

Silbione® RTV 4545 A/B

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Biocompatible Elastomers for Orthopedic

Description Silbione® RTV 4545 A/B is a two component silicone elastomer that crosslinks at room temperature by polyaddition reaction. The polymerization 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 material. Polymerization occurs without the evolution of heat.

Applications

- Shoe inlays
- Liners for limb prostheses
- Prosthetic bandages

Advantages

- Very good mechanical properties
- Sterilizable
- Low viscosity
- Easy processing – mixing ratio 100 : 100

Typical Properties

Typical properties of the non-cured product

Properties	RTV 4545 A/B	
	A	B
Appearance	low viscosity, translucent liquid	low viscosity, translucent liquid
Color		
Density approx. [g/cm ³] at 23 °C	1,07	1,07
Viscosity approx. [cps] at 23 °C	2000	1800

Polymerization

Properties	RTV 4545 A/B
Mixing Ratio A : B parts by weight	1 : 1
Working Time approx. [min] at 23 °C	40
Mixing Viscosity approx. [cps] at 23°C	1900

Typical properties of the cured product

Curing conditions: 1h at 80 °C

Properties	RTV 4545A/B
Hardness Shore 00 ASTM D 2240	45
Tensile strength approx. [psi] ASTM D 412	450
Elongation approx. [%] ASTM D 412	800
Tear strength approx. [ppj] ASTM D 624 Die B	50

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

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Bio-compatibility

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 Elkem Silicones contact.

Instructions for use

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 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. 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. Polymerization

The system polymerizes 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 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,
- certain organic solvents, e.g. ketones, alcohols, ether etc.

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

Storage and shelf life

Silbione® RTV 4545 A/B when kept in its original unopened packaging, at a temperature between -10 °C and +30 °C, may be stored up to 6 months from the date of manufacture. Beyond this date, Elkem Silicones no longer guarantees the conformity of the product with the sales specifications.

Safety

Please read the container labels for **Silbione® RTV 4545 A/B** or consult the Safety Data Sheet (SDS) before handling for safe use, physical and health hazard information.

Packaging

Silbione® HS Gel Flesh 5 CLR is available in 18kg and 200kg packages.

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