Product Information
Healthcare

DOW CORNING

SILASTIC® BioMedical Grade Liquid Silicone Rubbers (7-6830, 7-6840, Q7-4840, Q7-4850, 7-4860, 7-4870, 7-6860) Parts A and B

Liquid Silicone Rubber raw materials for medical device and component fabrication in the Healthcare Industry

FEATURES

- Contains no peroxides, peroxide by-products, chlorophenyls or PCBs
- No organic plasticizers, phthalates or latex additives
- Solventless
- Non-blocking
- Can be post-cured
- Pigmentable

BENEFITS

- Qualified to address the tests described in ISO 10993-1 for "limited" (≤24 hours) and "prolonged" (≤30 days) contact duration:
  - Meets or exceeds acceptance criteria for Cytotoxicity, Sensitization, Irritation/Intracutaneous reactivity, Systemic toxicity (acute) and Subchronic toxicity (as tested by implantation)
  - Meets requirements of screening tests described by specific ISO standards for Hemocompatibility and Genotoxicity
- Meets or exceeds testing requirements of:
  - United States Pharmacopoeia (USP) Class VI
  - European Pharmacopoeia (Ph. Eur. or 'EP') silicone elastomers for closures and tubing—"Substances soluble in hexane" and "Volatile matter"
- Batch-to-batch consistency

COMPOSITION

- Two-part silicone elastomer

APPLICATION

- SILASTIC BioMedical Grade Liquid Silicone Rubbers (7-6830, 7-6840, Q7-4840, Q7-4850, 7-4860, 7-4870 and 7-6860) are heat-cured elastomer raw materials for use by customers fabricating medical devices, including those intended for implantation in humans for less than 30 days.

DESCRIPTION

SILASTIC BioMedical Grade Liquid Silicone Rubbers (7-6830, 7-6840, Q7-4840, Q7-4850, 7-4860, 7-4870 and 7-6860) are a series of two-part platinum-catalyzed silicone elastomers specifically designed for liquid injection molding or supported extrusion. Each elastomer is supplied as a two-part kit (Part A and Part B), equal portions (by weight) of which must be thoroughly blended together prior to use. The elastomer is thermally cured via an addition-cure (platinum-catalyzed) reaction. When blended and cured as indicated, the resulting elastomer consists of crosslinked dimethyl and methyl-vinyl siloxane copolymers and reinforcing silica.

The SILASTIC BioMedical Grade Liquid Silicone Rubbers are available in a range of nominal hardness from 30 to 60, Durometer-Shore A.
The elastomers can be used without any post-cure although if necessary, this may be employed to stabilize final properties. Furthermore, the elastomers are heat stable up to 204°C (400°F), can be autoclaved, and exhibit high gas permeability compared with most thermoset elastomers and thermoplastics.

HOW TO USE

Mixing

SILASTIC BioMedical Grade Liquid Silicone Rubbers are supplied as two-component kits (Parts A and B), which must be mixed in equal portions, by weight, prior to use.

Airless mixing, metering and dispensing equipment are recommended for production operations. Information is available from Dow Corning on the suppliers of suitable pumping, mixing, and molding equipment.

De-airing

If hand mixing, a vacuum of 711 to 737mm Hg (28 to 29 inches of mercury) should be sufficient to de-air the material in 20 to 30 minutes. Use a container 3-4 times the volume of the mixture to allow for expansion.

Cure

Cure of the mixed elastomer is initiated by heat. Raising the temperature of the fabrication to 140°C (284°F) results in a rapid cure to a tough elastomeric material.

Cure profiles for these products can be found in Figure 1. Please note that mixing parts A and B at anything other than a 1:1 ratio will likely change the molding times, and the resulting material's properties.

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 some room temperature vulcanized and peroxide-cured silicone elastomers may also inhibit the cure.

Post-curing

These materials crosslink via an addition-cure (platinum-catalyzed) reaction. No organic residues such as peroxides or their by-products are present and post-cure is not normally required for most applications.
The user must confirm that molding conditions or short oven cures are suitable for any specific application.

