

FLEXcon® dermaFLEX™ H-520 Adhesive Biocompatibility Statement

Below are the biocompatibility test results for FLEXcon's dermaFLEX™ H-520 adhesive, as provided by FLEXcon's adhesive supplier. FLEXcon's "H-520" 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.

A request was made by FLEXcon to conduct a battery of ISO compliant biocompatibility tests according to ISO 10993 guidelines. Based on the proposed use of "H-520" and duration of contact, test for cytotoxicity, skin irritation and skin sensitization were determined to be needed for biocompatibility according to ISO 10993-1. Two-mil thick "H-520" samples were prepared and test for 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). All tests were conducted in the spirit of good laboratory practices (non-GLP).

Agarose-overlay cytotoxicity test: Three 1 cm x 1 cm portions of "H-520" were cut and release liners were removed. The adhesive side was placed against the agarose surface for testing. Based on the results of the study, "H-520" was demonstrated to be non-cytotoxic in the ISO 10993-5 Cytotoxicity test using the Agarose-overlay method.

Skin irritation test: Two 25 mm x 25 mm cut sections of "H-520" 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 hrs after the removal of "H-520". Very slight edema was observed on the applied skin throughout the observation timepoints. Based on the results of the study, "H-520" was categorized as a non-irritant (PII 0.1) in the test for irritation according to ISO 10993-10.

Skin sensitization test: Twenty-five mm x 25 mm cut sections of "H-520" was occlusively patched onto intact skin of 10 animals for 6 hrs, 3 times per week over a three-week period. Following a 2-week recovery period, the animals were occlusively patched with "H-520". All sites were observed for evidence of dermal reactions at 24 and 48 hrs after patch removal. "H-520" 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 the three biocompatibility tests, "H-520" has been determined to be safe as a medical device intended for use on surface of the skin with no restrictions on duration of use based on tests conducted according to ISO 10993-1 guidelines.

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