Medical Materials & Technologies
BIOCOMPATIBILITY SUMMARY
Product Name: 3M™ Medical Tape 1510
Effective: January 2021

The adhesive used in 3M™ Medical Tape 1510 has been subjected to the following safety evaluations by an outside laboratory under GLP:

In-Vitro Cytotoxicity: L929 Agar Overlay Test

The cytotoxicity of the test article was determined using cultured L929 mouse cells under an agar overlay as per the ISO 10993-5 standard and USP 24, Biological Reactive Tests In-Vitro (87). Near confluent cultures of L929 cells in 60 mm dishes were covered with medium containing 1.0% molten agar. After agar solidification the cultures were treated with 0.01% solution of a vital dye (neutral red) for 30 minutes. The excess dye was then removed by aspiration. Each dish was dosed by gently placing a piece of test article on the agar in the central region of the dish, such that the area of contact with the agar layer was approximately 1 cm^2. A total of three dishes were used to evaluate each test article. Positive control and negative control materials were also evaluated in triplicate. Twenty-four hours after the application of the test and control articles to the agar layer, the dishes were evaluated for the Reactivity Grade and the extent of the Reactivity Zone. **Results:** Dishes dosed with the test article had Reactivity Grades of 0-1, the negative control dishes had grades of 0 and the positive control dishes (latex) had grades of 3. The test article does meet the requirements of the L929 Agar Overlay Cytotoxicity test as detailed in ISO 10993-5 and USP 24, Biological Reactive Tests In-Vitro (87).

Biocomp-Report-05-750164_1

Acute Primary Dermal Irritation in Rabbits

Three healthy New Zealand White rabbits (1 male – 2 females) were dosed dermally with the test article. The test article (a 2.5 mm strip) was applied dermally to one intact site/rabbit. The test article was kept in contact with the skin for 4 hours at which time the wrappings were removed. Dermal reactions were scored at 60 minutes after removal of wrappings. Reactions were scored again at 24, 48, and 72 hours. The skin was also evaluated for ulceration and necrosis or any evidence of tissue destruction at these time periods. A modified Primary Irritation Index was calculated. Body weights were recorded pretest and termination. **Results**: There was no erythema or edema noted at any observation period. There were no abnormal physical signs noted during the observation period. All body weight changes were normal. The Modified Primary Irritation Index is 0.0/8.0. The test article is not a dermal irritant.

Biocomp-Report-05-750162_1

21-Day Human Cumulative Irritation Study

This study was conducted to determine the cumulative irritation potential of the test material by applying patches onto the backs of human subjects for a 21-day period. Twenty-six subjects completed the study. The adhesive tape product was cut to approximately ¾ inch squares. Care was taken to ensure that the adhesive side of the tape was placed against the skin. Subjects were then occlusively patched with both the test and control material daily for 21 days. An occlusive patch dosed with 100 µl of 1% Sodium Lauryl Sulfate (SLS) served as the positive control and an undosed occlusive patch served as the negative control. Assignment of the test material to test sites was randomized based on a pre-

determined rotational randomization scheme. Patches were removed by each subject approximately 24 hours after each application, and sites were graded (Berger and Bowman methodology) approximately two hours after each patch removal. **Results:** Under the exposure conditions of this test, standardized cumulative irritation score classified the negative control as "mild material – no experimental irritation," the test material as "possibly mild in normal use," and the positive control as "experimental cumulative irritant."

CLIN-MISC-US-05-242814_1

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.