

DOW CORNING® Class VI Elastomers (C6-135, C6-150, C6-165, C6-180) Parts A & B

FEATURES

- Contains no peroxides, peroxide by-products, chlorophenyls or PCBs
- Contains no organic plasticizers, phthalates or latex additives
- Non-tacky surface
- Non-blooming
- Can be post-cured
- Pigmentable

BENEFITS

- Qualified to meet or exceed the test requirements of:
 - United States Pharmacopeia (USP®) Class VI
 - European Pharmacopoeia (Ph. Eur. or 'EP') silicone elastomers for closures and tubing—"Substances soluble in hexane" and "Volatile matter"
 - ISO 10993-1 "Surface devices": cytotoxicity, sensitization and irritation/intracutaneous reactivity
- Batch-to-batch consistency
- Cost-effective

COMPOSITION

- Two-part silicone elastomer

High Consistency Rubber silicone elastomers for device and component fabrication in the healthcare industry

APPLICATIONS

- DOW CORNING Class VI Elastomers (C6-135, C6-150, C6-165, C6-180) Parts A & B are platinum-catalyzed heat-cured silicone High Consistency Rubbers for part fabrication, extrusion and medical devices, including those intended for implantation in humans for up to 29 days.

DESCRIPTION

DOW CORNING Class VI Elastomers (C6-135, C6-150, C6-165, C6-180) Parts A & B are a series of two-part platinum-catalyzed silicone elastomers. Each elastomer is supplied as a two-part kit (Part A & Part B), equal portions 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 elastomers are available in a range of nominal hardness from 35 to 80, durometer, Shore A. The elastomers can normally 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

These elastomers are supplied as two-component kits (Parts A & B) that must be thoroughly mixed in equal portions, by weight, prior to use. Typically, a two-roll mill is used for the blending process. If stored in a cold environment, warming to room temperature before unwrapping can help avoid condensation on the elastomer, which may cause voids in molded or extruded parts.

Blending

When using a two-roll mill, it is recommended to first soften the required amount of Part B while the mill is cool. Remove this from the mill and then soften the same amount, by weight, of Part A. When the Part A is sufficiently pliant, the Part B can be returned to the mill and the two Parts thoroughly cross-blended together. 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 up to 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.

Caution: The temperature of the blended material should be kept as low as possible to give maximum table life or working time.

Cure

Cure of the blended elastomer is accelerated by heat. The elastomer will cure in a mold cross-section up to 1.905mm (0.075 inch) thick in approximately 10 minutes at 116°C (240°F). Proportionally more time is required to cure thicker cross-sections. The cure profiles for these products can be found in Figures 1 and 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 some room temperature vulcanized 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, which is very difficult to remove. The residue may result in crumbs of elastomer being picked up by the next lot, causing imperfections.

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 polydimethylsiloxanes 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. Summaries of Qualification Data are available upon request.

ORDERING AND PRODUCT INFORMATION

For ordering and product information, contact your local Dow Corning Global Connection.

QUALITY

DOW CORNING Class VI materials are manufactured using appropriate principles of current Good Manufacturing Practice (cGMP) regulations. 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

DOW CORNING Class VI Elastomers, when fully cured and water rinsed, meet the requirements of FDA regulation 21CFR177.2600, "Rubber Articles Intended For Repeated Food Contact."

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 to be implanted for up to 29 days, Dow Corning makes no end-use representation based on such testing. These products are not designed for, tested for, intended for and therefore not suitable for implantation greater than 29 days 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 12 months from the date of production.

PACKAGING

DOW CORNING Class VI Elastomers (C6-135, C6-150, C6-165, C6-180) Parts A & B are supplied in 13.6 and 408.2 kg (30 and 900 lb) kits, containing equal portions each of Parts A & B. Each component is sealed in a polyethylene bundle.

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.

