

Medical Materials & Technologies**BIOCOMPATIBILITY SUMMARY****Product Name: Solventum™ Medical Silicone Tape 2476-A****Effective: December 2024**

The finished product Solventum™ Medical Silicone Tape 2476-A construction 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 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 72 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 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). **Study Number 24-003**

ISO Skin Skin Irritation in Rabbits

The test article was evaluated for primary skin irritation in rabbits. This study was conducted in accordance with the guidelines of ISO 10993-23, Biological evaluation of medical devices - Part 23: Tests for irritation. 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 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. The response of the test article was categorized as negligible. **Study Number 24-004**

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 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. **Study Number 24-005**

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.