DuPont™ Liveo™ BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765 and Q7-4780) Parts A & B

Raw materials for medical device fabrication in the Healthcare Industry

Applications

Liveo™ BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765 and Q7-4780) are heat-cured high consistency silicone rubbers designed for use by customers fabricating medical devices, including those intended for implantation in humans for less than 30 days.

Description

Liveo™ BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765 and Q7-4780) are a series of two-part, Enhanced Tear-Resistant (ETR) silicone elastomers that consist of dimethyl and methylvinyl siloxane copolymers and reinforcing silica. The elastomers exhibit a range of hardness from soft (20 Shore A) to firm (80 Shore A). Each elastomer is supplied as a two-component kit (Part A and Part B), equal portions (by weight) of which must be thoroughly blended together prior to use. The elastomer is then thermally cured via addition-cure (platinum-cure) chemistry.

Manufacturing Environment

The site maintains ISO 9001 and 14001 registrations to the most current standards, details of the registrations are available upon request. The Healthcare Industries Materials Site (HIMS) in Hemlock, MI, is dedicated to the production of silicone materials for healthcare applications. It is registered with the FDA (CFN 1816403) as a Drug Establishment. The site quality system is based on principles of current Good Manufacturing Practices for both Bulk Pharmaceutical Products and Medical Devices.

The site maintains ISO 9001 and 14001 registrations to the most current standards, details of these registrations are available upon request.

Functional benefits

- No peroxide volatiles or residues generated during cure
- Non-blooming
- No phthalates or other organic plasticizers
- Optional post-cure to stabilize properties
- Sterilizable by ETO, autoclave and gamma irradiation
- High gas permeability compared to most thermoset elastomers and thermoplastics
- Pigmentable

Composition

- Two-part silicone elastomer

How to Use

These elastomers are supplied as A and B components that must be combined in equal portions by weight on a two-roll mill prior to use.

Blending
The recommended sequence of blending the two components is to first soften Part B on a cooled two-roll mill. Remove from the mill and soften Part A. Add an equal portion, by weight, of softened Part B, and cross-blend the components until thoroughly mixed. The temperature of the blended material should be kept as low as possible to give maximum table life.

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.

Cure
Cure of the blended elastomer is accelerated by heat. The recommended cure conditions for a cross-section up to 1.905mm (0.075 inch) thicknesses are 10 minutes at 116°C (241°F). More time is required to cure thicker cross-sections. The cure profiles for these products can be found in Figure 1.

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 silicone RTV elastomers 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. The residue may result in crumbs of elastomer being picked up by the next lot, causing imperfections.

Post-curing
Because these materials vulcanize via addition-cure, no residues are present and post-cure is not required. The user must confirm that press molding or short oven cures are suitable for any specific application. The principal volatile components of post-curing are short-chained polydimethylsiloxane fluids and water vapor. See the Typical Properties chart for specific post-cure information.

Biocompatibility

The results of selected biocompatibility tests are summarized in Table I. Elastomer samples were sterilized by autoclaving before testing. Toxicological Summaries are available upon request.

Regulatory Status

DuPont™ Liveo™ BioMedical Grade ETR Elastomers, when fully cured and washed, meet the requirements of FDA regulation 21CFR177.2600, covering rubber articles intended for repeated food contact. A Master File for Liveo™ BioMedical Grade ETR Elastomers Q7-4735, Q7-4750, Q7-4765 and Q7-4780 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the file must contact DuPont.

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 this Material has passed screening tests that are applicable to products intended for implantation for up to 29 days, DuPont makes no end-use representation based on such testing. Nor does DuPont make any representation concerning the suitability of this product for applications of greater than 29 days of implantation in the human body.

Handling Precautions

Product safety information required for safe use is not included in this document. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The safety data sheet is available from your DuPont sales representative, or distributor, or by calling DuPont customer service.

Usable Life and Storage

When stored at or below ambient temperature in the original unopened containers, Liveo™ BioMedical Grade ETR Elastomers Q7-4720 and Q7-4735 have a usable life of 12 months, whereas Liveo™ BioMedical Grade ETR Elastomers Q7-4750, Q7-4765 and Q7-4780 have a usable life of 18 months. The usable life begins from the date of production.

Packaging Information

Liveo™ BioMedical Grade ETR Elastomers Q7-4735, Q7-4750, Q7-4765 and Q7-4780 are supplied in 13.6 kg and 408.2 kg (30 lb and 900 lb) kits, each containing equal portions of Part A and B. Each component is sealed in a polyethylene bundle. Liveo™ BioMedical Grade ETR Elastomer Q7-4720 is available in a 13.6 kg kit.

Samples are available in 908 g (2 lb) kits.

Health and Environmental Information

To support customers in their product safety needs, DuPont 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 or consult your local DuPont representative.

