁾ 4125 HC*	Extruding and molding parts for healthcare and medical devices, including tubing, catheter balloons, needle entry ports.	25	8.9	900	30	1.1	slight haze
	HCRU ⁽²⁾ 4135 HC*		31	8.2	850	29	1.12	slight haze
	HCRU ⁽²⁾ 4160 HC*		58	9.6	600	48	1.16	slight haze
	MM 71791/40 U**		43	9	600	31	1.1	transparent
	MM 71791/60 U**		62	10	500	38	1.15	transparent
	MM 71791/70 U**		72	9.5	410	34	1.18	transparent

* Sold to North America
** Sold to Europe and Asia

(1) - The biocompatibility testing listed addresses the categories of evaluation specified in ISO 10993 for device use of less than 30 days duration.
(2) - HCRU is an uncatalysed base. Typical properties are achieved with the addition of a peroxide catalyst.

RTV Adhesives

Silbione® RTV adhesives are solventless high strength adhesives that cure at room temperature. Designed for assembling and sealing medical device parts, these adhesives bond silicone to silicone or silicone to other substrates.

SILBIONE® ADHESIVE SILICONES

	Silbione® Product	Typical Applications	Typical properties							
			Solids Content	Peel Strength ppi	Solvent	Viscosity	Durometer ShA	Cohesive Strength N/mm	Tensile Strength N/mm ²	Elongation %
Pressure sensitive adhesive	Silicone PS									
	Silbione® PSA in HCFC	Temporary bonding to body surfaces; skin patches; Non-permanent bonding to metal, glass, fabric, silicone, organic rubber; Can be applied by brushing, spraying, dipping or pouring.	18.5%	2.3	dichloro-penta-fluoro-propane	115				
RTV adhesive	Silicone-To-Silicone									
	Silbione® MED ADH 4100 RTV	1-part high strength elastic silicone to silicone bonding that cures at room temperature.			no solvent		29	5.3	5.7	780
	Silbione® MED ADH 4300 RTV	1-part high strength elastic bond to silicone, plastic or other substrate. Cures at room temperature.			no solvent		24	3.2	5.4	650
	Silbione® RTV 4418 ADH A/B	Adhesion promoter for silicone elastomers and fabrics				Thixotropic (mixed product)	20		5	600

Biocompatibility Tests ⁽¹⁾									
EU Pharmacopoeia (EUP) 3.1.9	Cytotoxicity	Skin Sensitization	Intracutaneous Tox	Systemic Toxicity	Mutagenicity	Pyrogenicity (USP)	7-Day Implant	USP Class VI	FDA Master File (MAF)
	●		●	●	●			●	●
	○		○	○	○			○	
●	●	●	●	●	●	●	●	●	
●	●	●	●	●	○	●	●	○	
	●	○	●		●		○	○	
●	○	○	○				○	○	
●	○	○	○				○	○	
	○		○	○	○			○	
	○		○	○	○			○	
			○	○			○	○	○
●	○	○							
●	●	●							
●	○	○							

Silbione® Pressure Sensitive Adhesives

Bluestar Silicones' Pressure Sensitive Adhesive (PSA) is a one-component skin adhesive ideal for adhering colostomy and ileostomy devices, tracheostomy tubing, as well as, surgical dressings, pads and patches to the body.

				Regulatory	Biocompatibility Tests				
Tear Strength N/mm	Spec. Gravity	Tack Free Time (min.)	Appearance	FDA Master File (MAF)	Cytotoxicity	Systemic Toxicity	Intracutaneous Tox	Mutagenicity	Skin Sensitization
SA									
					●		●		●
e Bonding									
14.9	1.09	9	Clear	●	●	●	●	●	○
12.3	1.08	8	Clear	●	●	●	●	●	○
20					●	●			●

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- Indicates test not performed on the material; however, it is substantially equivalent to another tested Silbione® product.

Note: The typical properties listed above are not intended for use in preparing specifications for any particular application of Bluestar Silicone materials.

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Specialty Fluids, and Dispersions

Typical applications for Bluestar Silicones' Silbione® fluids and dispersions include lubrication or hydrophobic coatings and demolding.

