Product Information
Healthcare

DOW CORNING

Silastic® BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765, and Q7-4780) Parts A & B

Raw materials for medical device fabrication in the Healthcare Industry

FEATURES

- No peroxide volatiles or residues generated during cure
- Non-blooming
- No phthalates or other organic plasticizers
- Optional post-cure to stabilize properties
- Sterilizable by ETO, autoclave, and gamma irradiation
- High gas permeability compared to most thermoset elastomers and thermoplastics
- Pigmentable

COMPOSITION

- Two-part silicone elastomer

APPLICATIONS

- *Silastic*® BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765, and Q7-4780) are heat-cured high consistency silicone rubbers designed for use by customers fabricating medical devices, including those intended for implantation in humans for less than 30 days.

DESCRIPTION

Silastic BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765, and Q7-4780) are a series of two-part, enhanced-tear-resistant (ETR) silicone elastomers that consist of dimethyl and methylvinyl siloxane copolymers and reinforcing silica. The elastomers exhibit a range of hardness from soft (20 Shore A) to firm (80 Shore A). Each elastomer is supplied as a two-component kit (Part A and Part B), equal portions (by weight) of which must be thoroughly blended together prior to use. The elastomer is then thermally cured via addition-cure (platinum-cure) chemistry

MANUFACTURING ENVIRONMENT

Silastic BioMedical Grade ETR Elastomers are manufactured under strict quality-control guidelines. The Dow Corning Healthcare Industries Materials Site (HIMS) in Hemlock, MI, is dedicated to the production of silicone materials for healthcare applications. It is registered with the FDA (CFN 1816403) as a Drug Establishment. The site quality system is based on principles of current Good Manufacturing Practices for both Bulk Pharmaceutical Products and Medical Devices.

The site has been ISO registered with BSI since 1990. These elastomers are strained through a 200-mesh (75 micron) or finer screen to remove particulate contamination.

HOW TO USE

These elastomers are supplied as A and B components that must be combined in equal portions by weight on a two-roll mill prior to use.

Blending

The recommended sequence of blending the two components is to first soften Part B on a cooled two-roll mill. Remove from the mill and soften Part A. Add an equal portion, by weight, of softened Part B, and cross-blend the components until thoroughly mixed. The temperature of the blended material must be kept as low as possible to give maximum table life.

Blend only the amount that will be used in 3 to 4 hours. If carefully wrapped, blended material may be stored in a freezer (<0°C/32°F) for at least 7 days. Material stored in this manner should be warmed to room temperature before unwrapping to avoid condensation on the elastomer. Condensation may cause voids in molded or extruded parts.

Cure
Cure of the blended elastomer is accelerated by heat. The recommended cure conditions for a cross-section up to 1.905mm (0.075 inch) thicknesses are 10 minutes at 116°C (241°F). Proportionally more time is required to cure thicker cross-sections. The cure profiles for these products can be found in Figures 1and 2.

CAUTION: The cure may be inhibited by traces of amines, sulfur, nitrogen oxide, organotin compounds and carbon monoxide. Because organic rubbers often contain these substances, they should not come in contact with the uncured elastomer. Catalyst residues from silicone RTV elastomers and peroxide-cured silicone elastomers may also inhibit the cure.

All equipment should be thoroughly cleaned at the end of each use to avoid a build-up of cured stock. The residue may result in crumbs of elastomer being picked up by the next lot, causing imperfections.

Post-curing
Because these materials vulcanize via addition-cure, no residues are present and post-cure is not required. The user must confirm that press molding or short oven cures are suitable for any specific application. The principal volatile components of post-curing are short-chained polydimethylsiloxane fluids and water vapor. See the Typical Properties chart for specific post-cure information.

BIOCOMPATIBILITY
The results of selected biocompatibility tests are shown in Table I. Elastomer samples were sterilized by autoclaving before testing. Toxicological Summaries are available upon request.

REGULATORY STATUS
Silastic BioMedical Grade ETR Elastomers, when fully cured and washed, meet the requirements of FDA regulation 21CFR177.2600, covering rubber articles intended for repeated food contact.

