Product Information
Healthcare

DOW CORNING

Dow Corning® Class VI Elastomers (C6-235, C6-250, C6-265)

FEATURES & BENEFITS

- Non-tacky surface
- Flexible curative selection
- Blendable to modify durometer
- No phthalates or other organic plasticizer additives
- Pigmentable
- Qualified to meet or exceed the test requirements of:
  - United States Pharmacopeia (USP®) Class VI
  - ISO 10993-1 Surface devices: cytotoxicity, sensitization and irritation/intracutaneous reactivity
  - European Pharmacopoeia (Ph. Eur. or EP) Silicone Elastomers for closures and tubing: substances soluble in hexane and volatile matter
- Batch-to-batch consistency
- Cost-effective

COMPOSITION

- One-part uncatalyzed silicone elastomer raw material

High consistency rubber raw materials for healthcare industry fabrication

APPLICATIONS

- *Dow Corning*® Class VI Elastomers (C6-235, C6-250, C6-265) are uncatalyzed silicone elastomer bases designed for compounding into elastomer for part fabrication and medical devices, including those intended for implantation in humans for up to 29 days.

DESCRIPTION

Dow Corning Class VI Elastomers (C6-235, C6-250, C6-265) are a series of one-part uncatalyzed silicone elastomer raw materials. The addition of a catalyst is necessary to accomplish cure.

The resulting elastomers range in hardness from soft to firm (nominally 35 to 65, shore A durometer). These materials may be blended if desired to achieve intermediate hardnesses.

After appropriate compounding with a catalyst, cure and post-cure, 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 elastomer raw materials are fully compounded except for curatives. The user must experimentally determine the choice and amount of curing agent, as well as the cure profile. Because of this, the *Dow Corning* Class VI Elastomers (C6-235, C6-250, C6-265) are recommended for customers who are familiar with compounding silicone elastomers. These elastomer raw materials allow the user a versatile selection of curing agents.

Dow Corning has used a number of common catalysts with elastomer raw materials of equivalent or similar formulation to *Dow Corning* C6-235, C6-250 and C6-265 elastomers, including, but not limited to those listed below. By mentioning our experience with these curing agents, we are not specifically sanctioning or otherwise endorsing their use. Proper selection and use of a curing agent is the user's responsibility.

1. Addition Cure masterbatches (*Dow Corning*® QP1-51 Catalyst, *Dow Corning*® QP1-48 Cure Inhibitor). The incorporation of a platinum catalyst and inhibitor masterbatch provides the necessary curatives for extruding and molding of these high consistency rubbers.

2. 50% 2,4-dichlorobenzoyl peroxide (PERKADOX® PD-50S). This peroxide may be favored for continuous hot air vulcanization because it produces low porosity silicone rubber parts without the application of pressure. This might not be the best peroxide choice for thermal moldings with thin sections. Partial cure before flow is complete, a problem known as scorch, might occur.

3. 2,5-dimethyl-2,5-di (tbutylperoxy) hexane (VAROX® DBPH) Preferred for molded parts with thick sections, this curing agent can produce elastomers with good tensile strength and elongation and low compression set.

4. Dicumyl peroxide (DI-CUP® R) This is another curing agent favored for thick section molding. It also produces elastomers with low compression set.

Catalyst addition and blending
Typically, a two-roll mill is used for the blending process. If the elastomer stock has been stored in the cold, warming to room temperature before unwrapping could help avoid condensation on the elastomer, which might cause voids in molded or extruded parts.

Peroxide materials
The stock should be softened to a smooth consistency on a two-roll mill. Then the peroxide is added and thoroughly blended into the stock, using care not to generate excess heat.

Use of insufficient curing agent will result in undercured elastomer that is soft or cheesy (crumbly and noncohesive), unsuitable for its intended purpose. The amount of peroxide needed for a given application cannot always be predicted by stoichiometry or laboratory experiment because peroxide may be lost (by evaporation, oxidation and other means) from the elastomer before cure is complete. It might be necessary to determine the amount of curing agent through experiment using the same elastomer raw materials and equipment that will be used for production.

