Flexcon® DermaFlex™ H-566 Adhesive Biocompatibility Statement

Below are the summary biocompatibility test results for Flexcon's DermaFlex™ H-566 adhesive, as provided by Flexcon's adhesive supplier. Flexcon's "H-566" 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.

ISO Biocompatibility testing results

Based on the proposed use of the test article, "H-566", and duration of contact, tests for cytotoxicity, skin irritation, and skin sensitization were determined to be needed for biocompatibility according to ISO 10993-1. Two-mil thick H-566 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 according to Good Laboratory Practices (GLP) practices (21 CFR, Part 58).

Cytotoxicity:

Three 1 cm x 1 cm portions of the test article, "H-566" were cut and placed on an agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37°C in the presence of 5% CO2 for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. There were no signs of toxicity or lysis.

Based on the results of the study, the test article, was demonstrated to be non-cytotoxic in the ISO 10993-5 Cytotoxicity test using the Agarose-overlay method.

Skin Irritation:

Two 25 mm x 25 mm cut sections of the test article, "H-566, and control 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 the test article.

No evidence of edema and slight erythema were observed on the applied skin throughout the observation timepoints. Based on the results of the study, the test article was categorized as negligible for irritation (PII 0.3) in the test for irritation according to ISO 10993-10.

Sensitization:

Twenty-five mm x 25 mm cut sections of the test article, "H-566", was occlusively patched onto intact skin of 10 animals for 6 to 8 hrs, 3 times per week over a three-week period. Following a 2-week recovery period, the animals were occlusively patched with the test article. All sites were observed for evidence of dermal reactions at 24 and 48 hrs after patch removal. The test article 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, the test article, "H-566", has been determined to be safe as a medical device intended for use on surface of the skin based on tests conducted according to ISO 10993-1 guidelines.