Medical Materials & Technologies
BIOCOMPATIBILITY SUMMARY
Product Name: 3M™ Medical Tape 1525L
Effective: March 2021

The adhesive used in 3M™ Medical Tape 1525L has been subjected to the following preclinical biocompatibility evaluations per ISO 10993 standards under FDA GLP Regulations (21 CFR Part 58):

Cytotoxicity Study Using the ISO Agarose Overlay Method - Solid

The test article was evaluated 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 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 sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in the presence of 5% CO_2 for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. **Results**: The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

CLIN-MISC-US-05-225870_2

Cytotoxicity Study Using the ISO Elution Method

This *in vitro* study was conducted to evaluate the test article for potential cytotoxic effects following the guidelines of International Organization of Standardization 10993-5: Biological Evaluation of Medical Devices, Part: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X 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% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. **Results**: The test article 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 a grade 2 (mild reactivity).

CLIN-MISC-US-05-225872_1

ISO Skin Irritation Study in Rabbits

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application. **Results**: There was very slight to well-defined erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.8. The response of the test article was categorized as slight.

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ISO Closed Patch Sensitization Study in Guinea Pigs

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6 to 8 hours, three times a week, over a 3 week period. The control article was similarly patched to five animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test article and the control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. **Results**: The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

CLIN-MISC-US-05-225871_2

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.