



Dear Valued Customer,

The Cytotoxicity of Foster's proprietary formulation for NanoMed™ was tested in a representative polyamide compound 108-016C, under the test article name "Pellets." Testing was performed by a third party (NAMSA) under ISO 13485 conditions. A summary of the tests and results are below:

"The test article, Pellets, was evaluated for potential cytotoxic effects using an *in vitro* mammalian cell culture test. This study was conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (IX MEM) at 37°C for 24 hours. The negative control, reagent control, and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37°C in the presence of 5% CO₂ for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity)."

The test results are specific to the representative compound prepared. Any further extrapolation of the results would be the responsibility of the end user of the compound(s) containing the above mentioned additive.

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

Respectfully Submitted,

Foster Regulatory Support
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