

Test data provided by raw material manufacturer or an ISO 17025 registered 3rd party lab.
Original test data is stored in the Darcoïd Compound Database



5/4/2022

Darcoïd Compound 5019

COMPOUND DATA SHEET

USP Class VI Silicone, 50 Shore A, Clear

This compound will meet or exceed the specifications listed and has the following physical properties:

ASTM D2000 ISO 10993-1 for Surface Devices with "limited" (<24 hours) or
"prolonged" (1 to 30 days) contact duration.

United States Pharmacopeia (USP), Class V & VI
European Pharmacopeia (EP) (Ph.Eur.)
EP - Volatile Matter
EP - Substances soluble in Hexane
21CFR177.2600
3-A Sanitary Standards 18-03 Class III & IV

ORIGINAL PROPERTIES	RESULT
Hardness, Shore A, pts.	50
Tensile Strength, PSI (MPa)	1269 (8.8)
Ultimate Elongation, %	847
Modulus @ 50% Elongation	151 (1.0)
Modulus @ 100% Elongation	238 (1.6)
Specific Gravity, g/cc	1.12
Tear Resistance, Die B, ppi (kN/m)	216 (37.8)

30-Day Implant	RESULT
Exceeds USP VI	PASS

SKIN SENSITIZATION	RESULT
	PASS

CYTOTOXICITY	RESULT
	PASS

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