SA 450/65 Material Data Sheet

General Product Information

SA 450/65 is a speciality medical grade platinum cured elastomer, offering high clarity combined with excellent physical properties with a dry and none tacky surface.
The excellent physical properties of SA 450/65 allow the tubing to be used in a wide variety of applications. These include use within roller or peristaltic pumps, including dialysis machines, blood and fluid handling equipment, feed lines and I.V. lines.
The excellent clarity of SA 450/65 is also an added benefit in the above and in many other applications.

Physical Properties

Test	Range	Unit	Test Standard
Hardness	60 - 70	Shore A	ASTM D2240
Specific Gravity	1.13 - 1.23	g/cm³	Electronic analysis
Tensile Strength	8.0 minimum	N/mm²	BS 903/A2
Elongation	400 minimum	%	BS 903/A2
Tear Strength	25 minimum	kN/m	BS 903/A3
Temperature Range	-50 up to 200	°C	
Compression Set	TBA	%	BS 903/A6
Colour	Translucent		

Cure Conditions

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

10 minutes press cure @ 150+/-5°C
4 hours post cure @ 200+/-5°C

Advantages of SA 450/65

Available in sizes to order.
High tear resistance.
No Phthalates to leach out from the tubing as can happen with PVC tubes.

Notes on using SA 450/65 in pumping applications

Great care should be taken to avoid over-occlusive settings. Roller settings should always allow blood cells to pass through the tubing undamaged.

Over-occlusive settings may cause excessive wear and damage, particularly to the inner bore of the tubing. This could in some instances result in the release of small particles (spalls) from the wall of the tubing, filtration of the return line to the patient is therefore recommended.

Care should be taken to avoid handling and using the tubing in such a way that may cause tears or nicks to occur.

Do not lubricate the tubing with silicone fluids or greases, this could cause swelling and weakening of the tube walls.

Repeated use of silicone tubing in pump applications is not recommended. Pump application tubing is specifically intended for single use.

Tubing clamps, both on the pump and elsewhere, should not be adjusted so as to cause damage to the tubing.

Care must be taken not to load tubing into the pump head in a twisted manner. This could damage the tubing resulting in a serious loss of performance.

Cleaning

Unless otherwise specified, Silicone Altimex tubing is not delivered in a sterile condition. Production in a Federal Standard 209E cleanroom class 10000 environment ensures that the tubing is delivered in a clean state. If washing of the tubing is still required, then distilled water or hot water with a mild soap solution may be used (do not use synthetic detergents or oil based soaps). Rinse thoroughly in hot water followed by distilled water.

Sterilization methods

1) Ethylene Oxide

When sterilization by Ethylene Oxide is carried out subsequent to delivery, the user should be satisfied that full sterilization has been effected by carrying out bacterial tests, and that degassing is complete.

2) Gamma Radiation

Radiation sterilization 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
c) Reduce tensile strength

A dosage of around $5x10^{7}$ may reduce elongation by 30-40% and tensile by 20%. $5x10^{8}$ kGy may reduce elongation by up to 75%.

The user should be satisfied that the radiation sterilization has been carried out under known controlled conditions and be satisfied that the sterilization is not detrimental to the end use of the product.
Care should be taken that any additional components in an assembly are not damaged b the radiation sterilization.

3) Autoclave

Autoclaving at cycles of 10 minutes @ 130°C and 30 psi or 30 minutes @ 121°C and 15 psi can be carried out.
If repeated autoclaving is to take place then the user must be satisfied as to the usability of the tubing following each cycle.
Care must be taken that all autoclave procedures are carried out under the correct conditions of temperature and pressure.

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

Biocompatibility

The materials used in the formulation of SA 450/65 have been type approved to the following:-

Test	Comment
FDA CFR 177.2600	
BGVV XV	
European Pharmacopeia VI.1.3.2	
USP Class VI	

NOTE:
Tubing and other products manufactured in SA 450/65 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 proscribed

Appearance of Tubing

The surface of the tubing shall be free from flaws and defects which may weaken or detract from the performance of the tubing.
The tube shall be free from scratches, flow marks, bubbles or bubble patterns. In no instance will any of the aforementioned defects be sufficient to cause the properties of the tube to be impaired.

Product Improvements & Amendments

Silicone Altimex have a policy of continuous improvement, material specifications are regularly reviewed using statistical analysis. Product specifications are liable to change based on this analysis. Silicone Altimex reserve the right to amend materials and specifications at any time. If you would like copies of amended specifications please request these from the Quality manager.

Health and Safety

Health and safety data on all our compounds can be obtained on request from Silicone Altimex.

Storage

Silicone Altimex certifies that the product will meet the sales specification requirements for 5 years from the despatch date providing that the goods are stored in the original unopened container and stored in such a way that damage to the
container is avoided.
Product should be stored at ambient
temperature.

Warranty

Due to the numerous applications our compounded profiles may be used for, Silicone Altimex will not warrant any product produced in this material. The compound is only guaranteed to perform as stated within the parameters of the specific material specification. The customer must satisfy themselves that profiles and components produced in the material are fully tested for their required end use. Silicone Altimex will not accept liability for products produced in the material which have not been fully 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 problems.

Visit our web site @ **www.silalt.co.uk**

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