DOW CORNING

SILASTIC®
BioMedical Grade ETR Elastomers (Q7-4535, Q7-4550, Q7-4565)

Enhanced Tear Resistant (ETR) High Consistency Rubber silicone elastomers for peroxide cure

FEATURES

- Flexible peroxide selection
- Blendable to modify durometer
- No organic plasticizers, phthalates or latex additives
- Non-tacky surface
- 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 tests including cytotoxicity, sensitization, intracutaneous reactivity, acute toxicity, subchronic toxicity, genotoxicity, hemocompatibility, and implantation.
- Batch-to-batch consistency

COMPOSITION

- One-part uncatalyzed silicone elastomer raw material

APPLICATIONS

- SILASTIC BioMedical Grade ETR Elastomers (Q7-4535, Q7-4550, Q7-4565) are uncatalyzed elastomer materials designed for compounding into elastomer for part fabrication and medical devices.

DESCRIPTION

SILASTIC BioMedical Grade ETR Elastomers (Q7-4535, Q7-4550, Q7-4565) are a series of one-part uncatalyzed silicone elastomer raw materials. The addition of a peroxide catalyst is necessary to accomplish vulcanization.

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 peroxide 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 catalyst, and as a result, the choice and amount of vulcanizing agent, as well as the cure profile, must be experimentally determined by the user. Because of this, these products are recommended for customers who are familiar with compounding silicone elastomers.

These elastomer raw materials allow the user a versatile selection of organic peroxide vulcanizing agents.

Dow Corning has used a number of common peroxide catalysts with elastomer raw materials of equivalent or similar formulation to Q7-4535, Q7-4550, and Q7-4565, including, but not limited to those listed below. By mentioning our experience with these peroxide agents, we are not specifically sanctioning or otherwise endorsing their use. Proper selection and use of a vulcanizing agent is the user's responsibility.

1) 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 vulcanization before flow is complete—a problem known as "scorch"—might occur.

2) Benzoyl Peroxide (CADOX® BSD)
   This peroxide might be preferred for thin moldings, because it is less likely to scorch. This catalyst might also be appropriate if the elastomer raw material is used to make a liquid dispersion, although four to ten times the amount of peroxide might be needed for liquid dispersions than for thermal molding.

3) 2,5-Dimethyl-2,5-di(t-butylperoxy) Hexane (VAROX® DBPH) preferred for molded parts with thick sections, this vulcanizing agent can produce elastomers with good tensile strength and elongation and low compression set.

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

5) Tert-butyl peroxybenzoate (TBPB). This agent is typically used to generate sponge-type rubbers.

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.

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 vulcanizing agent will result in undercured elastomer that is soft or cheesy (crumbly and non-cohesive), unsuitable for its intended purpose. The amount of peroxide to use will vary with operating conditions. Table 1 provides suggested starting amounts, however 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 vulcanization is complete. It might be necessary to determine the amount of vulcanizing 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 peroxide's decomposition products is also the user's responsibility

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 vulcanizing agent and molding conditions through experiment using the same materials and equipment that will be used for production. The proportions and conditions given in Table 1 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.

Calendering

After blending with peroxide catalyst, these elastomer stocks may be calendered into sheeting with or without reinforcement. Non-reinforced sheeting is usually made by calendering onto a liner, which is stripped off after vulcanization. Suitable liner materials include cellulose (e.g., Kodacel) and polyester (e.g., Mylar®) films and Holland cloth. If Cadox TS-50 is used, the recommended vulcanizing temperature is 116°C (241°F).

For this system, the usual vulcanizing time is 10 minutes for a sheet about 3 mm (1/8 inch) thick, and an additional three minutes for each additional 3 mm (1/8 inch). If a linear film (e.g., Kodacel or Mylar) is used, it should be removed while the sheet is still warm. If Holland cloth is used, soak in warm water to remove. The vulcanized sheeting should be post cured.

Extruding

These elastomers can be extruded to make profiles such as filament (rod) and tubing. Extrusion can also make wire coating. A vulcanizing agent of the 2,4-dichlorobenzoyl peroxide-type (such as PERKADOX PD-50S) may be used with these elastomer bases to help prevent the 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 vulcanized with peroxide agents must be post-cured. Post-cure provides two important benefits:

1) Post-cure helps remove residual byproducts generated from the decomposition of the peroxide vulcanization 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 2 hours when catalyzed with PERKADOX PD-50S.

