

Product Information

Healthcare

DOW CORNING® Class VI Elastomers (C6-530, C6-540, C6-550 C6-560, C6-570) Parts A & B

FEATURES

- Contains no peroxides, peroxide by-products, chlorophenyls or PCBs
- No organic plasticizers, phthalates or latex additives
- Solventless
- 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
- Fast cure system
- Easy processing
- Batch-to-batch consistency
- Cost-effective

COMPOSITION

- Two-part silicone elastomer

Liquid Silicone Rubber for device and component fabrication in the healthcare industry

APPLICATIONS

- DOW CORNING Class VI Elastomers (C6-530, C6-540, C6-550, C6-560, C6-570) Parts A & B are platinum-catalyzed materials designed for part fabrication and medical devices, including those intended for implantation in humans for up to 29 days.

DESCRIPTION

DOW CORNING Class VI Elastomers (C6-530, C6-540, C6-550, C6-560, C6-570) Parts A & B are a series of two-part platinum-catalyzed silicone elastomers. Each elastomer is supplied as a two-part kit (Part A and 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 30 to 70, 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

These elastomers are supplied as two-component kits (Parts A and B) that must be thoroughly 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.

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 accelerated by heat. Raising the temperature of the mixed material to 110°C (230°F) results in a rapid cure to a tough, elastomeric material. Cure profiles for these products can be found in Figures 1 and 2. Please note that mixing parts A & B at anything other than a 1:1 ration, by weight, 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 quick molding 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 ASSURANCE

DOW CORNING Class VI materials are manufactured using appropriate principles of Good Manufacturing Practice (GMP) 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 18 months from the date of production.

PACKAGING

DOW CORNING Class VI Elastomers (C6-530, C6-540, C6-550, C6-560, C6-570) are supplied in 36kg and 400kg (80 lb and 900 lb) kits, containing equal portions each of Parts A and B.

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 customer's 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.

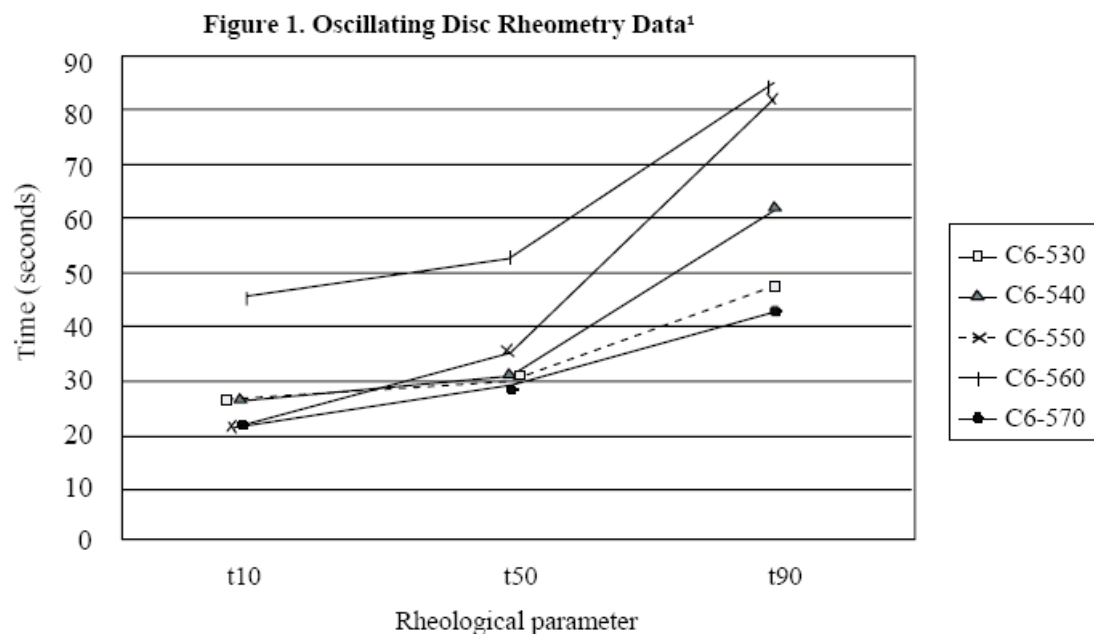
**DOW CORNING SPECIFICALLY
DISCLAIMS ANY OTHER
EXPRESS OR IMPLIED
WARRANTY OF FITNESS FOR A
PARTICULAR PURPOSE OR
MERCHANTABILITY.**

