Medical Material - Liquid Silicone Rubber (LSR)

Characteristics

Vulcanised articles manufactured from this 'two-component', multi-purpose platinum catalysed liquid silicone rubber moulding grade, exhibit a unique combination of characteristics and properties. They are noted for their very short curing times, good flexibility, high transparency (when un-pigmented) and excellent mechanical properties. They are also particularly suitable for the economical production of large quantities of injection-moulded articles, primarily for the medical, pharmaceutical and biopharmaceutical sectors. The material can be easily pigmented and has very good processing characteristics.

Product data

Material Reference: PR 415 / 10 (Liquid Silicone Rubber)

Special Features:

- Temperature range from –55ºC to 230ºC
- Excellent flexibility, good blend of physical properties
- High resiliency
- No imparted taste or odour
- No added organic plasticisers, phthalates or latex additives
- No peroxide by-products
- Easily sterilised (see overleaf)
- Very short cure times & consistent performance
- Platinum catalysed
- Complies with BfR & FDA 177.2600 food contact regulations
- WRC/ WRAS approved
- USP VI and ISO10993 approved

Colour: Translucent

Safety Information

Detailed, safety specific information can be obtained from the Primasil Material Safety Data Sheets (MSDS), which are available upon request.

Regulatory Status

Primasil medical liquid silicone rubber has been tested using known and established protocols and requirements for the food and medical sectors.

Typical Physical Properties

Test	Standard	Units	Typical Values
Density	ISO 2781: 2008	g/cm³	1.08
Hardness	ISO 7619-1: 2010	SHORE ºA	10
Tensile Strength	ISO 37: 2005	MPa	3.7
Elongation @ Break	ISO 37: 2005	%	660
Tear Strength	ISO 34:2004	KN/m	10
Rebound Resilience	DIN 53 512	%	41
Compression Set: (22Hrs @ 175ºC)	ISO 815-1: 2008	%	22

Typical Laboratory Cure Conditions

Press-cure	3 minutes @ 165ºC
Post-cure	4 hours @ 200ºC
Catalyst type	Platinum

This data is obtained from test pieces moulded in the laboratory and are intended as a guide. They should not be used in preparing specifications.

Quality Assurance

All Primasil Liquid Silicone Rubber products are manufactured to the Qualty Standard 'ISO 13485: 2003', ensuring full documentation and full traceability. Critical properties are controlled throughout the entire manufacturing process.

Production Conditions

All Primasil Liquid Silicone Rubber products are manufactured in an ISO Class 7, 10,000 Clean-room to ISO 13485: 2003 Quality standard

Sterilizing Conditions

It is the user's responsibility to validate a sterilisation process for silicone mouldings / products. The user should conduct testing if sterilisation conditions vary and/or if minor property changes could affect performance. Common sterilisation procedures include:

1. Autoclave (Steam-sterilisation). Silicone mouldings can be effectively sterilised by steam in an autoclave. However, silicone materials are more difficult to heat than other materials, such as thermoplastics, because they have thermal insulating properties and so care must be taken to ensure properties are not altered.

2. Gamma Radiation Sterilisation. Gamma radiation studies of the effects on the physical properties of the silicone elastomer have shown that doses of radiation up to 2.5 Mrad (25kGy) do not adversely affect hardness, elongation, modulus, tensile or tear strength. Repeated gamma sterilisation or processing at higher doses and for longer periods however, may affect some of the physical properties of the elastomer. Testing should therefore be conducted by the user if sterilisation conditions vary and if minor property changes could affect application performance.

3. Ethylene Oxide Sterilisation. ETO has been used to sterilise silicone products with no degradation of physical properties. Sterilisation by this method is only recommended if procedures allow sufficient time for complete out-gassing of residual ETO and ETO by-products