

Material Data Sheet

Bio-Chem Valve, Inc.
Silicone Tubing for use in Bio-Chem Valve pinch valves

Biocompatibility Tests

Tests conducted per the standards set by the United States Pharmacopeia National Formulary XVII(NF XVII), 1990, Class VI Biological Test for Plastics.

This tubing is FDA Masterfile listed (MAF 819) which includes the following test results:

<u>Test</u>	<u>Results per Standard</u>
Hemolysis Test	0.0%
Heavy Metals as Lead	None Detected
Cell Culture Toxicity	None
USP Class VI 7-Day Implant Study	Complies
USP Muscle Implant Study with Histopathology (12 weeks)	Complies
Dichlorobenzoic Acid Residue	None Detected
Odor Test	Complies
Particulate Analysis	Complies
PCB's by EPA 8080	Complies
Trace Impurities	Complies
Appearance, Haze, and Luminous Transmittance	Complies
Crystallinity by X-Ray Diffraction	Complies
Peristaltic Pump, Flow Rate Accuracy	Excellent
Elevated Temp. Pinch-off days at 185F	No effect after 35
USP Physiochemical Tests	Complies

<u>Physical Property</u>	<u>ASTM Method</u>	<u>Typical Value</u>
Hardness, Durometer A	D-2240	50
Tensile Strength, psi	D-412	1250
Elongation, %	D-412	575
Tear Resistance, Die B	D-624	200
Compression set %, 22 hrs. at 350F	D-395	40