



PR 410/50 Medical Silicone Rubber

High Consistency Silicone Rubber (HCR)

Characteristics

Vulcanised articles manufactured from this multi-purpose platinum catalysed (addition curing) silicone rubber exhibit a unique combination of characteristics and properties. They are noted for their short cure times, good flexibility and excellent mechanical properties. PR410/50 can be moulded and or extruded, is transparent but can be easily pigmented* and has very good processing characteristics.

Product Data

Material Reference: PR 410 / 50 (Medical HCR)

- Special Features:**
- Temperature range from -55 °C to 200 °C
 - Excellent flexibility, good blend of physical properties
 - Suitable for moulding or extrusion
 - Short cure times
 - Easily sterilised (see overleaf)
 - No imparted taste or odour, no peroxide by-products
 - No organic plasticisers, phthalates or latex additives
 - Complies with BFR and FDA CFR 21 § 177.2600
 - Complies with WRAS (BS 6920-1: 2000)
 - Meets USP Biological Tests, Classification VI
 - Meets ISO 10993-1 Biocompatibility Tests

Colour: Transparent (*N.B. pigment addition may affect approvals / certifications)

Safety Information

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

Physical Properties

Test	Standard	Units	Typical Values
Hardness	ISO 7619-1	Shore A	50
Density	ISO 2781	g/cm ³	1.14
Tensile Strength	ISO 37	MPa	9.8
Elongation @ Break	ISO 37	%	725
Tear Strength	ASTM D 624 B	kN/m	41
Compression Set: (22 Hrs @ 175 °C)	ISO 815-1	%	16

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Typical Cure Conditions

Press-Cure	5 minutes @ 165 °C
Post-Cure	4 hours @ 200 °C (in ventilated air)
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 Silicone Rubber products are manufactured in accordance to the Quality Management Systems of ISO 9001 and if required; ISO 13485 and TS 16949. Full documentation and full traceability are ensured.

Production Conditions

At Primasil Silicones, controls are implemented to ensure critical parameters are monitored throughout the entire production process to achieve customer requirements.

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).

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.

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