SILBIONE® FLUIDS, EMULSIONS AND DEFOAMERS

Silbione® Product	Typical Applications	Typical properties				Regulatory
		Viscosity (cps)	Specific Gravity	Volatile Content	Color	FDA Master File (MAF)
Fluids						
Silbione® MDM 350	Lubrication or Hydrophobic coatings of devices	350	0.95	0.05	clear	○
Silbione® MDM 1000		1,000	0.98	0.03	clear	●
Silbione® MDM 12500		12,500	0.98	0.70	clear	○

Silbione® Product	Biocompatibility Tests										
	Cyto-toxicity	Systemic Toxicity	Intracuta-neous Tox	Muta-genicity	Skin Sensi-tization	30-day toxicity	Teratology	2-gen rat repro-duction	Dermal absorption	Oral absorption	2-year Chronic Toxicity
Fluids											
Silbione® MDM 350	○	○	○	○	○	○	○	○	○	●	●
Silbione® MDM 1000	●	●	●	●	○	●	●	○	○	○	●
Silbione® MDM 12500	○	○	○	○	○	○	○	○	○	○	○

- Indicates test performed on the material; successfully passed.
- Indicates test not performed on the material; however, it is substantially equivalent to another tested Silbione® product and/or to the extensive testing conducted and reported in the scientific literature.

SILBIONE® DISPERSIONS

Silbione® Product	Typical Applications	Viscosity (cps)	% Solids	Cure System	Specific Gravity	Durometer ShA	Tensile MPa	Elongation %	Tear Strength kN/m
Silbione® Dimethyl Elastomer Dispersion	Fabricating high strength, elastic silicone membranes and balloons of any shape/ thickness. Dipping Coating	4500	35	Platinum	1.10	40	12	800	33
Silbione® HS Elastomer Dispersion, RTV in Xylene		800	40	Acetoxo	1.08	24	6.9	1000	28

Silbione® Product	Regulatory								
	FDA Master File (MAF)	FDA 21CFR 347.10							
Silbione® Dimethyl Elastomer Dispersion	●		●	●	●	●	●	●	●
Silbione® HS Elastomer Dispersion, RTV in Xylene	●	●	●	●	●		●		

● Indicates test performed on the material; successfully passed.



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Orthotics, Prosthetics & Comfort Care

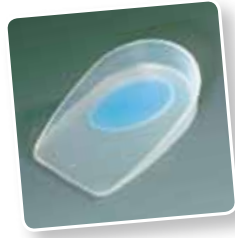
Combining Comfort with Durability
to Optimize Prosthetic Performance

Comfort is the priority in Healthcare applications. Silbione® LSRs, RTVs, Gels and Foams deliver outstanding performance to enable the production of comfort care devices.

The cushioning effects, form definition and life-like feel of Silbione® silicones, make them ideal materials for prosthetic devices such as liners, artificial limbs and pressure relief cushions.

Bluestar Silicones offers a full range of Silbione® soft silicone technologies that combine:

- Comfort with high mechanical properties for producing a variety of devices for the prosthetic market.
- Comfort and performance versatility.
- Exceptional freedom of movement for liners.
- Light weight, outstanding feel.



Orthotics, Prosthetics & Comfort Care

Combining Comfort with Durability to Optimize Prosthetic Performance

Silbione® RT Gels for Breastcare & Pressure applications

The range is composed of addition cure gels that have been designed in order to meet the specific requirements of this application such as penetration, viscoelasticity and low viscosity. In addition, we offer light weight gels that are 25 to 40 % lighter than standard gels.

Low viscosity Silbione® RT Gel 4220 offers excellent damping to provide even distribution of pressure, leading to greater comfort in a prosthetic device. When encased in a Silbione® RTV, the new Silbione® RT Foam 4241, creates a comfortable cushioning effect.

SILBIONE® RT Gels

	Products	Specific Gravity (g/cm ³)	Color	Viscosity (mPa.s) at 23°C	Maximum Working Time	Penetration (mm/10)	Application
Standard	RT Gel 4021 QC A/B	0.98	Part A: transparent Part B: Skin colored	300	70'	220	Breastcare
	RT Gel 4022 A/B	0.98		300	24h	220	Breastcare
	RT Gel 4122 A/B	0.98		Part A: 100 Part B: 1400	500'	215	Breastcare
	RT Gel 4123 A/B	0.98		Part A: 120 Part B: 1100	> 24h	230	Breastcare
	RT Gel 4023 ADV A/B	0.98		250	7' at 70°C	240	Breastcare
	RT Gel 4030 ADV A/B	0.98		300	35'	260	Breastcare
	RT Gel 4317 A/B	0.98	transparent	3000	60'	170	Breastcare - Adhesives
	RT Gel 4220 A/B	0.98	transparent	1100	50'	200	Pressure Sore Applications
Light Weight	RT Gel 4421 LD A/B	0.8	white	9000	15' at 50°C	215	Breastcare
	RT Gel 4725 SLD2 A/B	0.62	white	10000	15' at 50°C	235	Breastcare
	RT Gel 4521 LD A/B	0.72	white	6000	60'	190	Pressure Sore Applications

NEW

SILBIONE® RT Foam

Product	Mixed Ratio	Mixed Viscosity (mPa.s)	Rise Time (min)	Demold Time (min)	Hardness DS 00	Specific Gravity
RT Foam 4241 A/B	1:1	15000	3 to 5	30	40	0.25

For medical parts, cushioning or damping, Bluestar Silicones developed this innovative technology to meet the market needs on key challenges like breathability, thermal regulation and flexibility.



