Solventum MedTech OEM
Biocompatibility summary
Product Name: Solventum™ Medical Silicone Tape 2480
Effective: March 2021

The adhesive used in Medical Silicone Tape 2480 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. **Results:** The test article showed evidence of causing slight cell lysis or toxicity. However, the test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).
Biocomp-Report-05-728708_1

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. **Results:** The test article showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).
Biocomp-Report-05-728788_1

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. **Results:** There was no 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 0.0/8.0. The response of the test article was categorized as negligible.
Biocomp-Report-05-728798_1

The adhesive used in Solventum Medical Silicone Tape 2480, as part of a different construction, has been subjected to the following preclinical biocompatibility evaluations per ISO 10993 standards under FDA GLP Regulations (21 CF4 Part 58):

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. In addition, the test article was applied to the same animals. All sites were scored for dermal reactions at 24 and 48 hours after patch removal. Results: The test article extracts and the test article 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.

CLIN-RPT-FINAL-INV-US-05-306466_1

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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