

Silbione® RTV 4510 A/B

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Biocompatible Silicone Elastomer for Orthopedic Devices

Description

SILBIONE® RTV 4510 A&B is a two-component silicone elastomer which cures at room temperature by a polyaddition reaction. The polymerization can be accelerated by heat.

The silicone material is delivered as two low viscous liquid components, which once mixed and cured, transform into an elastic and resistant material. Polymerization occurs without formation of heat.

Applications

- Heel cushions
- Toe separators
- Liners for limb prostheses

Advantages

- Very high stretch ability
- Sterilisable
- Fast mixing and easy processing due to low viscosity

Typical Properties

1. Characteristics of the non cured product

<i>Properties</i>	SILBIONE® RTV 4510	
	A	B
Contains	Pt	SiH
Appearance	Low viscous liquid	
Color	Translucent	
Density (At 23°C, g/cm ³ , approx.)	1.08	
Viscosity (At 23°C, mPa·s, approx.)	1200	1400

2. Polymerization

<i>Properties</i>	SILBIONE RTV 4510 A&B
Mixing Ratio A : B (parts by weight)	1 : 1
Potlife (At 23°C, minutes, approx.)	60
Demolding time (At 23°C, minutes, approx.)	90

3. Characteristics of the cured product

Curing conditions: 60 minutes at 80°C

<i>Properties</i>	SILBIONE RTV 4510 A&B
Hardness Shore 00 (DIN 53505, approx.)	11

Processing

Remix each of the two components (part A and B) every time before using.

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 by using a low-speed electric or pneumatic mixer to minimize 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. Wait a few minutes to complete the degassing and then release the vacuum. The silicone is ready for pouring, either by gravity or under low pressure.

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

3. Polymerization

The system polymerizes at 23°C. The curing may be slowed down at lower temperature or accelerated by heat.

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

- Natural rubbers vulcanized with Sulphur.
- RTV 2 silicone elastomers catalyzed with metal salts, e.g. tin-compounds.
- PVC stabilized with tin salts and additives. - Epoxy resins catalyzed 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.

Biocompatibility and Toxicity

After curing performed according the conditions described above, **SILBIONE® RTV 4510 A&B** complies with a number of regulations for Medical Devices.

Contact Elkem Silicones for more detailed information.

Limitations

Silbione® silicone products may be used for healthcare applications in accordance with Elkem's healthcare product guidelines. Elkem 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. The purchaser has the sole responsibility to select a particular **Silbione®** 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.

Silbione® RTV 4510 A/B

Storage and shelf life

When stored in its original packaging at a temperature of between -10°C and +30°C, **SILBIONE® RTV 4510 A&B** may be stored for up to 6 months from its date of manufacture. Beyond this date, Elkem Silicones no longer guarantees that the product meets the sales specifications.





Safety

Please consult the Safety Data Sheets of **SILBIONE® RTV 4510 A&B**.

Packaging

SILBIONE® RTV 4510 A&B is delivered in 25 kg pails.

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