

Silbione® RT Gel 4123 A&B

October 2017

Light Weight Gel for Breast Care

Description Silbione® RT Gel 4123 SLD 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 gel. Polymerization occurs without the evolution of heat.

Applications External light weight breast prosthesis.

- Advantages**
- Good imitation of female breast tissue
 - Low density and realistic touch of final breast form
 - Good adhesion to PU film
 - Fast and easy processing due to low viscosity and 1:1 mixing ratio

Typical Properties

1. Typical properties of the non-cured product

Properties	RT G EL 4123	
	A	B
• Appearance	Low viscosity liquid	
• Color	white	
• Density, approx. [g/cm ³] at 23 °C	.63	
• Viscosity, approx. [mPa·s] at 23 °C	1 000	

2. Polymerization

Properties	RT GEL 4123 A&B
• Mixing Ratio A : B parts by weight	1 : 1
• Working Time, approx. [min] at 23 °C	15
• Mixing Viscosity, approx. [mPa·s] at 23 °C	11000

3. Characteristics of the cured product

Properties	RT GEL 4123
• Penetration , approx. [mm/10], hollow cone (62,5 g), DIN ISO 2137	238
• Density approx. [g/cm ³], at 23 °C	0.63

Note:

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

**Instructions
for use****1. Preparation of the two components**

The silicone components contain a lightweight filler that gives the low density of the final gel. As this filler tends to rise to the surface it is necessary to stir up the components prior to use.

The homogenized components are stable for up to one hour without the need for remixing. After one hour we advise that the components are remixed before use.

Alternatively, they can be kept in slowly stirred tanks. Using this method requires temperature control to avoid degrading the product and alterations of the potlife.

2. 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.

3. 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.

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4. 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.

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 Pharmacopoeia class VI. Toxicological summaries, statements and specific regulatory status are available upon request from your Elkem Silicones contact.

Storage and shelf life

Silbione® RT GEL 4123 A&B when stored in its original unopened packaging, at a temperature between -10 °C and +30 °C, may be stored for 6 months from the date of manufacture. Beyond this date, Elkem Silicones no longer guarantees that the product meets the sales specifications.





Safety

Please read the container labels for **Silbione® RT GEL 4123 A&B** or consult the Material Safety Data Sheet (MSDS) before handling for safe use, physical and health hazard information. The MSDS is not included with the product packaging, but can be obtained by contacting Elkem Silicones at 866-474-6342 or consult your Elkem Silicones representative.

Packaging

Silbione® RT GEL 4123 A&B is available in 25kg packages.

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