TOXICOLOGY AND BIOCOMPATIBILITY TESTING

SUMMARY OF STUDIES DONE

OxiTex has been used both in consumer goods and in medical goods. All medical goods treated have to be cleared for sale by FDA. As a part of the FDA submission process, biocompatibility testing is well defined for each class of products. OxiTex technology is utilized in a number of medical devices that are cleared for usage periods of up to 7 days on surfaces that include both unbroken and broken skin. Below we detail some of the testing executed for wound dressing applications, with detail on how this relates to consumer textile goods.

Notes on test articles described. The below testing is from FDA submissions on various test articles. We describe the concentration of Oxi-Tex treatment based on the amount of peroxide that can be titrated from the treated article. For consumer textiles the typical ranges of peroxide content of the fabric are between about 0.15 - 0.35 wt%. The test articles described below were assessed with concentrations up to 0.99 wt% peroxide content.

PRIMARY SKIN IRRITATION TEST

This is the most common irritation test. The specific test utilized in testing is the direct contact Primary Skin Irritation Test.

Summary from NAMSA test report T1262_809 on test article 513-35-3 (0.99%).

The test article, Stay Fresh Skin Fold Management Textile (SFMT), was evaluated for primary skin irritation in rabbits. This study was conducted in accordance with the guidelines of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for a minimum of 23 hours and a maximum of 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 treated with the test article. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible. The test article met the sponsor's acceptance criteria.

DELAYED HYPERSENSITIZATION TEST

This test is also called Sensitization. The specific test executed is called Buehler Sensitization. As the test report appended at right indicates, the sensitization test is passed also.

TOXIKON

Buehler Sensitization Test – ISO
Direct Contact
Project #: 12-5149-G2
Stay Fresh Skin Fold Management Textile

STUDY SUMMARY

The test article, Stay Fresh Skin Fold Management Textile, was evaluated for its potential to produce skin sensitization reactions following topical application to albino guinea pigs. The test article is not considered to be a skin sensitizer since none of the test animals exhibited skin reaction scores at the challenge exposure following an induction phase. No reactions were observed in the negative control group.

Based on the criteria of the protocol and the ISO 10993–10 guidelines, the test article meets the requirements of the test.

The above two tests are the most relevant and commonly performed tests, and have been executed many times for the Oxi-Tex technology products without failures.