

DOW CORNING® Class VI Elastomer C6-350LH Parts A & B

FEATURES

- Low hysteresis loss (high resiliency)
- Contains no peroxides, peroxide by-products, chlorophenyls or PCBs
- No organic plasticizers, phthalates or latex additives
- Non-tacky surface
- Non-blooming
- Can be post-cured
- Pigmentable

BENEFITS

- Longer service life in highly mechanical operations
- 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
- Lot-to-lot consistency
- Cost-effective

COMPOSITION

- Two-part silicone elastomer

High Consistency Rubber with platinum cure
Raw materials with enhanced physical properties for healthcare industry fabrication

APPLICATIONS

- DOW CORNING Class VI Elastomer C6-350LH is a platinum-catalyzed heat-cured silicone High Consistency Rubber for part fabrication, extrusion and medical devices, including those intended for implantation in humans for up to 29 days.
- This material exhibits enhanced physical properties and may be particularly beneficial for fabricating devices and products where high resilience (low hysteresis loss) is important.

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 this product.

CTM ¹	ASTM ²	Test	Unit	Result
No post cure				
0022	D792V	Relative density		1.15
0099	D2240	Durometer hardness, Shore A		49
0137A	D412	Tensile strength	MPa	8.54
			psi	1238
0137A	D412	Elongation	%	732
0137A	D412	Modulus at 200%	MPa	2.21
			psi	321
0159A	D624	Tear strength, die B	kN/m	37.8
			ppi	216
0157		Shrinkage	%	1.7
0085	D395	Compression set	%	60
Post-cured 2 hours at 177°C (350°F)				
0099	D2240	Durometer hardness, Shore A		56
0137A	D412	Tensile strength	MPa	7.97
			psi	1155
0137A	D412	Elongation	%	511
0137A	D412	Modulus at 200%	MPa	3.49
			psi	506
0159A	D624	Tear strength, die B	kN/m	43.3
			ppi	247

TYPICAL PROPERTIES (continued)

CTM ¹	ASTM ²	Test	Unit	Result
Post-cured 4 hours at 177°C (350°F)				
0099	D2240	Durometer hardness, Shore A		56
0137A	D412	Tensile strength	MPa	8.08
			psi	1172
0137A	D412	Elongation	%	510
0137A	D412	Modulus at 200%	MPa	3.39
			psi	491
0159A	D624	Tear strength, die B	kN/m	45.2
			ppi	258
Post-cured 8 hours at 177°C (350°F)				
0099	D2240	Durometer hardness, Shore A		57
0137A	D412	Tensile strength	MPa	7.79
			psi	1130
0137A	D412	Elongation	%	473
0137A	D412	Modulus at 200%	MPa	3.61
			psi	524
0159A	D624	Tear strength, die B	kN/m	42.4
			ppi	242

Properties obtained from 1.905mm (0.0750 inch) thick ASTM slab cured 10 minutes at 116°C (240°F) and allowed to equilibrate a minimum of 3 hours at ambient conditions.

1. CTM: Corporate Test Method, copies of CTMs are available on request.
2. ASTM: American Society for Testing and Materials.

DESCRIPTION

DOW CORNING C6-350LH Elastomer, Parts A & B is a two-part platinum-catalyzed silicone elastomer. It 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.

DOW CORNING C6-350LH Elastomer differs from our conventional high consistency rubber (HCR) products in that it exhibits enhanced physical properties. In particular, it exhibits lower hysteresis losses (more resiliency) compared to other platinum-catalyzed HCRs (Figure 1), and a reduction in crack growth propagation (Figure 2).

The elastomer can normally be used without any post-cure, although if necessary, this may be employed to stabilize final properties. Furthermore, the elastomer is heat stable up to 204°C (399°F), can be autoclaved, and exhibits high gas permeability compared with most thermoset elastomers and thermoplastics.

HOW TO USE

The elastomer is supplied as two-component kit (Parts A and 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 [$<32^{\circ}\text{F}$]) 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.

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. Cure profiles for these products can be found in Figures 3 and 4.

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 for specific post-cure information.

QUALIFICATION TESTING

The results of selected qualification tests are shown in Table 1.

A Qualification Data Summary is available upon request.

ORDERING AND PRODUCT INFORMATION

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

QUALITY ASSURANCE

DOW CORNING Class VI materials 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

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, this product has a usable life of 12 months from the date of production.

PACKAGING

DOW CORNING C6-350LH Elastomer is supplied in 13.6 and 408.2 kg (30 and 900 lb) kits, containing equal portions each of Parts A and 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.