It is the responsibility of the user to observe all precautions for the safe handling of the peroxide. Appropriate removal of the peroxides decomposition products is also the user s responsibility.

Platinum materials
The stock should be softened to a smooth consistency on a two-roll mill. Then the inhibitor masterbatch is added and thoroughly blended before adding the platinum masterbatch into the stock, using care not to generate excess heat. The temperature of the blended material should be kept as low as possible to give maximum table life or working time.

It might be necessary to determine the optimal amount of catalyst and inhibitor through experiment using the same elastomer raw materials and equipment that will be used for production.

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 cured 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.

Pigmenting and cross blending
Cross blending any combination of this series of stocks on a two-roll mill will give elastomers of intermediate durometer (hardness). Pigmenting can be accomplished by milling the pigment into the stock on a two-roll mill. Toxicity and suitability of the pigment for the application should be checked by the user.

Molding
These elastomers can be molded using standard techniques of compression or transfer molding. It might be necessary to determine the amount of curing agent and molding conditions through experiment using the same materials and equipment that will be used for production. The proportions and conditions given in the typical properties table are suggested starting points. The optimal parameters can only be determined through experimentation. 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 might result in crumbs of elastomer being picked up by the next batch, causing gels and imperfections.

Extruding
These elastomers can be extruded to make profiles such as filament (rod) and tubing. Extrusion can also make wire coating. A curing agent of the 2,4- dichlorobenzoyl peroxide-type (such as PERKADOX PD-50S) or platinum masterbatch may be used with these elastomer bases to help prevent formation of gas bubbles in the extruded profile. The extrusion of silicone elastomers (which are thermosetting) is generally accomplished using no heat in the barrel, and hot air vulcanization chambers downstream of the die.

For processing ease, compounded stock should be thoroughly softened on a two-roll mill the day of extrusion. The durometer (hardness) and mechanical properties (e.g., tensile strength) of extruded products may be lower than values obtained on molded test slabs.

Post-curing
Elastomers cured with peroxide agents must be post-cured. Post-cure provides two important benefits:
1. Post-cure helps remove residual by-products generated from the decomposition of the peroxide curing agent. If not properly removed, some of these residues can adversely affect biocompatibility of the elastomer.
2. Post-cure stabilizes and enhances elastomer physical properties.

Post-curing can be accomplished by heating the fabricated part in a hot-air circulating oven to the required temperature for the required length of time. The time required for post-curing at a given temperature depends upon the rate at which the volatiles evolve from the elastomer, which in turn depends upon thickness of the part and the exposed surface area. As an example, a molded standard 1.905mm (0.075 inch) thick ASTM

slab should be post-cured in a hot-air circulating oven at 177°C (350°F) for two hours when catalyzed with PERKADOX PD-50S.

QUALIFICATION TESTING

The results of selected qualification tests are shown in Table 1, page 6. 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 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, meet the requirements of FDA regulation 21CFR177.2600, Rubber Articles Intended For Repeated Food Contact. *Dow Corning* Class VI Elastomers are manufactured in an ISO 9001-registered facility using appropriate principles of current Good Manufacturing Practice (cGMP) regulations.

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 IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND MATERIAL 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 DOW CORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

USABLE LIFE AND STORAGE

When stored at or below ambient temperature in the original unopened containers, these products have a usable life of 24 months from the date of production.

PACKAGING INFORMATION

Dow Corning Class VI Elastomers (C6-235, C6-250, C6-265) are supplied double wrapped in boxes of 11.3 and 408.2kg (25 and 900 lb). The box contains uncatalyzed elastomer stock sealed in polyethylene-wrapped bundles of 11.3kg (25 lbs).

