

FLEXcon® dermaFLEX™ H-506 Adhesive Biocompatibility Statement

Below are the biocompatibility test results for FLEXcon's dermaFLEX™ H-506 adhesive, as provided by FLEXcon's adhesive supplier. FLEXcon's "H-506" adhesive part number is in place of the adhesive supplier's part number. "FLEXcon's Adhesive Supplier" is in place of references to vendor identity.

"H-506" was not tested under ISO biocompatibility studies. "FLEXcon's Adhesive Supplier" evaluated the starting materials and finished composition of the adhesive "H-506" and determined through a read-across that a previously tested 'source' adhesive was sufficiently similar in composition and residual profile to the "H-506" 'target' adhesive to make a conclusion regarding its safety. The approach of comparing similar medical devices is included in the ISO guideline 10993-1 for evaluation and risk assessment of medical devices. Briefly, the source adhesive's proposed use and duration of contact was similar to the target adhesive. The tests performed on the source adhesive were: cytotoxicity using the Agarose-overlay method (ISO 10993-5), skin irritation study in rabbits (ISO 10993-10), and skin sensitization in guinea pigs (ISO 10993-10). The reliability of each test was evaluated for the source adhesive, and all tests were conducted in the spirit of good laboratory practices (non-GLP). The test summaries below were conducted on the source adhesive.

Agarose-overlay cytotoxicity test: Three 1 cm x 1 cm portions were cut and both white and yellow release liners were removed. A PET backing was used as structural support. Based on the results of the study, no evidence of cytotoxicity in the ISO 10993-5 Cytotoxicity test using the Direct Contact method.

Skin irritation test: Two 25 mm x 25 mm cut sections were topically applied to the skin of three rabbits and left in place for no less than 24 hrs. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal. No erythema and no edema observed. Based on the results of the study, the adhesive was categorized as a non-irritant (PII 0.0) in the test for irritation according to ISO 10993-10.

Skin sensitization test: Twenty-five mm x 25 mm cut sections were occlusively patched onto intact skin of 10 animals for 6 hours, 3 times per week over a three-week period. Following a 2-week recovery period, the animals were occlusively patched with adhesive. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. Samples did not show any evidence of delayed dermal contact sensitization according to the ISO 10993-10 test for skin sensitization.

Based on the results of three compatibility tests on the source adhesive, conducted according to ISO 10993-1 guidelines, and the similarity of the source adhesive to the target adhesive in a read-across, "H-506", has been determined to be safe as a medical device intended for use on the surface of skin with no restrictions on duration of use.

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