The hardness, viscosity and density can be customised upon request.



Bluestar Silicones to win the Product Differentiation Excellence Award, 2012 from Frost & Sullivan with the Silbione® RT Foam.

Silbione® Soft RTV for Foot Care Applications

For foot care applications, Silbione® RTVs offer an outstanding balance between low viscosity and high mechanical properties, as well as an excellent compromise between damping and rebound.

SILBIONE® RTV

	Products	Color	Aspect/ Viscosity (mPa.s) at 23°C	Mix Ratio	Maximum Working Time at 23°C	Total Setting Time (min)	Hardness		Tensile Strength (N/mm ²)	Elongation (%)	Tear Strength (N/mm)	Application
							Shore A	Shore 00				
Pastes	RTV 4335 A/B	pink	paste	1:1	2'	5'	35	-	-	-	-	foot care
	RTV 4345 A/B	brown	paste	1:1	1'50"	3'50"	45	-	-	-	-	foot care
Fluids	RTV 4511 A/B	trans. / blue	1200	1:1	60'	90'	-	11	-	-	-	cushions/ shoe inlays
	RTV 4515 A/B QC	skin colored	1500	1:1	7'	30'	-	15	-	-	-	cushions/ shoe inlays
	RTV 4528 A/B	trans.	4000	1:1	70'	180'	-	28	1.5	800	2	liners (textile coated), pads
	RTV 4404 A/B	trans.	1900	1:1	40'	120'	4	-	2.5	800	8	liners (textile coated), pads
	RTV 4407 A/B	trans.	1000	1:1	20'	45'	7	-	1.5	600	4	cushions/ shoe inlays
	RTV 4408 A/B	trans.	1500	1:1	120'	360'	8	-	3	600	12	liners/insoles
	RTV 4411 A/B	trans.	7500	1:1	60'	180'	11	-	3	800	12	liners
	RTV 4420 A/B	trans.	4000	1:1	60'	180'	20	-	3,5	550	15	multi-purpose
	RTV 4420 QC A/B	trans.	6000	1:1	3'	35'	20	-	4	500	15	multi-purpose
	RTV 4428 A/B	trans.	20000	10:1	90'	960'	28	-	-	600	20	multi-purpose

Silbione® Products for Prosthetic Liners and Life-Like Prosthetic Skin

For prosthetic liners, Silbione® soft RTV, HCR and LSR technologies offer exceptional comfort and high elongation to allow comfortable freedom of movement.

For life-like parts, the Silbione® range enables manufacturers to achieve high quality parts in just a fraction of the time of traditional molding material.

SILBIONE® LSR-HCR

Products	Durometer Sh A	Specific Gravity	Tear Strength kN/m	Tensile MPa	Elongation (%)	Appearance	Application
Silbione® Soft Silicone LSRs*							
LSR 4301 A/B	1	1.07	8	1.8	1090	clear	Liners & Life-like Prosthetic Skin
LSR 4305 A/B	5	1.07	10	3.0	1100	clear	
LSR 4310 A/B	10	1.09	20	5.5	1090	clear	
Silbione® Soft Silicone HCRs*(1)							
HCRA 4120 A/B	25	1.12	38	9.9	1260	clear	Liners & Life-like Prosthetic Skin
HCRA 4130 A/B	29	1.12	38	10.3	1100	clear	

* Available also in high durometers
(1) Sold to North America

Bluestar Silicones supports the sales of these Silbione® silicone products to customers involved in manufacturing and assembling approved medical devices for less than 30-day implantation.

NEW



- Large range of products with constant evolution to present innovations to your customers.
- Unique formulations for shock and vibration absorption, and even pressure distribution.
- State-of-the-art technology provides an exceptional touch to the feel of breast prostheses.

- Easy to use 1:1 mix ratios.
- Very fast self de-gassing.
- Quick curing material tailored to match your productivity requirements.



- Outstanding batch-to-batch consistency.
- Phthalate-free, hypoallergenic, sterilizable.
- Antimicrobial features if needed.
- Regulatory and biocompatibility support on demand.

- Build complex prostheses with light weight gels, foams, and fluids available.
- Adhesives available to improve adhesion on a wide variety of substrates (PU, textile, Silicone).
- Neutral odor patented technology: colors or fragrances available.

