SA 152 Material Data Sheet

General Product Information
SA 152 is a speciality medical grade peroxide cured silicone elastomer. Offering high clarity combined with excellent physical properties make SA 152 ideal for a variety of applications. These include use within roller or peristaltic pumps including dialysis machines, blood and fluid handling, equipment feed lines and intravenous lines. The clarity of SA 152 and its excellent physical properties make it the ideal choice for numerous applications.

Material Physical Properties		
Test	Range	Unit
Hardness	50 - 60	Shore A
Specific Gravity	1.13 – 1.19	g/cm^3
Tensile Strength	7.5 minimum	N/mm^2
Elongation	400 minimum	%
Tear Strength	20 minimum	Kn/m
Temperature Range	-50 up to 200	°C
Compression Set	N/A	
Colour	Translucent / Any	

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 @ 116+/-5°C
4 hours post cure @ 200+/-5°C

Advantages of using SA 152

1) Pump life typically in excess of 150 hours*
2) Available in custom sizes to order
3) High Tear resistance
4) No Phthalates to leach out of the tubing as can happen with PVC tubes

Notes on using SA 152 in Pumping Applications

1) Care should be taken to avoid over-occlusive settings. Roller settings should always allow blood cells to pass through the tubing undamaged
2) Over Occlusive settings may cause excessive wear and damage, particularly to the inner bore of the tubing. This could 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
3) Care should be taken when handling to avoid damage to the tubing, particular care should be taken to avoid tears or nicks which would rapidly propagate.
4) Do not lubricate the tubing with any silicone fluids or grease, this can cause swelling and weakening of the tube walls.
5) Repeated use of silicone tubing in pump applications is not recommended. Tubing for pump applications is recommended for single use only
6) Tubing clamps, both on the pump and elsewhere should be adjusted so as to cause no damage to the tube walls
7) Care must be taken when loading the tubing into pump heads, avoid twisting the material as this will damage the tubing a lessen performance

Pump Life

Repeated laboratory tests on two roller pumps set at 100RPM have shown pump life to failure is on average in excess of 150 hours. Commonly over 200 hours is achieved

Cleaning

Unless otherwise specified, Silicone Altimex tubing is not delivered in a sterile condition. Production is carried out within an ISO Class 7 clean room environment ensuring the tubing is delivered in a clean state.
If washing or cleaning of the tubing 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 152 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 Tubing

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

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 using SA 152 defines the typical particles deemed acceptable.

Biocompatibility

SA 152 has been tested and complies with the requirements of the following tests:

L929 MEM Elution Test	Meets the requirements of Elution test USP 23 and is considered non-cytotoxic
Physicochemical test for Elastomeric Closures	Meets the USP requirement
Haemolysis – Rabbit blood	Exhibited 0.73% haemolysis and is considered non-haemolytic
Rabbit Pyrogen (material mediated)	Meets or exceeds the requirement of the USP test
USP Class VI	Meets the requirement of USP 23, biological test for plastics 1995 Class VI - 70°C
European Pharmacopoeia physicochemical test for silicone elastomer for closures and tubing	Meets or exceeds the requirement of the European Pharmacopoeia
Kligman Maximisation Test	ISO 10993
Salmonella Typhimurium and Escherichia Coli Reverse mutation assay	ISO 10993
FDA CFR 21 177.2600	Rubber articles intended for repeat use in contact with food
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 but this cannot be guaranteed.	

Tubing and other products manufactured in SA 152 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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