Solventum MedTech OEM
Biocompatibility Summary
Product Name: Solventum™ Medical Tape 4076
Effective: August 2021

The adhesive used in Medical Tape 4076 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. This study was conducted based on the requirements of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. 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. Each article was placed 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. The test article met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity).

EM-05-014758

Cytotoxicity Study Using the ISO Elution Method
The test article was evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test. This study was conducted following the guidelines of ISO 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 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°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 evidence of causing severe cell lysis or toxicity. The test article extract did not meet the requirements of the test since the grade was greater 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 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. 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 no 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 0.8. The response of the test article was categorized as slight.

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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. 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. 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.
EM-05-014758

As noted above, Solventum Medical Tape 4076 has been evaluated for *in vitro* cytotoxicity as per ISO 10993-5:2009 and showed evidence of producing cell lysis or toxicity in the ISO Elution Method but not in the ISO Agarose Overlay Method. However, *in vitro* cytotoxicity methods do not necessarily predict the *in vivo* toxicity of a medical device and can only be fully evaluated when Solventum Medical Tape 4076's *in vivo* toxicity potential is determined. As stated in Section 10 of the ISO 10993-5:2009 testing guideline: "Any cytotoxic effect can be of concern. However, it is primarily an indication of the potential for *in vivo* toxicity and the device cannot necessarily be determined to be unsuitable for a given clinical application based solely on cytotoxicity data." In view of this, Solventum Medical Tape 4076 was also evaluated for both dermal irritation and dermal sensitization potential according to the ISO 10993-10:2010 test guideline. The results of *in vivo* dermal irritation test for Solventum Medical Tape 4076 gave a Primary Irritation Index (PII) = 0.8/8.0 (i.e. irritation response categorized as "slight"). The results of the *in vivo* dermal sensitization test showed no evidence that Solventum Medical Tape 4076 caused a delayed dermal contact sensitization (i.e. no evidence of a dermal allergic reaction). The favorable results of the both the dermal irritation and dermal sensitization tests strongly suggest that the *in vitro* cytotoxicity tests overestimate the *in vivo* toxicity potential of Solventum Medical Tape 4076.
CONCLUSION: Based on these *in vivo* irritation and sensitization testing results, it is concluded that Solventum Medical Tape 4076 is safe for its normal, intended use on intact skin.

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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