

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.

Cytotoxicity:

The test article, "H-566", was evaluated to determine the potential for cytotoxicity based on the requirements of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. Triplicate wells were dosed with a 1cm x 1 cm portion of the test article. Triplicate wells were dosed with a 1 cm length portion of high density polyethylene as a negative control. Triplicate wells were dosed with a 1 cm x 1 cm portion of latex as a positive control. Each was placed on an agarose surface directly overlaying a subconfluent 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.

The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity).

Skin Irritation:

The test article, "H-566", was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 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 0.3. The response of the test article was categorized as negligible.

Sensitization:

The test article, "H-566", was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig 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 occlusively patched to the intact skin of ten animals for 6 to 8 hours, three times a week, over a 3 week period. The control article was similarly patched to five animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test article and the control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal.

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

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