The principal volatile components evolved during post-curing are low molecular weight polydimethyl-silicone fluids and water vapor.

See Typical Properties chart (Table 1) for specific post-cure information.

QUALIFICATION TESTING

The results of selected qualification tests are shown in Table 2. Qualification Data Summaries are available upon request.

QUALITY

SILASTIC BioMedical Grade Liquid Silicone Rubbers are manufactured using appropriate principles of Good Manufacturing Practice (GMP) requirements. Dow Corning is globally registered to the ISO 9001 Quality Standard. Registration certificate number FM 10734 has been obtained through the British Standards Institution (BSI). Certification to ISO 9001 through an independent third party indicates that Dow Corning operates a quality management system in accordance with the standard, ensuring full documentation and traceability.

REGULATORY STATUS

SILASTIC BioMedical Grade Liquid Silicone Rubbers, when fully cured and thoroughly cleansed, may be used in accordance to the requirements of FDA regulation 21 CFR 177.2600, "Rubber Articles Intended For Repeated Food Contact".

FDA MASTER FILES

Master Files for select SILASTIC BioMedical Grade Liquid Silicone Rubbers have been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the files 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 these materials have 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 these products 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 www.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, these products have a usable life of 18 months from the date of production.

PACKAGING

SILASTIC BioMedical Grade Liquid Silicone Rubbers (7-6830, 7-6840, Q7-4840, Q7-4850, 7-6860) are supplied in 36.2kg pail and 408.2kg drum (80 lb and 900 lb) kits, each containing equal portions of part A and B. Samples are available in 907g (2 lb) kits.

SILASTIC BioMedical Grade Liquid Silicone Rubber (7-4860 and 7-4870) are supplied in 36kg pail and 400kg drum (79.4 lb and 882 lb) kits, each containing equal portions of part A and B. 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 website, www.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 customers' tests to ensure that Dow Corning's 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 the product will meet the Dow Corning 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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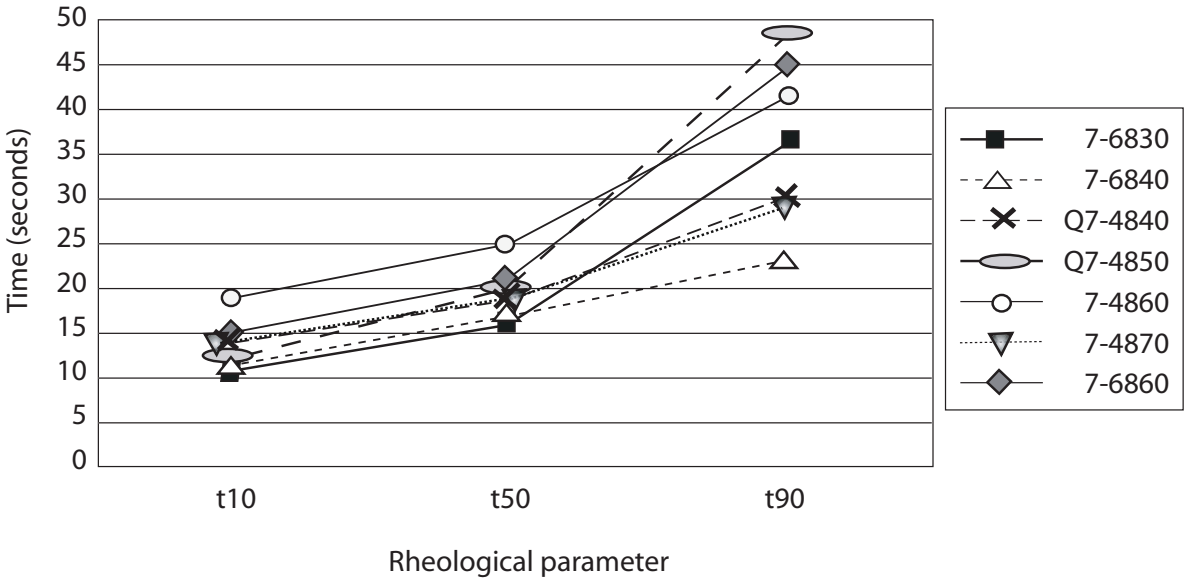
Figure 1: Moving die rheometry data[1]



2. Rheological properties measured with the Alpha Technologies Rheometer MDR 2000. Rheometer conditions: 149°C (300°F), 3-minute sweep time, 5.0-gram sample weight.