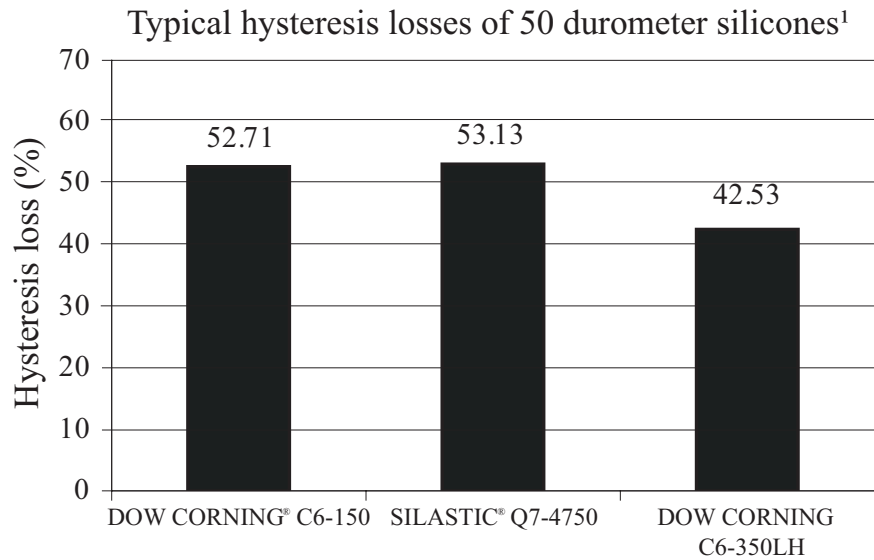
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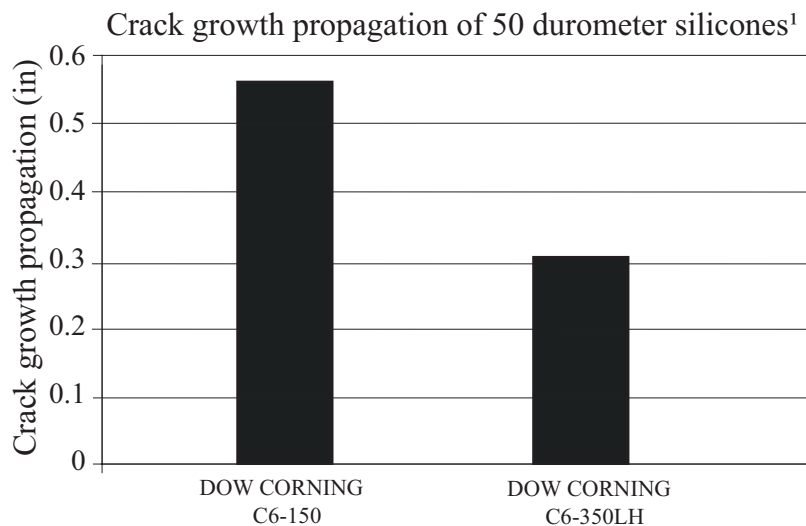
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Figure 1.



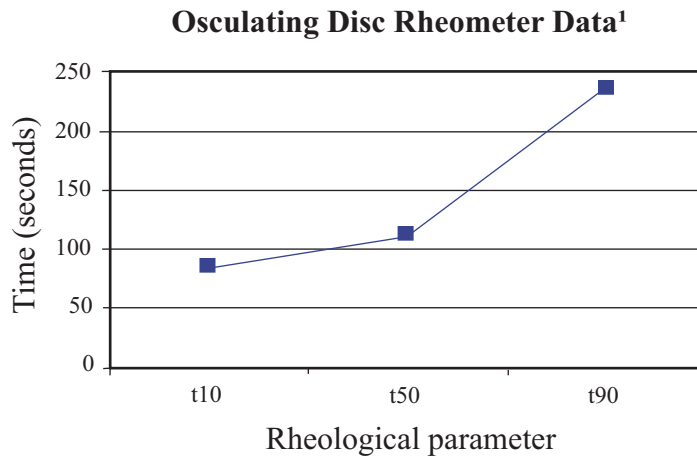
¹Testing performed per DOW CORNING CTM 0120, available upon request.

Figure 2.



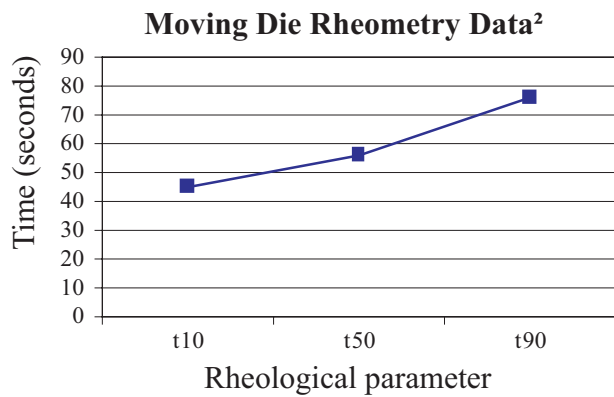
¹Testing performed per DOW CORNING CTM 0694, available upon request.

Figure 3.



1. Rheological properties measured with the Alpha Technologies Rheometer ODR 2000. Rheometer conditions 6-minute sweep time, 12.5 gram sample weight. C6-350LH: 116°C (240°F).

Figure 4.



2. Rheological properties measured with the Alpha Technologies Rheometer MDR 2000. Rheometer conditions 6-minute sweep time, 12.5 gram sample weight. C6-350LH: 116°C (240°F).

Table 1: Selected Qualification Data for DOW CORNING Class VI Elastomers C6-350LH

<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• 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	Nonirritating and nontoxic relative to controls
Implant	Elastomer ³	Reaction equivalent to or less than negative control at 7- and 30-days post-implantation
European Pharmacopoeia ⁴ - Substances soluble in hexane - Volatile matter	Hexane extract of elastomer Elastomer	≤ 3% residue ≤ 2% weight loss

1. Unless otherwise indicated, the elastomer tested was cured 10 minutes at 116°C (240°F), not post-cured, and was autoclaved before testing.

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

3. The elastomer implant tested was cured 5 minutes at 116°C (240°F), no post-cure, and was autoclaved before testing.

4. European Pharmacopoeia monograph 3.1.9: Silicone Elastomer for Closures and Tubing. Samples were not sterilized prior to this testing.