Solventum MedTech OEM
Biocompatibility summary
Product Name: Solventum™ Medical Tape 1776
Effective: July 2022

The adhesive used in Medical Tape 1776, as part of a different construction, 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
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 1cm x 1cm 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 1cm x 1cm 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 degrees C in the presence of 5% CO2 for 24 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. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

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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 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 at 37 degrees 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 degrees 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 met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

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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 25mm x 25mm 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 There was no erythema and no edema observed on the skin of the animals. The Primary Irritation Index (PII) for the test article was calculated to be 0.0/8.0. The response of the test article was categorized as negligible.

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ISO Guinea Pig Maximization Sensitization Test

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. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

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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.

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