Master Files for *Silastic* BioMedical Grade ETR Elastomers (Q7-4735, Q7-4750, Q7-4765, and Q7-4780) have been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the file must contact Dow Corning Corporation.

IMPORTANT INFORMATION *THE USER'S ATTENTION IS IN PARTICULAR DRAWN TO THE FOLLOWING STATEMENT:*
It is the User's responsibility to ensure the safety and efficacy of these materials for all intended uses. While this Material has passed screening tests that are applicable to products intended for implantation for up to 29 days, Dow Corning makes no end-use representation based on such testing. Nor does Dow Corning make any representation concerning the suitability of this product for applications of greater than 29 days of implantation in the human body.

HANDLING PRECAUTIONS
Product safety information required for safe use is not included. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The material safety data sheet is available on the Dow Corning website at dowcorning.com. You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

USABLE LIFE AND STORAGE
When stored at or below ambient temperature in the original unopened containers, this product has a usable life of 12 months from the date of production.

PACKAGING INFORMATION
Silastic BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765, and Q7-4780) are supplied in 13.6kg and 408.2kg (30 lb and 900 lb) kits, each containing equal portions of Part A and B. Each component is sealed in a polyethylene bundle.

Samples are available in 908g (2 lb) kits.

HEALTH AND ENVIRONMENTAL INFORMATION
To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our Web site, dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION – PLEASE READ CAREFULLY
The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that our products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall

not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that our products will meet the sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 1: Results of selected Biocompatibility Tests for *Silastic* BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765, and Q7-4780)

Test	Samples tested	*Silastic* BioMedical Grade ETR Elastomers Q7-4720 Q7-4735 Q7-4750 Q7-4765 and Q7-4780
Cell culture with neutral red uptake	Elastomer	No cytopathic effect (morphology changes)
	Cell culture medium extract of elastomer	No cytopathic effect (morphology changes) ≥75% viability
Ames Bacterial Reverse Mutagenicity	Acetone extract of elastomer	No evidence of genetic activity or cytotoxicity
	Saline extract of elastomer	No evidence of genetic activity or cytotoxicity
Hemolysis	Elastomer	Non-hemolytic
	Saline extract of elastomer	Non-hemolytic
USP Pyrogen	Saline extract of elastomer	Non-pyrogenic
USP Class V extractables	Saline extract of elastomer	Non-irritating and non-toxic relative to controls
System toxicity	5% ethanol in saline extract of elastomer	Non-irritating and non-toxic relative to controls
Intracutaneous reactivity	Polyethylene glycol (PEG 400) extract of elastomer	Non-irritating and non-toxic relative to controls
	Cottonseed oil extract of elastomer	Non-irritating and non-toxic relative to controls
Skin sensitization	Elastomer	No sensitization
	Saline extract of elastomer	No sensitization
	Ethanol or acetone extract of elastomer	No sensitization
90-Day implant	Elastomer	Reaction equivalent or lesser than negative control

Table 2: TYPICAL PROPERTIES

Specification Writers: Please contact your local Dow Corning sales office or your global Dow Corning connection before writing specifications on these products.