**DOW CORNING DISCLAIMS
LIABILITY FOR ANY
INCIDENTAL OR
CONSEQUENTIAL DAMAGES.**

We help you invent the future.™

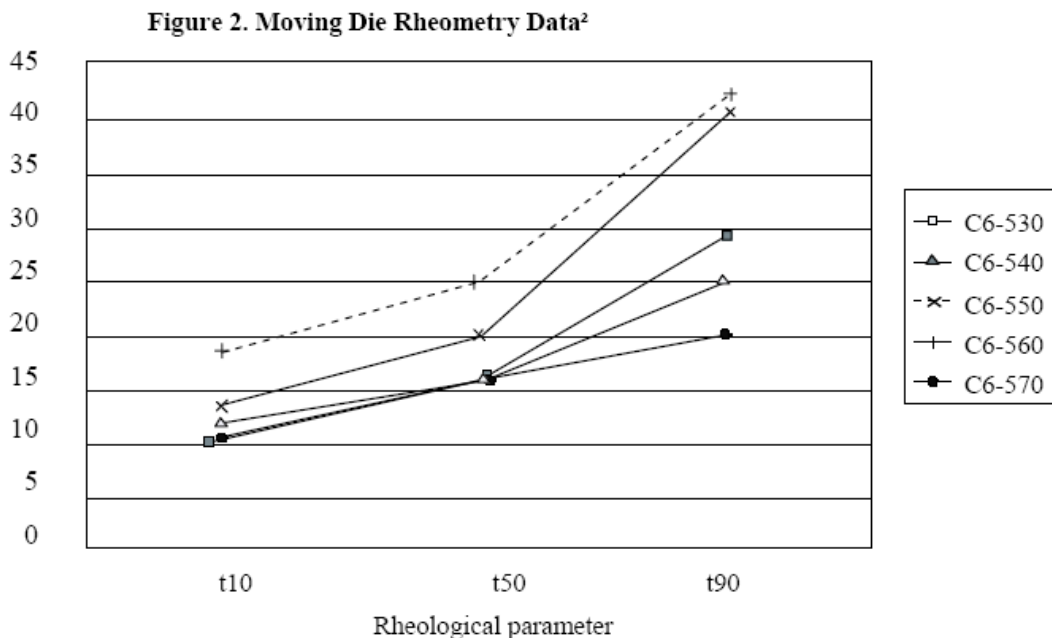
www.dowcorning.com

Figure 1:



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

Figure 2:



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

Table 1: TYPICAL PROPERTIES¹

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 ² | ASTM ³ | Test | Unit | C6-530 | C6-540 | C6-550 | C6-560 | C6-570 |
|--|-------------------|-----------------------------|------|--------|--------|--------|--------|--------|
| No Post-cure | | | | | | | | |
| 0022 | D792 | Relative density | | 1.13 | 1.13 | 1.14 | 1.10 | 1.15 |
| 0099 | D2240 | Durometer hardness, shore A | | 30 | 40 | 52 | 58 | 65 |
| 0137A | D412 | Tensile strength | MPa | 8.20 | 8.92 | 10.47 | 8.83 | 9.13 |
| | | | psi | 1190 | 1394 | 1518 | 1280 | 1324 |
| 0137A | D412 | Elongation | % | 831 | 742 | 661 | 540 | 442 |
| 0137A | D412 | Modulus, 200% | MPa | 0.89 | 2.12 | 3.20 | 3.97 | 5.24 |
| | | | Psi | 129 | 308 | 464 | 575 | 760 |
| 0159A | D624 | Tear strength - Die B | kN/m | 27.5 | 41.9 | 44.7 | 50.9 | 53.9 |
| | | | ppi | 157 | 239 | 255 | 290 | 308 |
| 1057 | | Shrinkage, linear | % | 2.0 | 2.0 | 2.0 | 2.7 | 1.9 |
| Post-cured - 2 hours at 177°C (350°F) | | | | | | | | |
| 0099 | D2240 | Durometer hardness, shore A | | 31 | 43 | 54 | 58 | 66 |
| 0137A | D412 | Tensile strength | MPa | 9.09 | 8.73 | 9.23 | 8.8 | 8.92 |
| | | | psi | 1318 | 1266 | 1339 | 1276 | 1294 |
| 0137A | D412 | Elongation | % | 833 | 642 | 530 | 503 | 380 |
| 0137A | D412 | Modulus, 200% | MPa | 1.15 | 2.70 | 3.92 | 4.27 | 5.78 |
| | | | psi | 167 | 391 | 569 | 619 | 839 |
| 0159A | D624 | Tear strength - Die B | kN/m | 28.2 | 45.0 | 49.0 | 47.5 | 49.4 |
| | | | ppi | 161 | 257 | 280 | 271 | 282 |
| Post-cured - 4 hours at 177°C (350°F) | | | | | | | | |
| 0099 | D2240 | Durometer hardness, shore A | | 32 | 42 | 54 | 59 | 67 |
| 0137A | D412 | Tensile strength | MPa | 8.51 | 8.72 | 9.04 | 8.79 | 9.05 |
| | | | psi | 1235 | 1265 | 1311 | 1274 | 1313 |
| 0137A | D412 | Elongation | % | 793 | 659 | 522 | 518 | 394 |
| 0137A | D412 | Modulus, 200% | MPa | 1.05 | 2.48 | 3.92 | 4.21 | 5.67 |
| | | | psi | 152 | 359 | 569 | 610 | 823 |
| 0159A | D624 | Tear strength - Die B | kN/m | 26.3 | 44.8 | 48.2 | 49.5 | 49.7 |
| | | | ppi | 150 | 256 | 275 | 282 | 284 |
| Post-cured - 8 hours at 177°C (350°F) | | | | | | | | |
| 0099 | D2240 | Durometer hardness, shore A | | 33 | 44 | 55 | 59 | 67 |
| 0137A | D412 | Tensile strength | MPa | 8.30 | 9.48 | 9.11 | 8.55 | 9.12 |
| | | | psi | 1204 | 1375 | 1322 | 1240 | 1323 |
| 0137A | D412 | Elongation | % | 796 | 660 | 508 | 492 | 386 |
| 0137A | D412 | Modulus, 200% | MPa | 1.10 | 2.85 | 4.12 | 4.29 | 5.83 |
| | | | psi | 160 | 413 | 598 | 622 | 846 |
| 0159A | D624 | Tear strength - Die B | kN/m | 27.0 | 45.7 | 49.9 | 50.7 | 50.3 |

1. Properties obtained from 1.905mm (0.075 inch) thick ASTM slab cured 5 minutes at 150°C (302°F) and allowed to equilibrate a minimum of 3 hours at ambient conditions.

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

3. ASTM: American Society for Testing and Materials.