FOSTER

Dear Valued Customer,

The biocompatibility of the ingredients used to formulate Foster's ProPell™S lubricant packages were tested in a hard (55D) and soft (80A) aromatic polyether polyurethane and hard (72) and soft (35D) polyether-amide elastomers by a third party testing service (NAMSA) under ISO 13485 conditions. A summary of the tests and results are below:

"The test article, ProPell™S, was evaluated for systemic toxicity in mice in accordance with the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo. The test article was extracted in alcohol saline, polyethylene glycol, 0.9% sodium chloride USP solution, and sesame oil, NF. A single dose of the appropriate test article extract was injected into a group of five animals. Similarly, a separate group of five animals were dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection. Body weights were recorded prior to dosing and on Day 3.

There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.

The potential of the test article, ProPell™S, to cause irritation following intradermal injection in rabbits was evaluated based on the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo. The test article was extracted in 0.9% sodium chloride USP solution (SC), sesame oil, NF (SO), alcohol in saline (AS) and polyethylene glycol (PEG). A 0.2 mL dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each of two animals. Similarly, the corresponding control was injected on the left side of the back of each animal. Observations for erythema and edema were conducted at 24, 48, and 72 hours after intracutaneous injection.

There was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. Each test article extract met the USP requirements."

The test results are specific to the samples prepared. Any further extrapolation of the results would be the responsibility of the user of the compound(s) containing the above mentioned lubricant package. It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, with all applicable laws and regulations

Foster Corporation makes not representation, promise, or express or implied warranty concerning the suitability of Foster's products for use in any medical device.

If you have any questions or require any additional information please do not hesitate to contact the undersigned.

Respectfully Submitted,

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