QUALIFICATION TESTING

The results of selected qualification tests are shown in Table 4. Summaries of Health Data are available upon request.

QUALITY

SILASTIC BioMedical Grade ETR Elastomers 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 ETR Elastomers, when properly catalyzed, cured and post-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".

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. 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.

ORDERING AND PRODUCT INFORMATION

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

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 24 months from the date of production.

PACKAGING

SILASTIC BioMedical Grade ETR Elastomers (Q7-4535, Q7-4550, Q7-4565) are supplied in boxes of 11.3kg (25 lb). Additionally, Q7-4550 is available in a 408.2kg (900 lb) box. Each box contains uncatalyzed elastomer stock sealed in polyethylene-wrapped bundles of 11.3kg (25 lb).

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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Table 1: How to use catalysts with SILASTIC BioMedical Grade ETR Elastomers (Q7-4535, Q7-4550, Q7-4565)

Catalyst	*Parts catalyst per 100 parts base*[1]	*Molding conditions minutes/degrees*
DI-CUP R	0.5	10/160°C (320°F)
PERKADOX PD-50S	1.0	5/115°C (239°F)
VAROX DBPH	1.0	10/171°C (340°F)
CADOX BSD	1.0	5/127°C (261°F)
TBPB	0.5	10/150°C (302°F)

1. Suggested starting amounts only. Adjustments up or down may be required in your process application.

Table 2: 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.

Property	**Unit**	**Q7-4535**					**Q7-4550**					**Q7-4565**				
		DI-CUP R	PERKADOX PD-50S	VAROX DBPH	CADOX BSD	TBPB	DI-CUP R	PERKADOX PD-50S	VAROX DBPH	CADOX BSD	TBPB	DI-CUP R	PERKADOX PD-50S	VAROX DBPH	CADOX BSD	TBPB
As molded																
Relative density		–	1.12	–	–	–	–	1.16	–	–	–	–	1.20	–	–	–
Durometer hardness, Shore A		33	29	35	34	34	48	51	55	50	48	61	63	67	61	60
Tensile strength	MPa	8.4	8.4	8.1	9.0	8.6	10.6	10.1	10.9	9.9	10.6	8.2	7.9	7.7	8.2	8.3
Tensile strength	psi	1225	1213	1177	1300	1250	1542	1460	1582	1430	1541	1190	1140	1112	1192	1210
Modulus at 200%	MPa	1.1	0.9	1.4	1.3	1.1	2.7	2.3	3.1	–	2.9	3.3	2.8	3.4	3.5	3.4
Modulus at 200%	psi	155	135	210	190	155	390	330	445	–	415	475	400	500	511	495
Elongation	%	977	1015	912	768	958	650	655	693	523	596	665	663	772	547	607
Tear strength - die B	kN/m	28	22	27	19	27	39	30	36	37	29	43	47	43	40	39
Tear strength - die B	ppi	158	128	153	108	154	222	173	207	213	165	246	268	246	228	221
Post-cured 2 hours at 177°C (350°F)																
Durometer hardness, Shore A		34	36	37	38	37	51	48	56	51	50	67	67	72	66	69
Tensile strength	MPa	8.3	8.1	10.1	8.5	8.2	11.0	9.4	9.7	10.5	10.8	8.3	7.9	7.8	7.9	8.3
Tensile strength	psi	1210	1180	1468	1230	1185	1602	1360	1411	1528	1560	1210	1150	1130	1152	1200
Modulus at 200%	MPa	1.2	1.0	1.5	1.4	1.5	3.0	2.5	3.2	3.2	3.1	3.3	3.1	3.5	4.4	3.9
Modulus at 200%	psi	180	140	215	210	215	440	362	460	470	445	475	445	510	640	570
Elongation	%	943	830	1041	808	817	596	680	593	520	559	608	620	672	448	533
Tear strength - die B	kN/m	25	25	27	21	26	34	32	38	29	27	40	39	42	29	32
Tear strength - die B	ppi	141	140	156	122	149	193	180	215	163	154	228	220	238	163	183
Post-cured 4 hours at 204°C (400°F)																
Durometer hardness, Shore A		39	35	40	41	40	55	51	57	53	54	75	72	75	46	75
Tensile strength	MPa	5.9	5.1	7.4	6.3	7.7	9.8	6.8	10.2	9.7	10.3	7.3	6.0	7.1	7.9	8.0
Tensile strength	psi	860	745	1075	910	1120	1425	990	1475	1410	1490	1060	875	1035	1150	1155
Modulus at 200%	MPa	1.4	1.3	1.6	1.6	1.6	3.2	2.0	1.6	2.9	3.4	3.7	3.3	3.7	4.7	4.3
Modulus at 200%	psi	200	185	230	237	225	470	295	225	420	490	541	480	541	675	625
Elongation	%	683	656	758	643	727	538	526	619	526	514	513	511	552	411	462
Tear strength - die B	kN/m	27	29	31	23	26	26	32	31	31	28	36	37	41	31	32
Tear strength - die B	ppi	154	164	179	133	147	151	185	178	177	162	208	212	233	175	185

