Solventum MedTech OEM
Product preclinical data summary
Product Name: Solventum™ Medical Tape 1538L
Effective: October 2020

Medical Tape 1538L has been subjected to the following safety evaluations:

ISO Skin Irritation Study in Rabbits
The test article 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 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 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 very slight 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 0.2. The response of the test article was categorized as negligible.

Biocomp-Report-05-720553

ISO Guinea Pig Maximization Sensitization Test
The test article was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted 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 test and control animals received a challenge patch of the appropriate test article extract and the vehicle control. In addition, the test article was applied to the same animals. All sites were scored for dermal reactions at 24 and 48 hours after patch removal.

The test article extracts and the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.

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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.

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