

Medical Materials & Technologies

3M PRODUCT CLINICAL DATA SUMMARY

Product Number 2477P

3M™ Double-Coated TPE Silicone Acrylate Medical Tape

Effective: April 2019

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Product #2477P has been subjected to the following safety evaluations through an outside laboratory under GLP:

Cytotoxicity Study Using the ISO Direct Contact Method (Acrylic Adhesive Side)

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. Culture wells of a 6-well tissue culture plate that contained a subconfluent monolayer of L-929 mouse fibroblast cells were used for testing. Triplicate wells were dosed with either a test article section, high density polyethylene as a negative control or latex as a positive control. Each article was placed in direct contact with the L-929 cells. After incubating for 24-26 hours, the cultures were examined microscopically (100X) for any abnormal cell morphology and cell lysis in proximity to the articles. The test article showed no evidence of causing cell lysis or cytotoxicity to L-929 cells. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Cytotoxicity Study Using the ISO Elution Method

An additional *in vitro* study was conducted to evaluate 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 (1X MEM) 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 of 0 (no reactivity). The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

ISO Skin Irritation Study in Rabbits (Acrylic Adhesive Side)

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 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 a minimum of 23 hours and a maximum of 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 none to well-defined erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 0.5. The response of the test article was categorized as slight.

ISO Guinea Pig Maximization Sensitization Test

The test article was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. The study was conducted based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization. The test article was extracted in 0.9% sodium chloride USP and sesame oil, NF. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). The extraction vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the vehicle control. All sites were scored for dermal reactions at 24 and 48 hours after patch removal. The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.

Cytotoxicity Study Using ISO Agarose Overlay Method (Silicone Adhesive Side)

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 1cm x 1cm portion of the test article (silicone side). Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar 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 mild cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

ISO Skin Irritation Study in Rabbits (Silicone Adhesive Side)

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 for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

3M Study # 05-012666

**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.**



Medical Materials & Technologies
3M Center, Building 275-5W-05
St. Paul, MN 55144-1000 USA

Phone 1-800-228-3957
Web 3M.com/MedTech

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