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Skin Care & Wound Management

Providing gentle adhesion,
even to the most delicate skin

Silicones have long been recognized as biocompatible and effective materials for a variety of wound and skin care applications, including:

- Wound dressings and bandages
- Medical and fashion tapes
- Transdermal patches for cosmetics and active ingredient delivery
- Scar management

Silbione® Skin Adhesives from Bluestar Silicones are two-part platinum catalyzed silicone gel elastomers, manufactured in a clean environment to ensure healthcare grade levels of purity and quality.

Available in a variety of tack properties, viscosities and cure kinetics, Bluestar Silicones can help you achieve the desired performance for your targeted application.



Skin Care & Wound Management

Providing gentle adhesion,
even to the most delicate skin

**Soft, Gentle
Adhesion for Easy,
Painless and
Non-Traumatic
Removal**

Key properties silicones offer include:

The specific nature of silicone gels enables gentle adhesion to healthy skin. For wound management applications, this means gentle adhesion on peripheral skin, without adhering to the moist wound. Silbione® Skin Adhesives' limited peel force enables easy painless removal.

**Repositionable
Reusable**

Silbione® Skin Adhesives retain adhesion properties upon removal, so they may be repositioned for several applications. Silbione® Skin Adhesives may be washed and still retain excellent tack properties when dried.

**Facilitates
Healing**

Silbione® Skin Adhesives are gas permeable, allowing the skin to breathe. Thanks to their hydrophobic nature, no adherence to moist wounds occurs, thereby enabling improved granulation and epithelialisation. Silbione® Skin Adhesives work well in conjunction with complementary wound technologies such as hydrocolloids, hydrogels and PU foams to optimize the overall dressing performance.

Silbione® RT Gel

Silbione® RT Gel are biocompatible skin adhesives suitable for use in applications with contact to healthy skin.

Typical properties ⁽¹⁾							Biocompatibility (ISO 10993)		
Silbione® RT Gel	Viscosity (mPa.s)	Mix Ratio	Penetration ⁽²⁾ (mm/10)	Probe Tack ⁽³⁾ (mJ/cm ²)	Working Time (minutes)	Appearance	Cytotoxicity	Skin irritation	Skin sensitization
RT Gel 4317 A/B	3 000	1:1	170	5.2	60'	transparent	●	●	●
RT Gel 4320 FC A/B	3 000	1:1	210	6.6	60'	transparent	○	○	○
RT Gel 4717 A/B	60 000	1:1	170	9	120'	transparent	○	○	○



Silbione® HC2

Silbione® HC2 are biocompatible skin adhesives suitable for use on breached skin and open wounds. They are produced with guaranteed microbial safety in an ISO 8 clean room part of a certified ISO 13485 facility.

Typical properties ⁽¹⁾									Biocompatibility (ISO 10993)		
Silbione® HC2	Viscosity (mPa.s)	Mix Ratio	Penetration ⁽²⁾ (mm/10)	Probe Tack ⁽³⁾ (mJ/cm ²)	Specific gravity (g/cm ³)	Working Time (minutes) at 25°C	Bioburden (cFu/g)	Appearance	Cyto-toxicity	Skin irritation	Skin sensitization
HC2 2011 A/B	3 000	1:1	170	5.2	0.98	120'	< 100	transparent	○	○	○
HC2 2031 A/B	50 000	1:1	170	9	0.98	120'	< 100	transparent	○	○	○

● Indicates test performed on the material; successfully passed.

○ Indicates test not performed on the material; however, it is substantially equivalent to another tested Bluestar skin adhesive product that successfully passed.

(1) - The typical properties listed above are not intended for use in preparing specifications for any particular application of Bluestar Silicones materials.

(2) - Approx. (mm/10), hollow cone (62,5g) DIN ISO 2137

(3) - Approx. (mJ/cm²), steel probe, 0,25mm layer.
Note: User has sole responsibility to determine product suitability for intended uses and applications.

Bluestar Silicones supports the sales of these Silbione® silicone products to customers involved in manufacturing and assembling approved medical devices for less than 30-day implantation.



- Gentle adhesion to, and easy removal from even the most delicate skin.
- No adherence to moist wounds, improved granulation and epithelialisation.
- Outstanding transparency and non-yellowing, mirror-like surfaces.
- Fewer surface defects with glass-like fast leveling.
- Contribute to scar morphology management.

- Increased efficiency and productivity with systems that will meet your productivity targets.
- Highly robust chemistry with batch-to-batch consistency for critical parameters.



- On-staff board certified PhD toxicologist, worldwide support.
- Regulatory and biocompatibility support.
- Readily available technical support.
- Purity & Quality manufactured in a certified clean and dedicated environment.

- Enable controlled release of active ingredients.
- Wide selection of tackiness available to achieve desired performance of end product.
- Customized formulations to deliver precisely what your customer wants.
- Odorless when coating on PU films.

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