



PRODUCT CLINICAL DATA SUMMARY

Product Number 4077

3M™ Elastic Nonwoven Tape with Extended Wear Adhesive

Effective: March 2020

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3M™ Elastic Nonwoven Tape with Extended Wear Adhesive (4077) has been evaluated in the following pre-clinical biocompatibility tests as part of a different construction:

In Vitro Cytotoxicity

Test Method: The test article, Tape 4076 (Non-Sterile), was evaluated to determine the potential for *in vitro* cytotoxicity. This study was conducted based on the requirements of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity and done under the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58). 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. The release liner was removed and excluded from the test article and the adhesive side was dosed 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 evidence of causing mild cell lysis or toxicity.

Test Results: The adhesive used for Elastic Nonwoven Tape 4077 met the requirements of the test since the test Grade was less than or equal to a Grade 2 (mild reactivity). 3M Study 05-014758

Primary Skin Irritation

Test Method: The test article, Tape 4076 (Non-Sterile), was evaluated for primary skin irritation in female New Zealand White rabbits. This study was conducted in accordance with the guidelines of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization and done under the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58). Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin (adhesive side towards the skin) of each of the 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 test article.

Test Results: Dermal observations consisted if no to well-defined erythema and no edema on the skin of the animals treated with the test article. The Primary Irritation Index (PII) for the test article was calculated to be 0.8/8.0. The dermal irritation response of the adhesive used for Elastic Nonwoven Tape 4077 was categorized as slight. 3M Study 05-014758

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Guinea Pig Dermal Sensitization (GPMT)

Test Method: The test article, Tape 4076 (Non-Sterile), was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test (GPMT). This study was conducted based on the requirements of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization and done under the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58). The test article was extracted in 0.9% sodium chloride USP and sesame oil, NF. Each of two test material extracts was intradermally injected into each of ten male Hla®:(HA)CVF® guinea pigs and then occlusively patched. 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.

Test Results: None of the test article extracts showed any evidence of causing delayed dermal contact sensitization in the guinea pig. Therefore, the adhesive used for Elastic Nonwoven Tape 4077 was not considered to be a dermal sensitizer in the guinea pig maximization test (GPMT). 3M Study 05-014758

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.