SILPURAN® 6610/40 A/B

SILPURAN®

Liquid Silicone Rubber (LSR)

Liquid silicone rubbers of the SILPURAN® 6610 series are paste-like, two-component compounds. Their vulcanizates are noted for their significantly reduced tendency towards a radical induced reattachment, i.e. healing, of slit valve surfaces during sterilization by gamma irradiation and ebeam (\leq 75 kGy). SILPURAN® 6610/40 A/B is designed for medical applications in compliance with the WACKER SILICONES HEALTH CARE POLICY including implantation for < 30 days.

Properties

SILPURAN® 6610/40 A/B meets selected test requirements of ISO 10993 and United States Pharmacopoeia (USP) Class VI. It is designed for medical applications in compliance with the WACKER SILICONES HEALTH CARE POLICY including implantation for < 30 days and is particularly suitable for the economical production of large series of injection molded articles.

At service temperatures above approx. 180 °C the addition of heat stabilizers is recommended. Further information about an improvement of the heat stability by use of specific ELASTOSIL® Color Pastes FL can be obtained from the Technical Information Sheet "ELASTOSIL® Color Pastes FL" or the latest edition of our brochures.

Specific features

- Food-contact
- Less self-healing
- Reduced volatile content

Technical data

Properties Uncured

Property	Condition	Value	Method
Viscosity, dynamic (1 s ⁻¹)	-	360000 mPa·s	DIN EN ISO 3219
Viscosity, dynamic (10 s ⁻¹)	-	180000 mPa·s	DIN EN ISO 3219

These figures are only intended as a guide and should not be used in preparing specifications.

Properties Cured

Cure conditions: 5 min / 165 $^\circ\text{C}$ in press, post-cured 4 h / 200 $^\circ\text{C}$

Property	Condition	Value	Method
Appearance	-	white	-
Hardness Shore A	-	40	DIN ISO 48-4
Density	-	1.21 g/cm ³	DIN EN ISO 1183-1 A
Tensile strength	-	7.2 N/mm ²	ISO 37 type 1
Elongation at break	-	510 %	ISO 37 type 1
Tear strength	-	22 N/mm	ASTM D 624 B
Compression Set ⁽¹⁾	22 h 175 °C	12 %	DIN ISO 815-1 type B method A
Rebound resilience	-	61 %	ISO 4662

¹post-cured 6 h / 200 °C

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All the information provided is in accordance with the present state of our knowledge. Nonetheless, we disclaim any warranty or liability whatsoever and reserve the right, at any time, to effect technical alterations. The information provided, as well as the product's fitness for an intended application, should be checked by the buyer in preliminary trials. Contractual terms and conditions always take precedence. This disclaimer of warranty and liability also applies particularly in foreign countries with respect to third parties' rights.

Applications

• Medical Devices

Application details

The following studies were performed on vulcanizates of SILPURAN® 6610/40 A/B according to ISO 10993:

- Cytotoxicity (ISO 10993-5)
- Sensitation LLNA (ISO 10993-10)
- Pyrogenicity (ISO 10993-11)
- The following studies were performed on vulcanizates of SILPURAN® 6610/40 A/B according to USP class VI:
- Acute systemic toxicity
- Intracutaneous toxicity
- Implantation test

No adverse effects have been detected at any of the studies performed.

A master file has been filed with the U.S. Food and Drug Administration. An authorization to reference the master file will be available upon request.

Properly cured and post-cured vulcanizates of SILPURAN® 6610/40 A/B can be used for food contact applications and are suitable for use under the Recommendation "XV. Silicones" of the BfR and FDA 21 CFR §177.2600 "Rubber Articles Intended for Repeated Use" considering any given limitations on extractable and volatile substances. Solely contact with acidic foodstuff is not recommended as this might lead to an elution of one type of filler.

Processing

The A and B components are delivered ready to use in 20 kg pail kits. With adequate metering equipment, they can be pumped directly from the original containers into the injection molding machine and mixed by a static mixer. The mixing ratio is 1 : 1. At room temperature, mixtures of A and B components have a pot life of at least three days. For detailed information please refer to the latest edition of our brochure "SOLID AND LIQUID SILICONE RUBBER - MATERIAL AND PROCESSING GUIDELINES".

Packaging and storage

Packaging

This product is available in 200 kg drums and 20 kg pail kits. SILPURAN® is neither produced nor packed under sterile conditions, so the final product has to be sterilized prior to use, if necessary.

Storage

Once opened, containers should always be resealed after use to prevent the platinum catalyst from being poisoned by amines, sulphur or phosphorus compounds. For detailed information about storage conditions please refer to the latest edition of our brochure "SOLID AND LIQUID SILICONE RUBBER - MATERIAL AND PROCESSING GUIDELINES". The 'Best use before end' date of each batch is shown on the product label. Storage beyond the date specified on the label does not necessarily mean that the product is no longer usable. In this case however, the properties required for the intended use must be checked for quality assurance reasons.

Safety notes

Comprehensive instructions are given in the corresponding Material Safety Data Sheets. They are available on request from WACKER subsidiaries or may be printed via WACKER web site http://www.wacker.com.

QR Code SILPURAN® 6610/40 A/B



For technical, quality or product safety questions, please contact:

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The data presented in this medium are in accordance with the present state of our knowledge but do not absolve the user from carefully checking all supplies immediately on receipt. We reserve the right to alter product constants within the scope of technical progress or new developments. The recommendations made in this medium should be checked by preliminary trials because of conditions during processing over which we have no control, especially where other companies' raw materials are also being used. The information provided by us does not absolve the user from the obligation of investigating the possibility of infringement of third parties' rights and, if necessary, clarifying the position. Recommendations for use do not constitute a warranty, either express or implied, of the fitness or suitability of the product for a particular purpose.