Solventum
1750 Yankee Doodle Rd
Eagan, MN 55121
USA

Medical Materials & Technologies
BIOCOMPATIBILITY SUMMARY
Product Name: Solventum™ Medical Tape 9832W
Effective: August 2005

The materials used in Solventum™ Medical Tape 9832W, as part of a different construction, have 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

This *in vitro* study was conducted to evaluate the test article for potential cytotoxic effects following the guidelines of International Organization for Standardization 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 at 37 degrees 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 degrees 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 and had a grade 0 (no reactivity). The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity). **Study No. 18-450**

ISO Primary Skin Irritation Study in Rabbits

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 23: Tests for Irritation. Two 25mm x 25mm sections of the test article and control article were topically applied to the skin of each of the three rabbits and left in place for 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. The Primary Irritation Index (PII) for the test article was calculated to be 0.0/8.0. The response of the test article was categorized as negligible. **Study No. 18-452**

ISO Guinea Pig Maximization Sensitization Test

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig 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

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after patch removal. 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. **Study No. 18-451**

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.