service chimie

: 5, place de l'Église
77400 St Thibault - France
: 33.01.64.30.89.22 • : 33.01.64.30.87.49
: Contact@Service-Chimie.fr

NuSil SILICONE TECHNOLOGY
Creative Partners in a Material World

Biological Testing Data
MED-4211

Test	Standard/ Method	Test Results
Cytotoxicity Study Using The ISO Elution Method (1X MEM Extract)	ISO 10993-5 USP <87>	A-Noncytotoxic B-Noncytotoxic C-Noncytotoxic
In Vitro Hemolysis Study (Modified ASTM-Extraction Method)	ISO 10993-4	A-Nonhemolytic
USP and ISO Systemic Toxicity Study Extract*	ISO 10993-11 USP <88>	A-Nontoxic
ISO Intracutaneous Study Extract*	ISO 10993-10 USP <88>	A-Nonirritant
ISO Muscle Implantation Study 1 Week* ISO Muscle Implantation Study 12 Week	ISO 10993-6 USP <88>	A-Nonirritant A-Nonirritant
Genotoxicity: Bacterial Reverse Mutation Study (DMSO and Saline Extracts)	ISO 10993-3	A-Nonmutagenic
USP Pyrogen Study Material Mediated	ISO 10993-11 USP <151>	A-Nonpyrogenic
ISO Maximization Sensitization Study	ISO 10993-10	A-Nonsensitization
Mammalian Mutagenesis Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Corning Silastic Materials.' "	-------	----------
Cytogenic Damage Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Corning Silastic Materials.' "	-------	----------

* Product meets USP Class VI test requirements.

Test Article Conditioning

Sample	Condition
A	Per NuSil Technology Product Specification
B	Condition A + Hot Air Oven 12 Hours @ 200°C
C	Condition A + Autoclave 2 Hours @ 15 psi

This test article has been tested and found compliant with the above requirements. Please contact the NuSil Technology LLC Healthcare Director if you require additional information.

Thomas P. Banigan
VP Quality Assurance/Regulatory Compliance

8/10/09 Rev A GB-071
8/10/09 Rev A MED-4211