About NuSil Technology

NuSil Technology is a global manufacturer of silicone materials for the pharmaceutical, drug delivery, and medical device industry. NuSil develops custom materials designed to meet specific application needs, regardless of the quantity. ISO 9001-certified since 1994, NuSil operates state-of-the art laboratories and processing facilities in North America and provides global customer support.

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NuSil SILICONE TECHNOLOGY
Creative Partners in a Material World

Class VI LSR Materials

SIL-5950, SIL-5960, and SIL-5970 are NuSil's USP Class VI supported liquid silicone rubbers. Members of the SIL-59X0 line are designed for injection molding of parts requiring a material with a high durometer including molded rubber stoppers, gaskets, seals, valves, o-rings and other precision parts. If colored silicones are required, SIL-59X0 products can be combined in any of these applications with NuSil's Healthcare color masterbatches. SIL-5950, SIL-5960, and SIL-5970 are supplied at an easy-to-use 1:1 mix ratio and cure via addition cure (platinum) chemistry. NuSil maintains our high levels of quality with this product line while delivering cost competitive offerings to the market.

SIL-59X0 is a line of versatile materials for manufacturing parts for healthcare and/or food contact applications via the following:

- Injection molding
- Over-molding

Below is a table detailing the typical physical properties of these products:

Product Name	Specific Gravity	Durometer	Tensile Strength (psi)	Tensile Strength (MPa)	Elongation %	Tear Strength (ppi)	Tear Strength (kN/m)
SIL-5950	1.14	50	1,450	10	550	190	33.5
SIL-5960	1.14	60	1,300	9	425	200	35.3
SIL-5970	1.14	68	1,250	8.6	400	225	39.7

It is the sole responsibility of each purchaser to ensure that any use of these materials is safe and complies with all applicable laws and regulations. It is the user's responsibility to adequately test and determine the safety and suitability for their applications and NuSil Technology makes no warranty concerning fitness for any use or purpose.

USP Class VI and ISO 10993 <88> Testing Information

The following list summarizes the biological testing completed on the formulation components of these materials. The product meets USP Class VI test requirements.

- USP and ISO Systemic Toxicity Study Extract: A-Nontoxic
- ISO Intracutaneous Study Extract: A-Nonirritant
  - The above tests utilized sodium chloride USP, sesame/vegetable oil, alcohol in saline, and polyethylene glycol as the solvents for extraction.
- ISO Muscle Implantation Study 1 Week: A-Nonirritant
- Test Article Conditioning
  - -Sample A: Per NuSil Technology Product Specification.
  - -Sample B: Condition A + Hot Air Oven 12 Hours at 200ºC.
  - -Sample C: Condition A + Autoclave 2 Hours at 15 psi.

The following biological testing is completed on a per lot basis.

- ISO 10993: Biological Evaluation of Medical Devices, Part 5: Cytotoxicity

FDA 21 CFR 177.2600 Status

As cured elastomers, SIL-59X0 products are compliant with USP Class VI testing and applicable ISO 10993 requirements. After being cured, post-cured for 2 hours @ 150°C (302°F) and washed, they meet the extraction requirements of FDA regulation 21 CFR 177.2600 "Rubber Articles Intended for Repeated Use (Food Contact)."

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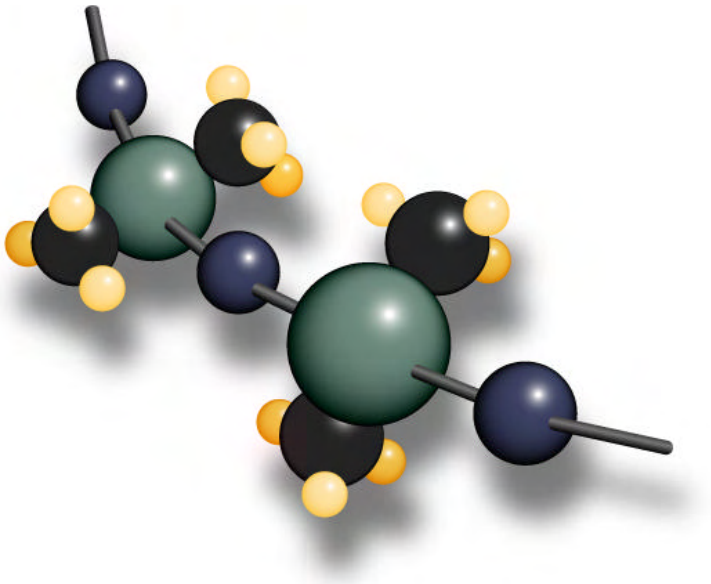

Version uploaded 09/08/2013