

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



4/23/2021

Darcoïd Compound 5012

## COMPOUND DATA SHEET

USP Class VI Silicone, 70 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.	74
Tensile Strength, PSI (MPa)	1017 (7)
Ultimate Elongation, %	672
Modulus @ 50% Elongation	415 (2.9)
Modulus @ 100% Elongation	531 (3.7)
Specific Gravity, g/cc	1.2
TR-10 Temperature, °F (°C)	-64 (-53)
Tear Resistance, Die B, ppi (kN/m)	254 (44.5)

30-Day Implant	RESULT
Exceeds USP VI	PASS

SKIN SENSITIZATION	RESULT
	PASS

CYTOTOXICITY	RESULT
	PASS

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