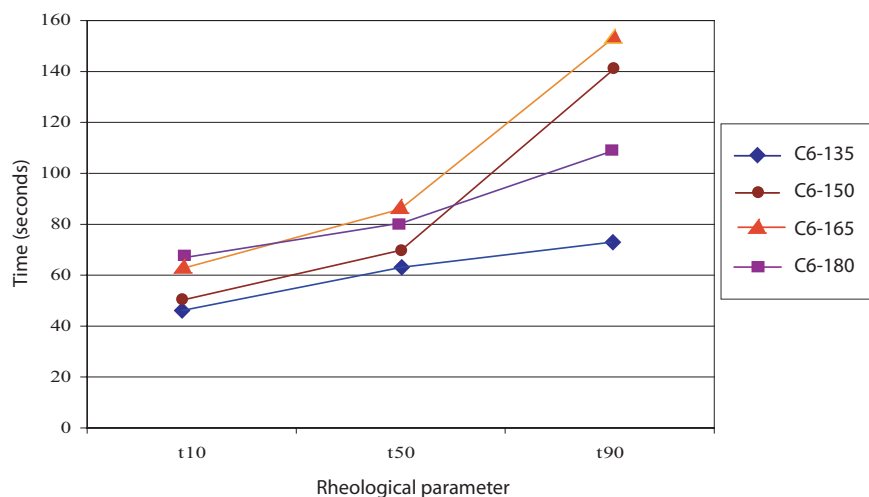
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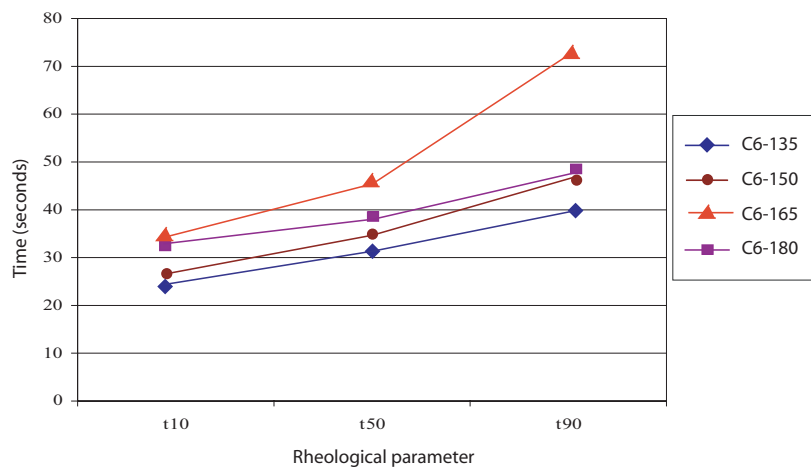
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Figure 1: Oscillating disc rheometry data¹



¹ Rheological properties measured with the Alpha Technologies Rheometer ODR 2000. Rheometer conditions: 116°C (240°F), 6-minute sweep time, 12.5g sample weight.

Figure 2: Moving die rheometry data²



² Rheological properties measured with the Alpha Technologies Rheometer MDR 2000. Rheometer conditions: 116°C (240°F), 3-minute sweep time, 5.0g sample weight.

