

SILPURAN® AUX 8250 RO



Silicone Rubber Additives

SILPURAN® AUX 8250 RO is a white, barium sulphate containing batch that is used as a radio-opaque additive for peroxide cured high consistency silicone rubber. SILPURAN® AUX 8250 RO is designed for medical applications in compliance with the WACKER SILICONES HEALTH CARE POLICY including implantation for < 30 days.

Properties

SILPURAN® AUX 8250 RO contains approx. 75 % barium sulphate which meets the requirements of the US and European Pharmacopoeia. SILPURAN® AUX 8250 RO is intended particularly for use with peroxide cure high consistency silicone rubber. For addition cure high consistency rubber, SILPURAN® AUX 8251 RO is the better choice.

SILPURAN® AUX 8250 RO meets selected test requirements of ISO 10993 and United States Pharmacopoeia (USP) Class VI.

Specific features

- Food-contact
- Medical
- X-ray opaque

Technical data

Properties Uncured

Property	Condition	Value	Method
Appearance	-	white	-
Density	-	2.24 g/cm ³	DIN EN ISO 1183-1 A

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

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

SILPURAN® AUX 8250 RO is used as an additive to get a radio opaque high consistency silicone rubber.

The following studies were performed on vulcanizates containing SILPURAN® AUX 8250 RO according to ISO 10993:

- Cytotoxicity (ISO 10993-5)
- Sensitation LLNA (ISO 10993-10)
- Pyrogenicity (ISO 10993-11)

The following studies were performed on vulcanizates containing SILPURAN® AUX 8250 RO according to USP class VI:

- Acute systemic toxicity
- Intracutaneous toxicity
- Implantation test

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

Properly cured and post-cured vulcanizates of a suited HTV and SILPURAN® AUX 8250 RO 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.

Processing

SILPURAN® AUX 8250 RO and the high consistency silicone base rubber are mixed homogenously on a roll mill. The mixing ratio depends on the required concentration.

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

SILPURAN® is neither produced nor packed under sterile conditions, so the final product has to be sterilized prior to use, if necessary.

Storage

Please store the cardboard boxes in a dry and cool place. Once opened, cardboard boxes should always be resealed after use to avoid any contamination. 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® AUX 8250 RO



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

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