Medical Specialties
3M Skin and Wound Care Division

3M Center
St. Paul, MN 55144-1000
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Preliminary PRODUCT CLINICAL DATA SUMMARY
Product Numbers 2477 aka MSX 6931B
3M Double-Coated TPE Tape with Silicone Adhesive and Acrylate Adhesives
Product Number 2477P aka MSX 6932B
3M Double-Coated TPE Tape with Silicone Adhesive and Acrylate Adhesives on Premium Liner
Effective: December 2011

A similar adhesive (next to the clear liner), used in product numbers 2477 and 2477P, in conjunction with a *different* liner, 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% CO_2 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). 3M Study 05-012205

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 very slight erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.1. The response of the test article was categorized as negligible. 3M Study 05-012155

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 extracts and test article were not considered to be sensitizers in the guinea pig maximization test. 3M Study 05-012153

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In addition, a 200+ human study using this adhesive has 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. 3M Study 05-012167
> **Results**: Does not indicate potential for dermal irritation or allergic contact sensitization.

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, 3M 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 the final suitability of our products for their application.