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SILPURAN®

SILPURAN® 6000/20 A/B

HIGH PURITY LIQUID SILICONE RUBBER FOR HEALTH CARE APPLICATIONS

Product description

Liquid silicone rubber of the SILPURAN® 6000 series is a paste-like, easily-pigmentable two-component compound with short curing times. The vulcanizate is noted for its high transparency and excellent mechanical and electrical properties.

Properties

SILPURAN® 6000/20 A/B meets selected test requirements of ISO 10993 and United States Pharmacopoeia (USP) Class VI. The results of the biocompatibility tests are shown in the table "Biocompatibility test data".

Postcured parts can be used for food contact applications and are suitable for use under the Recommendation "XV. Silicones" of the BfR and FDA § 177.2600 under observance of any given limitations on extractable and volatile substances.

Special features

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.

Application

SILPURAN® 6000/20 A/B is particularly suitable for the economical production of large series of injection-moulded articles.
SILPURAN® 6000/20 A/B is designed for medical and pharmaceutical applications including implantation for < 30 days.

Processing

SILPURAN® 6000/20 A/B is delivered in a ready to use two-component kit (A and B component). With standard metering equipment the A and B components can be pumped directly from the original containers via a static mixer into the injection molding machine. The mixing ratio is 1 : 1.
At room temperature mixtures of A and B components have a pot life of at least three days.

Storage

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.

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SILPURAN®

Product data

Typical general characteristics	Inspection Method	Value
Hardness Shore A	DIN 53505	20
Appearance		transparent
Density	DIN EN ISO 1183-1 A	1,08 g/cm³
Viscosity (shear rate 1 s^{-1})	DIN 53019	290000 mPa s
Viscosity (shear rate 10 s^{-1})	DIN 53019	190000 mPa s
Tensile strength	DIN 53504 S 1	8,00 N/mm^2
Elongation at break	DIN 53504 S 1	850 %
Tear strength	ASTM D 624 B	25 N/mm
Compression set *)	DIN ISO 815-B (22 h / 175 °C)	17 %

Cure conditions: 5 min / 165 °C in press; postcuring for 4 h / 200 °C in ventilated air
*) Cure conditions: 5 min / 165 °C in press, postcuring for 6 h / 200 °C in ventilated air.
These figures are only intended as a guide and should not be used in preparing specifications.

Biocompatibility test data of SILPURAN® 6000

Test	Test method	Test results
USP Class VI		
systemic toxicity intracuteaneous toxicity	test of extractables from the elastomer in 0.9% saline, ethanol in 0.9% saline, PEG 400 diluted with cotton seed oil; extraction at 121 °C	no irritant or adverse systemic effects relative to controls
implantation test	implant of elastomer strips (120 h)	no local tissue effects relative to controls
ISO 10993-5		
Cytotoxicity	test of extractables from elastomer in cell culture medium (DMEM)	no cytotoxic effect
ISO 10993-10		
Sensitisation LLNA	test of extractables from elastomer in acetone/olive oil	no sensitisation
ISO 10993-11 (USP 25)		
Pyrogenicity	test of extractables from the elastomer in 0.9% saline	no pyrogenicity

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

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