



## PRODUCT CLINICAL DATA SUMMARY

Product Number 4076

3M™ SC Nonwoven Extended Wear Tape

Effective: March 2020

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3M™ SC Nonwoven Extended Wear Tape (Tape 4076; non-sterile) has been evaluated in the following pre-clinical biocompatibility tests:

### *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% CO<sub>2</sub> 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:** Tape 4076 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 Tape 4076 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, Tape 4076 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.**