

CarboSil®

Thermoplastic Silicone

Polycarbonate Polyurethane (TSPCU)



DSM

BRIGHT SCIENCE. BRIGHTER LIVING.™

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 portion of CarboSil® TSPCU works synergistically with the polycarbonate component to improve stability. This medical grade polymer is highly biocompatible and well suited to be used in many types of medical devices.

Flexible

CarboSil® TSPCU is comparable in tensile strength to traditional polycarbonate urethanes and derives additional biostability from the silicone portion. The material is adaptable to various fabrication techniques to accommodate many different device shapes. It can be extruded, injection or compression molded, solvent bonded, dipped coated and sprayed.

Widely Used

Because of its tensile strength, biocompatibility and flexibility, CarboSil® TSPCU is used in a wide range of medical applications, including cardiovascular and nervous system electrostimulation, continuous glucose monitoring, drug eluting and orthopedic implants.

Tailor Made

CarboSil® TSPCU can be enhanced with SME® technology to incorporate end groups that can address the needs of specific device applications (silicone end groups are standard). This eliminates the need for additional surface processing steps after the device component is fabricated.

Summary of Product Benefits

- **Biostable and biocompatible**
- **Adaptable to many different processing techniques**
- **Excellent mechanical properties**
- **Thromboresistant**
- **Enhanced with SME® technology**
- **Comprehensive FDA Master File**

Physical Properties

Typical Property	Testing Method	CarboSil® TSPCU (20% Silicone Content)		
		80A	90A	55D
Color	Visual	Translucent to amber colored pellets		
Hardness, Durometer	ASTM D2240	80A	90A	55D
Density, g/cm ³	ASTM D792	1.16	1.16	1.18
Ultimate Tensile Strength	ASTM D1708	5084 psi / 35.1 MPa	5798 psi / 40.0 MPa	6175 psi / 42.6 MPa
Ultimate Elongation (%)	ASTM D1708	473	424	344
Tensile Stress				
at 50% elongation	ASTM D1708	704 psi / 4.9 MPa	1082 psi / 7.5 MPa	1934 psi / 13.3 MPa
at 100% elongation		945 psi / 6.5 MPa	1426 psi / 9.8 MPa	2472 psi / 17.0 MPa
at 300% elongation		2483 psi / 17.1 MPa	3779 psi / 26.1 MPa	5494 psi / 37.9 MPa
Flexural Modulus, 1% Secant Modulus	ASTM D790	NA	5910 psi / 40.7 MPa	NA
Tear Strength, Die 'C', pli	ASTM D624	NA	500	NA
Compression Set, %, 22 hrs @ 25°C	ASTM D395	NA	15	NA
Taber Abrasion, 1000g wt. Weight Loss, mg/1000 cycles	ASTM D1044 H-18 wheel	NA	57	NA
Melt Flow Rate g/10 min at 224°C	ASTM D1238	(1200g) 52	(1200g) 27	(2160g) 17
Tg, °C	ASTM D3418	-7	-4	5
Recommended Extrusion Conditions				
°F		370-410	370-410	370-410
°C		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 ras H2 Mouse Model	No increase in induced tumor formation

Data on file at DSM Biomedical Inc.
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Product Disclaimer

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