



Solventum MedTech OEM

Product clinical data summary

Product Name: Solventum™ Medical Tape 1522H

Effective: September 2023

Medical Tape 1522H was subjected to the following safety evaluations:

Agar Overlay Cytotoxicity Test

An agar overlay cytotoxicity test was performed according to ISO 10993-5:1999 and USP General Chapter 87. The test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than grade 2 (mild reactivity).

Study 08-114

Closed Patch Sensitization (Buehler) Test

A guinea pig closed patch sensitization test was performed according to ISO10993-10: 2002. The test article was occlusively patched for 6-to 8-hours of contact with intact skin of 10 guinea pigs on three times/week for 3 weeks. The challenge application was performed two weeks later. No erythema or edema was observed at the challenge phase. The test article showed no evidence of causing delayed dermal contact sensitization.

Study 08-113

Primary Skin Irritation Test

A rabbit primary skin irritation test was performed according to ISO 10993-10:2002. The test article was applied as a 25 x 25 mm section with the adhesive side moistened with 0.5 mL saline and applied to the skin for a 24-hour exposure. Observations were recorded at 1, 24, 48, and 72 hours post-dose. Very slight erythema and no edema was observed on the skin of the rabbits. The primary irritation index (PII) was 0.3 (response category negligible).

Study 08-115

Human Repeated Insult Patch Test (HRIPT)

A human repeated insult patch test was performed according to. Two hundred twenty-nine (229) subjects from 16 to 79 years old (with parental consent) received 1-x 1-inch patches with the adhesive on intact skin as an occlusive patch. Applications were performed three times/week for three weeks (9 applications). Two weeks after the last application a challenge patch was applied. Two hundred six (206) subjects completed the study. The remaining subject voluntarily discontinued the study for reasons unrelated to the test article. Under the conditions of this study, the test article indicated no potential for dermal irritation or allergic contact sensitization.

Study 15-194

A similar adhesive as used in Medical Tape 1522H has been subjected to the following safety evaluations:

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



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