



Solventum MedTech OEM

Product clinical data summary

Product Name: Solventum™ Medical Silicone Tape 2477

Effective: August 2012

The silicone adhesive (next to the clear liner), used in product number Medical Silicone Tape 2477 has been subjected to the following safety evaluations:

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for In Vitro Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO₂ for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test article showed no evidence of causing mild cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity). Study 05-012666 12-114

ISO MEM Elution

An additional in vitro study was conducted to evaluate 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. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity). Study 05-012666 12-115

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two 25mm x 25mm sections of the test article and control article were topically applied to the skin of each of 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 for the test article was calculated to be 0.0. The response of the test article was categorized as negligible. Study 05-012668 12-116

Guinea Pig Sensitization

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 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 ten test and five control animals received a challenge patch of the appropriate test and vehicle control. All sites were observed for evidence of dermal reactions at 24 and 48 hours 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 to be a sensitizer in the guinea pig maximization test. Study 05-012668 12-117

In addition, the acrylate adhesive used on the backside of Solventum Medical SiliconeTape 2477 in conjunction with a different liner and backing has been subjected to the following studies:

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for In Vitro Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO₂ for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity). Study # 05-011343

MEM Elution

An additional in vitro study was conducted to evaluate 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. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity). Study # 05-011343

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applied to the skin of each of 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 very slight to well-defined erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.8. The response of the test article was categorized as slight. Study # 05-011343

Guinea Pig Sensitization

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, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig for short-term application (up to 29 days). All laboratory testing was conducted in accordance with the FDA Good Laboratory Practices Regulation of 1978. Study # 05-011343

It is the responsibility of our customers to determine the final suitability of our products for their application.



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