Table 1: TYPICAL PROPERTIES.

Specification writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative prior to writing specifications on these products.

				SILASTIC BioMedical Grade Liquid Silicone Rubbers						
CTM[1]	***ASTM***	***Test***	***Unit***	***7-6830***	***7-6840***	***Q7-4840***	***Q7-4850***	***7-4860***	***7-4870***	***7-6860***
Cure temperature			°C	150	150	150	150	150	150	165
			°F	302	302	302	302	302	302	329
No Post-cure, Press-cured for 5 minutes										
0022	D792	Relative density		1.13	1.13	1.12	1.15	1.10	1.15	1.15
0099	D2240	Durometer hardness, Shore A		30	42	44	53	58	66	57
0137A	D412	Tensile strength	MPa	8.8	9.9	9.4	10.2	8.8	9.5	10.0
			psi	1280	1430	1370	1470	1280	1380	1450
0137A	D412	Elongation	%	790	700	540	630	540	420	580
0137A	D412	Modulus, 200%	MPa	0.9	2.4	2.6	3.8	4.0	5.7	4.5
			psi	130	340	380	550	580	830	650
0159A	D624	Tear strength, Die B	kN/m	25	37	37	45	51	47	48
			ppi	140	210	210	260	290	270	270
0157		Shrinkage (linear)	%	2.3	2.3	2.3	2.1	2.7	2.7	1.9
0085	D395	Compression set	%	48.3	44.2	77.3	36.4	33.0	46.2	56.9

Table 1: TYPICAL PROPERTIES. (continued)

				SILASTIC BioMedical Grade Liquid Silicone Rubbers						
Post-cure temperature			°C	200	200	200	200	177	200	166
			°F	392	392	392	392	350	392	330
Post-cured — 2 hours										
0099	D2240	Durometer hardness, Shore A		34	47	47	54	58	70	61
0137A	D412	Tensile strength	MPa	8.25	9.25	6.44	9.28	8.80	9.10	9.69
			psi	1196	1341	934	1346	1276	1325	1405
0137A	D412	Elongation	%	668	578	300	497	503	348	463
0137A	D412	Modulus, 200%	MPa	1.60	3.28	3.96	4.19	4.27	6.30	5.36
			psi	232	475	560	607	619	911	778
0159A	D624	Tear strength, Die B	kN/m	39.9	46.9	28.4	48.5	47.5	26.0	51.1
			ppi	228	268	162	277	271	148	292
0157		Shrinkage (linear)	%	2.8	3.0	3.0	2.9	—	2.9	2.6
0085	D395	Compression set	%	64.0	67.6	21.4	37.1	—	36.1	28.1
Post-cured — 4 hours										
0099	D2240	Durometer hardness, Shore A		36	46	48	56	59	71	62
0137A	D412	Tensile strength	MPa	9.04	8.95	7.14	9.61	8.79	9.2	9.25
			psi	1311	1294	1036	1394	1274	1334	1342
0137A	D412	Elongation	%	677	564	313	505	518	329	423
0137A	D412	Modulus, 200%	MPa	1.81	3.23	4.1	4.34	4.21	6.60	5.50
			psi	262	468	595	630	610	951	798
0159A	D624	Tear strength, Die B	kN/m	63.3	45.4	27.5	51.0	49.5	20.0	49.6
			ppi	207	259	157	291	282	113	283
0157		Shrinkage (linear)	%	2.9	3.0	3.1	2.9	—	3.0	2.7
0085	D395	Compression set	%	3.4	18.2	24.1	10.6	—	31.8	27.5
CTM[1]	***ASTM***	***Test***	***Unit***	***7-6830***	***7-6840***	***Q7-4840***	***Q7-4850***	***7-4860***	***7-4870***	***7-6860***
Post-cure temperature			°C	200	200	200	200	177	200	166
			°F	392	392	392	392	350	392	330
Post-cured — 8 hours										
0099	D2240	Durometer hardness, Shore A		37	48	49	56	59	70	63
0137A	D412	Tensile strength	MPa	8.87	9.27	7.45	9.29	8.55	8.8	9.67
			psi	1268	1347	1080	1347	1240	1280	1402
0137A	D412	Elongation	%	644	553	324	477	492	321	411
0137A	D412	Modulus, 200%	MPa	1.97	3.55	4.01	4.46	4.29	6.4	5.85
			psi	285	515	581	647	622	935	848
0159A	D624	Tear strength, Die B	kN/m	32.7	48.7	26.1	49.9	50.7	22.0	50.4
			ppi	187	278	149	285	289	125	288
0157		Shrinkage (linear)	%	3.0	3.1	3.2	3.0	—	3.0	2.8
0085	D395	Compression set	%	16.5	19.9	14.2	27.0	—	29.9	15.9