Table 1: Results of selected Biocompatibility Tests for DuPont™ Liveo™ BioMedical Grade ETR Elastomers (Q7-4720, Q7-4735, Q7-4750, Q7-4765 and Q7-4780)

Test	Samples Tested	Liveo™ BioMedical Grade ETR Elastomers Q7-4720, Q7-4735, Q7-4750, Q7-4765 and Q7-4780
Cell culture with neutral red uptake	Elastomer Cell culture medium extract of elastomer	No cytopathic effect (morphology changes) No cytopathic effect (morphology changes) ≥ 75% viability
Ames Bacterial Reverse Mutagenicity	Acetone extract of elastomer Saline extract of elastomer	Non-hemolytic Non-hemolytic
Hemolysis	Elastomer Saline extract of elastomer	Non-hemolytic Non-hemolytic
USP Pyrogen	Saline extract of elastomer	Non-pyrogenic
USP Class V extractables	Saline extract of elastomer	Non-irritating and non-toxic relative to controls
System toxicity	5% ethanol in saline extract of elastomer	Non-irritating and non-toxic relative to controls
Intracutaneous reactivity	Polyethylene glycol (PEG 400) extract of elastomer Cottonseed oil extract of elastomer	Non-irritating and non-toxic relative to controls Non-irritating and non-toxic relative to controls
Skin sensitization	Elastomer Saline extract of elastomer Ethanol or acetone extract of elastome	No sensitization No sensitization No sensitization
90-Day implant	Elastomer	Reaction equivalent or lesser than negative control

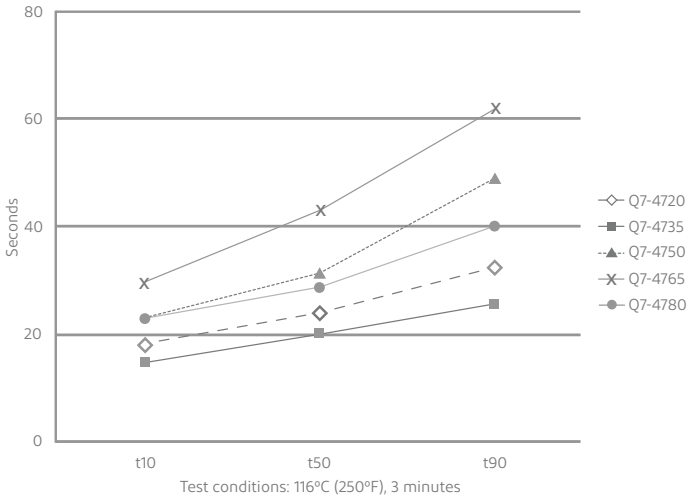
Table 2: Typical Properties

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

Test[1]	Property	Unit	Result: Liveo™ BioMedical Grade ETR Elastomers				
			Q7-4720	Q7-4735	Q7-4750	Q7-4765	Q7-4780
As molded - 10 minutes at 116°C (240°F)							
CTM 0022	Specific gravity		1.12	1.12	1.16	1.20	1.20
CTM 0099	Durometer hardness (Shore A)		25	35	55	69	78
CTM 0137A	Tensile strength	MPa psi	10.65 1545	10.44 1514	10.40 1509	8.47 1228	8.27 1200
CTM 0137A	Elongation	%	1488	1478	974	757	532
CTM 0137A	Modulus, 200%	MPa psi	0.57 83	1.39 201	2.61 379	3.46 502	4.29 622
CTM 0159A	Tear strength, Die B	kN/m ppi	38.5 220	39.6 226	47.1 269	46.4 265	32.4 185
CTM 0157	Shrinkage (linear)	%	2.3	2.4	2.2	2.1	2.0
CTM 0085	Compression set	%	82.9	62.1	62.9	76.8	68.8
Post-cured - 2 hours at 177°C (350°F)							
CTM 0099	Durometer hardness (Shore A)		39	46	60	71	80
CTM 0137A	Tensile strength	MPa psi	10.43 1513	10.79 1565	10.82 1570	8.63 1252	8.05 1167
CTM 0137A	Elongation	%	941	1128	835	698	452
CTM 0137A	Modulus, 200%	MPa psi	1.29 187	2.10 304	2.94 426	3.63 527	4.65 674
CTM 0159A	Tear strength, Die B	kN/m ppi	27.3 156	37.7 215	43.4 248	44.1 252	24.0 137
CTM 0157	Shrinkage (linear)	%	2.7	2.7	2.5	2.6	2.4
CTM 0085	Compression set, 22 hours at 177°C (350°F)	%	29.8	30.4	34.4	67.7	58.4
Post-cured - 4 hours at 177°C (350°F)							
CTM 0099	Durometer hardness (Shore A)		40	47	60	74	80
CTM 0137A	Tensile strength	MPa psi	9.83 1425	8.98 1303	10.29 1492	8.05 1168	7.6 1103
CTM 0137A	Elongation	%	874	971	792	653	415
CTM 0137A	Modulus, 200%	MPa psi	1.27 184	2.12 307	2.98 432	3.63 526	4.69 680
CTM 0159A	Tear strength, Die B	kN/m ppi	27.7 158	37.7 215	47.1 269	41.3 236	23.3 133
CTM 0157	Shrinkage	%	2.8	2.9	2.8	2.7	2.6
CTM 0085	Compression set, 22 hours at 177°C (350°F)	%	16.1	22.4	26.6	58.1	53.5
Post-cured - 8 hours at 177°C (350°F)							
CTM 0099	Durometer hardness (Shore A)		41	47	62	74	83
CTM 0137A	Tensile strength	MPa psi	9.62 1395	10.26 1488	10.64 1543	8.45 1226	6.94 1006
CTM 0137A	Elongation	%	861	1062	788	692	352
CTM 0137A	Modulus, 200%	MPa psi	1.30 188	2.17 315	3.12 452	3.70 536	4.87 706
CTM 0159A	Tear strength, Die B	kN/m ppi	27.0 154	37.7 215	46.9 268	39.4 225	23.3 133
CTM 0157	Shrinkage	%	3.0	3.1	2.9	2.9	2.8
CTM 0085	Compression set, 22 hours at 177°C (350°F)	%	14.6	22.6	25.4	48.0	51.6

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

Figure 1: MDR 2000 cure testing of Liveo™ BioMedical Grade ETR Elastomers



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