Table 3: Elastomer cure rates with various vulcanizing agents.

DI-CUP R		*116°C (240°F)*	*138°C (280°F)*	*160°C (320°F)*	*182°C (360°F)*
Q7-4535	**T90**	**>12**	**>12**	**>12**	**5.1**
	Torque				36
Q7-4550	**T90**	**>12**	**>12**	**>12**	**4.8**
	Torque				53
Q7-4565	**T90**	**>12**	**>12**	**>12**	**5.05**
	Torque				67
VAROX DBPH					
Q7-4535	**T90**	**--**	**--**	**6.5**	**3.4**
	Torque			37	39
Q7-4550	**T90**	--	--	**7.4**	**3.4**
	Torque			62	64
Q7-4565	**T90**	--	**>12**	**6.8**	**36**
	Torque			69	74
CADOX BSD					
Q7-4535	**T90**	**>12**	**3.4**	**1.95**	**S**
	Torque		40	39	39D
Q7-4550	**T90**	**>12**	**3.4**	**1.8**	**S**
	Torque		62	65D	64D
Q7-4565	**T90**	**>12**	**3.3**	**1.8**	**S**
	Torque		71	71	73
PERKADOX PD-50S					
Q7-4535	**T90**	**3.8**	**2.0**	**1.3**	**S**
	Torque	31	32	32	33D
Q7-4550	**T90**	**3.55**	**1.7**	**2.0**	**S**
	Torque	51	48	58	51.5D
Q7-4565	**T90**	**3.7**	**1.75**	**1.2**	**S**
	Torque	56	52	55	54
TBPB					
Q7-4535	**T90**	--	**>12**	**4.9**	**2.6**
	Torque			36	38D
Q7-4550	**T90**	--	**>12**	**5.1**	**2.55**
	Torque			62	64D
Q7-4565	**T90**	**N.C.**	**>12**	**5.1**	**2.5**
	Torque			68	68

Note: Data collected on Monsanto R-100 Rheometer; Range – 100, Arc – ±5°

D = Decomposing
N.C. = No Cure
S = Scorching
Cure rate = Time to reach 90% max. torque.

Table 4: Selected Qualification Data for SILASTIC BioMedical Grade ETR Elastomers (Q7-4535, Q7-4550, Q7-4565)

Test[1]	*Samples tested*[2]	*Summary result*
Cell culture	• Elastomer • Minimal essential medium extract of elastomer	Non-cytotoxic
Skin sensitization	• Elastomer • Saline extract of elastomer • Acetone extract of elastomer	No sensitization
USP Class V - Systemic toxicity - Intracutaneous reactivity	• 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, 30 and 90-days post-implantation
USP Pyrogen	• Saline extract of elastomer	Non-pyrogenic
Mutagenicity	• Saline extract of elastomer • Acetone extract of elastomer	No evidence of genetic activity in the bacterial reverse mutation assay
Hemolysis	• Elastomer • Saline extract of elastomer	Non-hemolytic
European Pharmacopoeia[3] - Substances soluble in hexane - Volatile matter	 • Hexane extract of elastomer • Elastomer	 ≤ 3% residue ≤ 0.5% weight loss

1. The requirements 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 is not a component of ISO 10993.
2. 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.
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.

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