Table 1: TYPICAL PROPERTIES

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

CTM ¹	ASTM	Test	Unit	Results			
				C6-135 ²	C6-150 ²	C6-165 ²	C6-180 ²
<i>No post-cure</i>							
0099	D2240	Durometer hardness, Shore A		36	50	61	77
0137A	D412	Tensile strength	MPa	8.28	10.65	8.05	7.23
0137A	D412	Tensile strength	psi	1201	1545	1168	1049
0137A	D412	Elongation	%	1117	976	939	614
0137A	D412	Modulus at 200%	MPa	1.23	1.94	2.45	3.68
0137A	D412	Modulus at 200%	psi	178	282	355	534
0159A	D624	Tear strength - die B	kN/m	35.2	42.7	42.2	39.1
0159A	D624	Tear strength - die B	ppi	201	244	241	223
0157		Shrinkage, linear	%	2.4	2.4	2.0	1.8
<i>Post-cured 2 hours at 177°C (350°F)</i>							
0099	D2240	Durometer hardness, Shore A		50	59	74	82
0137A	D412	Tensile strength	MPa	8.75	9.45	7.01	7.35
0137A	D412	Tensile strength	psi	1269	1371	1017	1066
0137A	D412	Elongation	%	847	730	672	500
0137A	D412	Modulus at 200%	MPa	2.10	2.69	3.36	4.07
0137A	D412	Modulus at 200%	psi	304	390	487	590
0159A	D624	Tear strength - die B	kN/m	37.8	43.6	44.5	22.2
0159A	D624	Tear strength - die B	ppi	216	249	254	127
0157		Shrinkage, linear	%	2.9	2.8	2.6	2.6
<i>Post-cured 4 hours at 177°C (350°F)</i>							
0099	D2240	Durometer hardness, Shore A		50	60	75	83
0137A	D412	Tensile strength	MPa	8.20	9.12	7.27	7.23
0137A	D412	Tensile strength	psi	1189	1322	1055	1048
0137A	D412	Elongation	%	814	675	691	481
0137A	D412	Modulus at 200%	MPa	2.11	2.83	3.36	4.05
0137A	D412	Modulus at 200%	psi	306	410	487	587
0159A	D624	Tear strength - die B	kN/m	35.9	45.7	40.3	22.4
0159A	D624	Tear strength - die B	ppi	205	261	230	128
0157		Shrinkage, linear	%	3.0	3.0	2.7	2.6
<i>Post-cured 8 hours at 177°C (350°F)</i>							
0099	D2240	Durometer hardness, Shore A		50	61	77	85
0137A	D412	Tensile strength	MPa	8.94	9.69	7.33	6.61
0137A	D412	Tensile strength	psi	1296	1406	1063	958
0137A	D412	Elongation	%	843	659	583	387
0137A	D412	Modulus at 200%	MPa	2.14	2.95	3.77	440
0137A	D412	Modulus at 200%	psi	310	428	547	638
0159A	D624	Tear strength - die B	kN/m	35.2	41.0	41.0	21.2
0159A	D624	Tear strength - die B	ppi	207	234	234	121
0157		Shrinkage, linear	%	3.0	3.1	2.6	2.8

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

2. Properties (except relative density) obtained from 1.905-mm (0.075-inch) thick ASTM slab cured 10 minutes at 116°C (240°F) and allowed to equilibrate a minimum of 3 hours at ambient conditions.

Table 2: Selected qualification data for DOW CORNING Class VI Elastomers (C6-135, C6-150, C6-165, C6-180)

<i>Test</i>	<i>Samples tested¹</i>	<i>Summary result</i>
Cell culture ²	<ul style="list-style-type: none">• Elastomer• Cell culture medium extract of elastomer	No cytopathic effect (morphology changes) No cytopathic effect (morphology changes); ≥ 75% viability (by neutral red)
Skin sensitization ²	<ul style="list-style-type: none">• Elastomer• Saline extract of elastomer• Ethanol or acetone extract of elastomer	No sensitization
USP Class V extractables - Systemic Toxicity - Intracutaneous reactivity ²	<ul style="list-style-type: none">• Saline extract of elastomer• Extract of elastomer in 5% ethanol/95% saline• PEG 400 extract of elastomer• Cottonseed oil extract of elastomer	Non-irritating and non-toxic relative to controls
Implant	<ul style="list-style-type: none">• Elastomer	Reaction equivalent to or less than negative control at 8 and 31 days post-implantation
European Pharmacopoeia ³ - Substances soluble in hexane - Volatile matter	<ul style="list-style-type: none">• Hexane extract of elastomer• Elastomer	≤ 3% residue ≤ 2% weight loss

1. Unless otherwise noted, DOW CORNING C6-135, C6-150, C6-165, C6-180 Parts A & B were molded approximately 10 minutes at 150°C (302°F) and tested without post-cure. Samples were autoclaved for all biocompatibility tests.

2. Tests meet ISO 10993-1 requirements for Surface Devices with “limited” (<24 hours) or “prolonged” (1 to 30 days) contact duration.

3. European Pharmacopoeia monograph 3.1.9: Silicone Elastomer for Closures and Tubing. C6-135 was post-cured 2 hours at 177°C (350°F) for European Pharmacopoeia testing only. C6-150, C6-165, and C6-180 were not post-cured. Samples were not sterilized prior to this testing.