			Silastic BioMedicalGrade ETR Elastomers				
CTM[1]	Test	Unit	Q7-4720	Q7-4735	Q7-4750	Q7-4765	Q7-4780
As molded - 10 minutes at 116°C (240°F)							
0022	Specific gravity		1.11	1.12	1.16	1.20	1.20
0099	Durometer hardness (Shore A)		22	35	50	64	76
0137A	Tensile strength	MPa	9.29	9.84	10.16	7.94	7.6
		psi	1347	1427	1473	1151	1111
0137A	Elongation	%	1283	1171	903	890	654
0137A	Modulus, 200%	MPa	0.40	1.11	2.14	2.82	3.78
		psi	58	161	311	409	548
0159A	Tear strength, Die B	kN/m	32.2	36.6	45.9	45.5	42.6
		ppi	184	209	262	260	243
1057	Shrinkage (linear)	%	N/A	1.6	1.7	1.8	1.9
0085	Compression set	%	30.1	43.4	56.4	70.3	70.9
Post-cured - 2 hours at 177°C (350°F)							
0099	Durometer hardness, Shore A		46	44	57	75	83
0137A	Tensile strength	MPa	9.78	8.35	9.96	7.48	6.96
		psi	1419	1210	1444	1085	1010
0137A	Elongation	%	767	833	647	649	483
0137A	Modulus, 200%	MPa	1.53	1.99	3.03	3.7	4.12
		psi	222	289	440	536	597
0159A	Tear strength, Die B	kN/m	30.6	34.5	46.4	39.4	26.3
		ppi	175	197	265	225	150
1057	Shrinkage	%	N/A	2.3	2.4	2.3	2.3
0085	Compression set, 22 hours at 177°C (350°F)	%	33.6	34.9	45.8	76.2	81.2

Table 2: TYPICAL PROPERTIES Continued

CTM[1]	Test	Unit	*Silastic* BioMedicalGrade ETR Elastomers Q7-4720	Q7-4735	Q7-4750	Q7-4765	Q7-4780
Post-cured - 4 hours at 177°C (350°F)							
0099	Durometer hardness (Shore A)		46	45	59	77	83
0137A	Tensile strength	MPa	9.65	8.32	10.36	7.85	6.69
		psi	1399	1206	1503	1138	970
0137A	Elongation	%	771	838	623	619	444
0137A	Modulus, 200%	MPa	1.42	1.99	3.19	3.93	4.18
		psi	207	289	463	570	606
0159A	Tear strength, Die B	kN/m	29.4	34.3	44.2	40.7	22.5
		ppi	168	196	253	232	129
1057	Shrinkage	%	N/A	2.6	2.3	2.4	2.4
0085	Compression set, 22 hours at 177°C (350°F)	%	41.1	26.4	69.4	58.7	62.5
Post-cured - 8 hours at 177°C (350°F)							
0099	Durometer hardness, Shore A		46	46	59	77	84
0137A	Tensile strength	MPa	9.11	8.26	9.94	7.86	6.04
		psi	1321	1199	1442	1140	876
0137A	Elongation	%	742	843	577	591	384
0137A	Modulus, 200%	MPa	1.48	1.95	3.33	4.04	4.21
		psi	215	283	483	586	611
0159A	Tear strength, Die B	kN/m	33.7	32.6	39.5	45	21.3
		ppi	193	186	226	257	122
1057	Shrinkage	%	N/A	2.5	2.4	2.3	2.7
0085	Compression set, 22 hours at 177°C (350°F)	%	25.6	39.7	44.0	76.0	73.4

1. Corporate test method (CTM) procedures correspond to standard ASTM tests in most instances. Copies of CTMs are available upon request.

Figure 1: MDR 2000 cure testing of *Silastic* BioMedical Grade ETR Elastomers

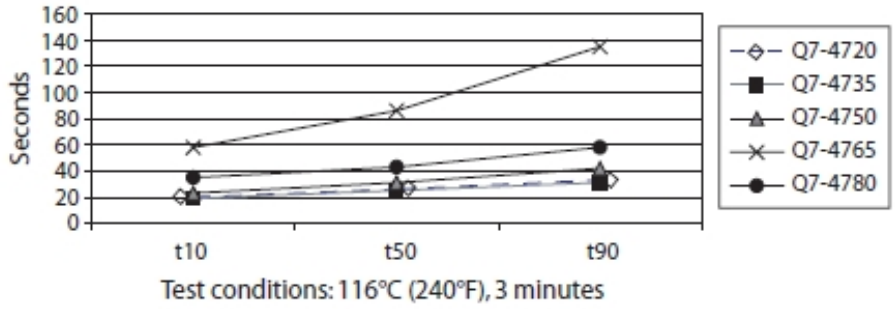

Figure 2: ODR 2000 cure testing of *Silastic* BioMedical Grade ETR Elastomers