

SILBIONE® RT GEL 4512 A & B

Solventless Biocompatible Adhesives for Wound Care and Scar Care

Description

SILBIONE RT GEL 4512 A & B is a two component silicone elastomer that crosslinks at room temperature by polyaddition reaction. The polymerisation can be accelerated by heat.

The silicone materials are delivered as two low viscous liquid components, which once mixed and cured, transform into an elastic and resistant gel. Polymerisation occurs without formation of heat.

Examples of applications

- Adhesive wound dressings
- Adhesive sheetings for scar treatment

Advantages

- Very good adhesion on dry skin
- No adhesion on moist wounds
- Proven biocompatibility
- Fast and easy processing due to low viscosity and 1:1 mixing ratio

Characteristics

Characteristics of the non cured product

<i>Properties</i>	SILBIONE RT GEL 4512	
	A	B
Contains	Pt	SiH
Appearance	Low viscous liquid	
Colour	Transparent	
Density [g/cm ³] at 23 °C, approx	0.98	
Viscosity [mPa·s] at 23 °C, approx	6000	

Polymerisation

<i>Properties</i>	SILBIONE RT GEL 4512 A & B
Mixing Ratio A : B parts by weight	100 : 100
Working Time [min] at 23 °C, approx	45
Mixing Viscosity [mPa·s] at 23 °C, approx.	6000

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Characteristics (cont')

Characteristics of the cured product

Curing conditions: 30 minutes at 120 °C

<i>Properties</i>	SILBIONE RT GEL 4512 A & B
Penetration <i>[mm/10], hollow cone (62.5 g), DIN ISO 2137, approx.</i>	120
Probe Tack <i>[mJ/cm²], steel probe, 0.25 mm layer, approx.</i>	1.2

Remarks:

Curing the silicone at elevated temperature has no influence on the final properties. Nevertheless, heating can alter the dimensions.

Due to the inherently weak structural network of silicone gels, mechanical properties cannot be measured on cured gels.

Processing

1. Mixing the two components

The components A and B are mixed by weight in the above indicated ratio. The mixing can be carried out either by hand or using a low-speed electric or pneumatic mixer to minimise the introduction of air and to avoid any temperature increase.

It is also possible to use a special mixing and dispensing machine for the two silicone components. Further information is available upon request.

2. Degassing

The mixture should be degassed preferably at 30 to 50 mbar to eliminate any entrapped air. If a dispensing machine is used, the two components are degassed separately prior to mixing.

The silicone mixture expands to 3 to 4 times of its initial volume and bubbles rise to the surface. The bubbles progressively disappear and the mixture returns to its initial volume after 5 to 10 minutes. Wait a few minutes to complete the degassing and then flash the vacuum. The silicone is ready for pouring, either by gravity or under low pressure.

Note: Flashing the vacuum once or twice accelerates the degassing. It is recommended to use a container with a high diameter / height ratio.

3. Polymerisation

The system polymerises at 23 °C. The curing may be slowed down at lower temperature and contrary accelerated by heat.

Contact with certain materials can inhibit the crosslinking. See list below:

- natural rubbers vulcanised with sulphur,
- RTV 2 silicone elastomers catalysed with metal salts, e.g. tin-compounds,
- PVC stabilised with tin salts and additives,
- epoxy resins catalysed with amines.

In case of doubts, it is recommended to test the substrate by applying a small quantity of the mixed silicone on a restricted area.

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Packaging

The silicone components are delivered in pails of 25 kg.

Storage and shelf life

When stored in its original unopened packaging, at a temperature of between -10°C and +30 °C, **SILBIONE RT GEL 4512 A & B** may be stored for up to 12 months from the date of manufacture clearly marked on the packaging.

Beyond this date, Bluestar Silicones no longer guarantees that the products meet the sales specifications.

Biocompatibility and Toxicity

Extensive toxicology testing on **SILBIONE®** products has demonstrated their adequate biocompatibility and suitability for the recommended applications. Our evaluations according to EN/ISO 10993 have shown that **SILBIONE®** products are neither 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 Pharmacopeia class VI. Toxicological summaries, statements and specific regulatory status are available upon request from your **BLUESTAR SILICONES** contact.

Safety

Please consult the Safety Data Sheet of **SILBIONE RT GEL 4512 A & B**.

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