

Silbione® RT GEL 4645 A&B

October 2017

Soft Skin Adhesive Gel

Description **Silbione® RT GEL 4645 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 material is delivered as two low viscous liquid components, which once mixed and cured, transform into an elastic and resistant gel. Polymerization occurs without formation of heat.

Examples of applications

- Scar care.
- Wound contact layer.
- Adhesive sheets in medical applications.

Advantages

- Good adhesion on polyurethane film, without primer.
- Very good adhesion on dry skin.
- Proven biocompatibility.
- Atraumatic removal.
- Suitability to coating processes.
- Quick cure at low temperature.

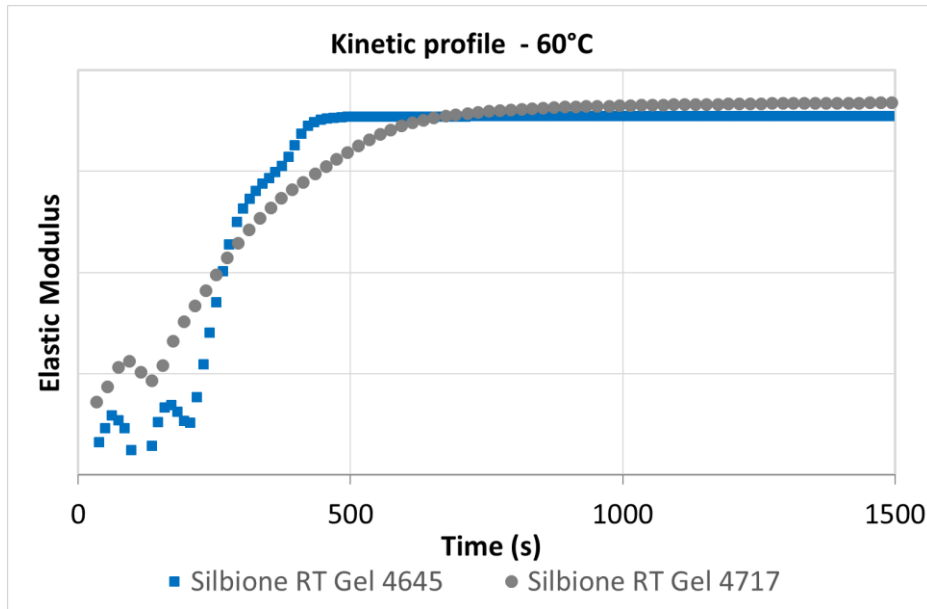
Typical Properties *The following values are not intended for use in preparing specifications. Please contact your local Elkem Silicones representative before writing specifications on this product.*

1. Characteristics of the uncured product

Properties	Silbione® RT GEL 4645 A&B	
	A	B
Contains	Pt	SiH
Appearance	Viscous liquid	
Color	Clear colorless	
Density (At 23°C, g/cm³, approx.)	0.97	
Viscosity (At 23°C, mPa, approx.)	10 000	10 000

2. Polymerization

Properties	Silbione® RT GEL 4645 A&B
Mixing Ratio A : B (Parts by weight)	100 : 100
Working Time (At 23°C, min, approx.)	100
Pot Life (At 40°C, min, approx.)	> 15
Mixing Viscosity (At 23°C, mPa, approx.)	10 000



3. Characteristics of the cured product

<i>Properties</i>	Silbione® RT GEL 4645 A&B
Penetration (<i>Hollow cone 62.5 g, DIN ISO 2137, mm/10, approx.</i>)	210

4. Characteristics of the coated product

coating performances - PU Film 200 gsm			
SILBIONE	PROBETACK [mJ/cm ²]	PEEL ADHESION* [N/25mm]	SUBSTRATE ADHESION**
RT GEL 4317	-	1.25	< 10
RT GEL 4717	16	2.25	< 10
RT GEL 4642	21	2.8	< 10
RT GEL 4645	20	2.25	> 50

* Peel Adhesion: 180° peel on Bristol paper

** Substrate adhesion: rub off test

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.

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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 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 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.

Important remark: If Part B of **Silbione® RT GEL 4645 A&B** comes in contact with strong acids, bases or oxidizing materials, hydrogen could generate. Ensure that containers are properly closed after each use in order to avoid any contamination of the contents.

HYDROGEN GAS EVOLUTION

Adequate ventilation must be provided to prevent localized build-up of hydrogen gas concentration upon curing or unforeseen contamination of part B. Keep away from sparks and open flames. Waste liquid material must be handled, disposed and stored considering this precautionary information, i.e. it should NOT be sealed in plastic bags and large quantities should not be allowed to accumulate.

Packaging

Silbione® RT GEL 4645 A&B components are delivered in 25 kg pails kit or 200 kg drums.

Storage and shelf life

When stored in its original packaging at a temperature of between -10°C and +30°C, **Silbione® RT GEL 4645 A&B** may be stored for up to 6 months from its date of manufacture.

Comply with the storage instructions and expiry date marked on the packaging.

Beyond this date, Elkem Silicones no longer guarantees that the product meets the sales specifications.

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Bio-compatibility and Toxicity

After curing performed according the conditions described above, **Silbione® RT GEL 4645 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.

Safety

Please consult the Safety Data Sheet of **Silbione® RT GEL 4645 A&B**.

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