

Adaptable...

Combining the biocompatibility of silicone with the strength of polycarbonate-urethanes

materials that belong to the body

CarboSil®

thermoplastic silicone polycarbonate-urethane

a DSM Product

CarboSil® thermoplastic silicone-polycarbonate-urethane (TSPCU) is a ground-breaking copolymer that combines the biocompatibility and biostability of conventional silicone elastomers with the processability and toughness of thermoplastic polycarbonate-urethanes. The silicone soft segment works synergistically with polycarbonate-based polyurethanes to improve *in vitro* and *in vivo* stability. This polymer is backed by a comprehensive FDA Master File.

Flexible

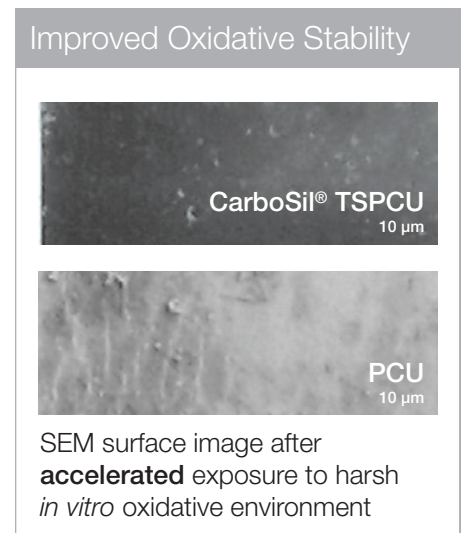
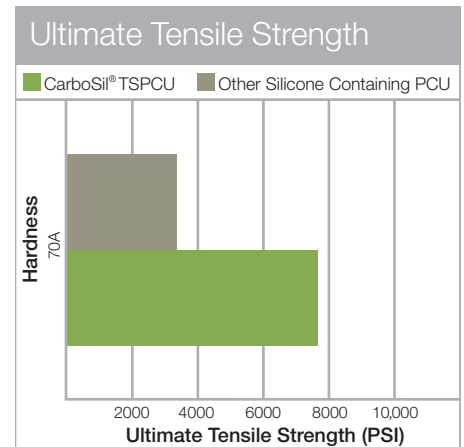
- Comparable in strength to traditional polycarbonate urethanes (PCU) and added biostability from the silicone soft segment and end groups
- Adaptable to various fabrication techniques to accommodate many different device shapes
- Capable of being extruded and injection or compression molded, as well as solvent bonded, dipped, coated and sprayed

Biocompatible

- Improved oxidative stability and thrombo-resistance relative to equivalent polyurethanes without silicone

Unique Surface Modification Techniques

- Customizable with SME® technology utilizing surface modifying end groups
- Enables the polymer to be equipped with different end groups such as fluorocarbon and/or polyethylene oxide. Silicone end groups are standard.
- Eliminates the need for additional surface processing steps after the device component is fabricated



Physical Properties

Typical Property	Testing Method	CarboSil® TSPCU Silicone Content (%)			
		5	20	20	20
Color		Translucent to amber colored pellets			
Hardness, Durometer	ASTM D2240	89A	80A	90A	55D
Specific Gravity	ASTM D792	1.20	1.16	1.16	1.18
Density, g/cm ³	ASTM D792	1.20	1.16	1.16	1.18
Ultimate Tensile Strength (psi)	ASTM D1708	7854	5084	5798	6175
Ultimate Elongation (%)	ASTM D1708	435	473	424	344
Tensile Stress					
psi at 50% elongation	ASTM D1708	1204	704	1082	1934
psi at 100% elongation		1624	945	1426	2472
psi at 300% elongation		4869	2483	3779	5494
Tear Strength, Die 'C', pli	ASTM D624	NA	NA	500	NA
Compression Set, %, 22 hrs @ 25°C	ASTM D395	NA	NA	15	NA
Taber Abrasion, 1000g wt.	ASTM D1044	NA	NA	57	NA
Wear Index, mg/1000 cycles	H-18 wheel				
Approximate Melt Index g/10 min at 224°C, 1200g	ASTM D1238	(1200g) 18	(2160g) 52	(1200g) 27	(2160g) 17
Tg, °C	ASTM DSC	NA	NA	-74	NA
Flexural Modulus, psi	ASTM D790	NA	NA	5910	NA
1% Secant Modulus					
Optimum Extrusion Conditions					
°F		370-410	370-410	370-410	370-410
°C		190-210	190-210	190-210	190-210

Note: Typical physical property values are not to be construed as sales specifications.

Representative Biological Test Results

Biological Test	Results
Cytotoxicity	No evidence of causing cell lysis or toxicity
Hemolysis	Non-hemolytic
ISO Maximization Sensitization	No evidence of causing delayed dermal contact sensitization
ISO Intracutaneous Irritation	No evidence of significant irritation
USP and ISO Systemic Toxicity	No evidence of systemic toxicity
Chronic Toxicity, Subcutaneous Implant	No evidence of systemic toxicity
USP Pyrogen Study	Non-pyrogenic
Genotoxicity: Bacterial Reverse Mutation (saline extract)	Non-mutagenic
Genotoxicity: Bacterial Reverse Mutation (95% ethanol extract)	Non-mutagenic
Genotoxicity: In Vitro Chromosomal Aberration	Non-genotoxic
Mouse Bone Marrow Micronucleus	Non-genotoxic
Muscle Implantation, 2 weeks	Non-irritant
Muscle Implantation, 12 weeks	Non-irritant
26 week Carcinogenicity Study in the Transgenic <i>ras</i> H2 Mouse Model	No increase in induced tumor formation

Tests performed by and data on file at DSM PTG.

SEM images courtesy of Case Western University.

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