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, 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.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, 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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TYPICAL PROPERTIES[1]

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

CTM[2]	ASTM	Test	Unit	*Dow Corning* C6-235				*Dow Corning* C6-250				*Dow Corning* C6-265			
				Dow Corning(r)[3] QP1Masterbatch	PERKADOX[4] PD-50S	DI-CUP R[5]	VAROX DBPH[6]	Dow Corning(r)[3] QP1Masterbatch	PERKADOX[4] PD-50S	DI-CUP R[5]	VAROX DBPH[6]	Dow Corning(r)[3] QP1Masterbatch	PERKADOX[4] PD-50S	DI-CUP R[5]	VAROX DBPH[6]
		Molded without Post-cure													
0022	D792	Relative density		1.12	-	-	-	1.16	-	-	-	1.20	-	-	-
0099	D2240	Durometer hardness	shore A	37	31	35	42	51	44	48	56	64	54	64	70
0137A	D412	Tensile strength	MPa	8.5	6.9	7.7	7.5	9.1	8.3	8.5	7.9	7.9	7.8	8.0	7.9
0137A	D412	Tensile strength	psi	1231	1000	1120	1090	1316	1200	1230	1150	1153	1130	1160	1150
0137A	D412	Modulus at 200%	MPa	1.5	1.0	1.0	1.6	2.2	2.3	2.3	3.0	3.2	2.7	3.0	3.9
0137A	D412	Modulus at 200%	psi	211	150	150	230	319	330	330	440	469	390	440	570
0137A	D412	Elongation	%	1107	810	950	770	842	560	610	520	828	590	620	560
0159A	D624	Tear strength - die B	kN/m	37	19	23	26	41	26	37	37	47	37	40	40
0159A	D624	Tear strength - die B	ppi	212	110	130	150	231	150	210	210	269	210	230	230
0157		Shrinkage, linear	%	2.1	-	-	-	2.0	-	-	-	2.0	-	-	-
		Post-cured 2 hours at 177°C (350°F)													
0099	D2240	Durometer hardness,	shore A	52	37	41	43	55	49	55	58	72	66	71	73
0137A	D412	Tensile strength	MPa	8.8	8.2	8.0	8.2	8.7	8.9	9.0	9.2	7.6	8.6	7.8	7.6
0137A	D412	Tensile strength	psi	1279	1190	1160	1190	1258	1290	1300	1340	1100	1250	1130	1100
0137A	D412	Modulus at 200%	MPa	2.6	1.2	1.4	1.7	2.6	2.6	3.1	3.3	3.8	3.3	4.2	4.1
0137A	D412	Modulus at 200%	psi	384	180	200	250	377	370	450	480	547	480	610	600
0137A	D412	Elongation	%	696	810	760	780	737	530	490	530	674	560	430	500
0159A	D624	Tear strength - die B	kN/m	43	21	23	33	42	26	30	37	40	35	35	40
0159A	D624	Tear strength - die B	ppi	244	120	130	190	241	150	170	210	228	200	200	230
0157		Shrinkage, linear	%	1.8	2.2	3.1	3.2	2.0	2.0	3.0	3.0	2.3	2.6	3.2	3.0

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TYPICAL PROPERTIES[1] (continued)

