



PRODUCT CLINICAL DATA SUMMARY

NO. 1577

3M Two In One Double Coated Tape

Effective: April 2011

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The adhesive used on the backside of No. 1577 3M Two In One Double Coated Tape, as part of another construction, has been subjected to the following safety evaluations:

***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 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 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 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).

MEM Elution

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 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).

Primary Skin Irritation

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 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 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 0.4. The response of the test article was categorized as negligible.

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Guinea Pig Sensitization

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 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and 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. 3M Study 011342 (all)

The faceside of No. 1577 3M Two In One Double Coated Tape, has additionally been subjected to the following safety evaluations:

In Vitro Cytotoxicity (L929 Agar Overlay)

Protocol reference: Guess, W. L. et al; "Agar Diffusion Method for Toxicity Screening of Plastics on Cultured Cell Monolayers" J. Pharm. Sci. 54:1545-1547 (1965).(3M study # T 7814.2)

This study meets the GLP requirements of EPA 40 CFR part 792 and 160, FDA CFR 58 as specified in The Testing of Chemicals, published by the Organization for Economic Cooperation & Development (OECD), 1997.

Results: 0.0/0.0

Acute Primary Skin Irritation in Albino Rabbits

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. (3M study # T 7814.1) This study was conducted in accordance with the Good Laboratory Practice requirements of the EPA, 40 CFR 160 and 792, FDA 21 CFR 58 , and the OECD, The Testing of Chemicals, 1997.

Results: 0.0/8.0

These tests are in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. No. 1577 **backside** has satisfied the requirements for devices in contact with intact skin for short-term application (up to 29 days). All laboratory testing was conducted in accordance with the FDA Good Laboratory Practices Regulation of 1978.

It is the responsibility of our customers to determine the final suitability of our products for their application.