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Medical Materials & Technologies

3M PRODUCT CLINICAL DATA SUMMARY

Product Number 9969
3M™ Adhesive Transfer Diagnostic Microfluidic Medical Tape
Effective: November 2018

Product #9969 has been subjected to the following safety evaluations through an outside laboratory under GLP:

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1 cm x 1 cm portion of the test article. Triplicate wells were dosed with a 1 cm length portion of high density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex as a positive control. Each was placed on an agarose surface directly overlaying a subconfluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in the presence of 5% CO2 for 24-26 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test article showed no evidence of causing any cell lysis or toxicity and had a grade 0 (no reactivity). The test article met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity).

MEM Elution

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects using a mammalian cell culture test following the guidelines of International Organization for Standardization 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 extracted. 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 and had a grade 0 (no reactivity). The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Hemolysis

This test was conducted to evaluate for the potential to cause hemolysis following the guidelines of ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood. Anticoagulated whole rabbit blood was pooled, diluted, and added to glassware with the test article in calcium and magnesium-free phosphate buffered saline (CMF-PBS) or in polystyrene tubes with a CMFPBS test article extract. Negative controls, positive controls, and blanks were prepared in a similar manner. Following incubation for at least 3 hours at 37°C, the samples were centrifuged, and each supernatant collected. The supernatant was mixed with Drabkin's reagent and the resulting solution was analyzed using a spectrophotometer at a wavelength of 540 nm. The hemolytic index for both the test article in direct contact with blood and for the test article extract was 0.0%. Both the test article in direct contact with blood and the test article extract were non-hemolytic.

3M Study EM-05-014433

It is the responsibility of our customers to determine final suitability of our products for their application. Final testing of a converted device made with this material is the responsibility of the customer.