Solventum MedTech OEM
Product Name: Solventum™ Medical Tape 1533L
Effective: September 2010

The adhesive used on this tape 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 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).

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 applies 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 slight.

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 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. Study 011345 (all)

In addition, earlier studies using a similar adhesive have shown the following results:

Repeated Insult Patch Test (Draize) in Humans

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. Study # MRFE 02761 **Results:** No evidence of induced sensitization.

21-day Cumulative Irritation in Humans

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. Study # MRFE 4970, HRFE 00043 Results: Consistent with responses characteristic of adhesive materials; within historically acceptable levels for surgical tapes.

The use of the term "hypoallergenic" has come to indicate a product that is non-sensitizing to the general public. The hypoallergenic claim for this product is supported by clinical evaluation using the repeated insult patch test in humans, commonly known as the Draize test. This protocol involves repeated application of samples on 200 healthy volunteers for a 2- to 3-week induction period, followed by a 2-week rest period and a challenge application. To be termed hypoallergenic, Medical Specialties products are required to show no evidence of sensitization potential under these test conditions.

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

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