

SA 153 Yellow Material Data Sheet

General Product Information

SA 153 Yellow is a speciality grade peroxide cured elastomer.

The material has excellent physical properties making it ideally suited for the application of a finger tourniquet.

Material Physical Properties

Test	Range	Unit
Hardness	35 – 45	Shore A
Specific Gravity	1.10 – 1.18	g/cm ³
Tensile Strength	7.0 minimum	N/mm ²
Elongation	400 minimum	%
Tear Strength	18 minimum	Kn/m
Temperature Range	-50 up to 200	
Compression Set	N/A	
Colour	Yellow	

Cure Conditions

Physical properties are measured using a 2.5mm test sheet (6.0mm for hardness), cured under the following conditions:-

5 minutes press cure @ 115+/-5°C

4 hours post cure @ 200+/-5°C

Cleaning

Unless otherwise specified, Silicone Altimex material is not delivered in a sterile condition. Production is carried out within an ISO Class 7 clean room environment ensuring the product is delivered in a clean state.

If washing or cleaning of the product is required, then distilled or warm water with a mild soap solution may be used (do not use synthetic detergents or soaps). Rinse thoroughly in warm water followed by distilled or filtered water.

Sterilisation Methods

SA 153 Yellow is suitable for sterilisation by the following methods:

- 1) Ethylene Oxide – When sterilisation by Ethylene Oxide is carried out subsequent to delivery, the user should be satisfied that full sterilisation has been effective by carrying out bacterial tests and that de-gassing is complete.
- 2) Gamma Radiation – Radiation sterilisation of typically 25 Kgy has a negligible effect on silicone rubber. Higher doses will result in increased material cross-linking which will
 - a) Increase hardness
 - b) Reduce elongation

Repeat cycles of 5 x 25 kGy have shown to reduce elongation by approximately 65% and increase hardness by around 5° Shore A

- 3) Autoclave – Typical autoclave cycles of 30 minutes @ 115°C, 15 minutes @ 121°C and 3 minutes @ 134°C can be carried out. If repeated autoclaving is to take place then the user must be satisfied as to the serviceability of the material after each cycle.

The user should be satisfied that the sterilisation method used is carried out under controlled conditions and that any additional components (i.e. assembled parts) are not damaged by the sterilisation method chosen.

Any goods supplied in a sterile condition by Silicone Altimex are subject to prior process validation procedures and certification by the sterilising agent to ensure effective sterilisation. Product bio-burden tests may be carried out together with sterilisation effectiveness tests at an independent laboratory.

Appearance of Product

The surface of the product shall be free from flaws and defects which may weaken or detract from the performance in application.

Contamination

Particles and gel particles will be present in silicone as a natural by-product of the process. Every precaution is taken to screen out particles during the production process. Final inspection endeavours to prevent excessive particles being released. Quality information supplied with all quotations defines the particles deemed acceptable.

Biocompatibility

The raw material polymer used in the formulation of SA 153 Yellow has been tested and complies with the requirements of the following tests:

Test	Comment
European Pharmacopoeia	
USP Class VI	Acute systemic toxicity Intracutaneous toxicity Implantation
ISO 10993	Cytotoxicity Haemolysis Pyrogenicity Sensitisation Dermal Irritation Implantation
FDA 177.2600	
KTW	
WRAS	
BgVV	
The above tests have been carried out on un-pigmented material. It would be expected for pigmented materials to meet or exceed the requirements of the tests	

Products manufactured in SA 153 material are suitable for applications requiring constant contact with body fluids or body tissue for up to a maximum of 29 days. Applications where contact exceeds 29 days are prohibited



Product Improvements & Amendments

Silicone Altimex have a policy of continuous improvement, material specifications are regularly reviewed and specifications are liable to change based on the reviews of data. Silicone Altimex reserve the right to amend specifications at any time. If you require copies of amended specifications for your product please communicate this to the quality department.

Health & Safety

Health and safety data is available for all of the compounds produced at Silicone Altimex on request

Storage

Silicone Altimex certify that the material will meet the sales specification for a minimum of 5 years from the date of manufacture provided the goods remain in the original packaging and are stored in such a way as to prevent damage. Product should be stored at ambient temperature.

Warranty

Due to the numerous applications our compound and profiles may be used for, Silicone Altimex will warrant any product produced in this material. The compound is only guaranteed to perform within the specification parameters as defined on this material sheet.

The customer must satisfy themselves that profiles and components produced in this material are fully tested for their require end use.

Silicone Altimex will not accept liability for products manufactured in materials which have not been fully customer tested and subsequently fail in applications for which the material is not fully suited.

Customer Care

Silicone Altimex have a very experienced team of experts readily on hand to help with any problems you may have regarding silicone applications. Standard materials can be adjusted or new materials developed to suit particular customer and application requirements. Silicone Altimex are happy to assist customers in designing the ideal solution to their silicone problems

Visit our website @ www.silalt.co.uk





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