CTM[2]	ASTM	Test	Unit	*Dow Corning* C6-235				*Dow Corning* C6-250				*Dow Corning* C6-265			
				Dow Corning(r)[3] QP1Masterbatch	PERKADOX[4] PD-50S	DI-CUP R[5]	VAROX DBPH[6]	Dow Corning(r)[3] QP1Masterbatch	PERKADOX[4] PD-50S	DI-CUP R[5]	VAROX DBPH[6]	Dow Corning(r)[3] QP1Masterbatch	PERKADOX[4] PD-50S	DI-CUP R[5]	VAROX DBPH[6]
		Post-cured 4 hours at 177°C (350°F)													
0099	D2240	Durometer hardness	shore A	53	37	41	44	56	46	55	58	74	67	70	72
0137A	D412	Tensile strength	MPa	8.8	9.0	7.6	7.6	8.7	9.7	8.3	9.0	7.4	7.6	7.6	7.6
0137A	D412	Tensile strength	psi	1278	1300	1100	1100	1259	1400	1200	1300	1077	1100	1100	1100
0137A	D412	Modulus at 200%	MPa	2.8	1.3	1.4	1.7	2.6	2.7	3.1	3.4	3.9	3.3	4.1	4.1
0137A	D412	Modulus at 200%	psi	400	190	210	240	375	390	450	490	563	480	600	600
0137A	D412	Elongation	%	671	810	750	800	720	550	480	520	609	520	450	500
0159A	0159A	Tear strength - die B	kN/m	43	21	23	28	46	26	30	35	40	37	33	42
0159A	D624	Tear strength - die B	ppi	243	120	130	160	262	150	170	200	228	210	190	240
0157		Shrinkage, linear	%	2.1	2.1	3.5	3.2	2.4	2.2	2.9	3.0	2.6	2.5	2.7	2.9
		Post-cured 8 hours at 177°C (350°F)													
0099	D2240	Durometer hardness	shore A	53	38	44	38	56	50	57	60	75	68	73	75
0137A	D412	Tensile strength	MPa	9.0	7.6	8.3	7.6	9.5	9.0	9.0	9.0	7.6	7.6	8.3	7.6
0137A	D412	Tensile strength	psi	1303	1100	1200	1100	1376	1300	1300	1300	1101	1100	1200	1100
0137A	D412	Modulus at 200%	MPa	2.7	1.3	1.8	1.9	2.8	2.7	3.4	3.9	4.2	3.5	4.6	4.6
0137A	D412	Modulus at 200%	psi	394	190	260	280	401	390	500	560	604	510	660	660
0137A	D412	Elongation	%	708	760	700	740	704	530	460	460	591	480	430	460
0159A	D624	Tear strength - die B	kN/m	42	24	25	30	47	25	25	28	44	32	33	37
0159A	D624	Tear strength - die B	ppi	237	140	140	170	268	140	140	160	253	180	190	210
0157		Shrinkage, linear	%	2.7	2.5	3.7	3.6	2.5	2.3	3.4	3.3	2.6	2.5	3.2	3.5

1. Properties (except relative density) obtained from 1.905-mm (0.075-inch) thick ASTM slab equilibrated 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. 0.15 parts QP1-48 Cure Inhibitor, 1.45 parts QP1-51 Catalyst compounded with 100 parts base, molded 10 minutes at 115°C (240°F).
4. 1.0 parts PERKADOX PD-50S compounded with 100 parts base, molded 5 minutes at 115°C (240°F).
5. 0.5 parts DI-CUP R compounded with 100 parts base, molded 10 minutes at 160°C (320°F).
6. 1.0 parts VAROX DBPH compounded with 100 parts base, molded 10 minutes at 171°C (340°F).

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Table 1: Selected Qualification Data For *Dow Corning* Class VI Elastomers (C6-235, C6-250, C6-265)

Test	Samples tested[1]	Summary result
Cell culture[2]	• Elastomer • Minimal essential medium extract of elastomer	Non-cytotoxic
Skin sensitization[2]	• Elastomer • Saline extract of elastomer • Acetone extract of elastomer	No sensitization
USP Class V extractables	• Saline extract of elastomer • Extract of elastomer in 5% ethanol/95% saline • PEG 400 extract of elastomer (diluted in saline) • Cottonseed oil extract of elastomer	Non-irritating and non-toxic relative to controls
Implant	• Elastomer	Reaction equivalent to or less than negative control at 7- and 30-days post-implantation
European Pharmacopoeia[3] - Substances soluble in hexane - Volatile matter	 • Hexane extract of elastomer • Elastomer	 ≤ 3% residue ≤ 0.5% weight loss

1. Elastomer was compounded with 50% 2,4-dichlorobenzoyl peroxide at 1:100 ratio. Unless otherwise noted, samples were molded 5 minutes at 116°C (240°F) and post-cured 2 hours at 177°C (350°F). Elastomer samples were autoclaved before 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. Samples were molded 5 minutes at 116°C (240°F) and post-cured
4. hours at 204°C (400°F). Samples were not sterilized prior to this testing.