1. CTM: (Corporate Test Method) corresponds to American Standard Test Methods (ASTM). Copies of CTM's are available upon request.

Table 2: Selected Qualification Data for SILASTIC BioMedical Grade Liquid Silicone Rubbers (7-6830, 7-6840, Q7-4840, Q7-4850, 7-4860, 7-4870, 7-6860).

Test[1]	*Samples tested*[2]	*Summary result*
Cell culture	• Elastomer	No cytopathic effect (morphology changes)
	• Minimal essential medium extract of elastomer	No cytopathic effect (morphology changes) ≥75% viability (by neutral red update)
Skin sensitization	• Elastomer	
	• Saline extract of elastomer	Non-sensitizing
	• Ethanol or acetone extract of elastomer	
USP Class V	• Saline extract of elastomer	
- Systemic toxicity	• Extract of elastomer in 5% ethanol / 95% saline	Non-irritating and non-toxic relative to controls
- Intracutaneous reactivity	• PEG 400 extract of elastomer (diluted in saline)	
	• Cottonseed oil extract of elastomer	
Implant	• Elastomer	Reaction equivalent to or less than negative control at 7, 30 and 90-days post-implantation[3]
USP Pyrogen	• Saline extract of elastomer	Non-pyrogenic
Mutagenicity	• Saline extract of elastomer	No evidence of genetic activity in the bacterial reverse mutation assay
	• Acetone extract of elastomer	
Hemolysis	• Elastomer	Non-hemolytic
	• Saline extract of elastomer	
European Pharmacopoeia[4]		
- Substances soluble in hexane	• Hexane extract of elastomer	≤3% residue
- Volatile matter	• Elastomer	≤2% weight loss

1. The categories of evaluation specified in ISO 10993-1 for medical devices with limited and prolonged exposure (not exceeding 30 days) are addressed by the tests listed here. European Pharmacopoeia testing is not a component of ISO 10993.
2. SILASTIC BioMedical Grade Liquid Silicone Rubber elastomer samples were prepared as follows: For 7-6830, 7-6840, Q7-4840, Q7-4850, 7-4860, and 7-4870: press-cured 5 minutes at 150°C (302°F). For 7-6860: press-cured 5 minutes at 165°C (329°F).
3. SILASTIC 7-6830, 7-4860 and 7-4870 explanted at 7, 30 and 90 days; 7-6840 explanted at 7, 30 and 91 days; Q7-4840 and Q7-4850 explanted at 8, 31 and 91 days; 7-6860 explanted at 7, 30 and 92 days.
4. European Pharmacopoeia monograph 3.1.9. Silicone Elastomer for Closures and Tubing. SILASTIC 7-6830, 7-6840, and Q7-4840 were post-cured 2 hours at 177°C (351°F) for European Pharmacopoeia tests.