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Fixate™ Design Polymer Toxicology Studies

The toxicology studies summarized below were performed on polymers with chemical compositions representative of Fixate™ Design polymer. Therefore, this toxicology data is expected to be predictive of the toxicity of the commercial grades of Fixate Design polymer.

Skin Irritation

The irritation potential of the test material was evaluated using the Episkin Standard Model (EPISKIN-SM™) following treatment periods of 15 minutes at two concentrations: 100% as supplied and 25% dilution in phosphate buffered saline (PBS). Skin irritation is expressed as the remaining cell viability after the exposure period to the test substance.

Triplicate Episkin Standard Model tissues were treated with 10 µl of the test item at two concentrations, or negative control, or positive control and exposed for 15 minutes, at room temperature. After the exposure period, tissues were washed with PBS to remove the test substance. Subsequently, the tissues were incubated for 42 hours at 37^{o}C in a humidified atmosphere of 5% CO2 in air. MTT colorimetric cell viability assay was conducted to assess cytotoxicity after treatment, and the data are presented in the form of percentage viability (enzymatic conversion of the vital dye MTT relative to the negative controls) for the exposure period.

The relative mean viability of the tissue treated the test item was 99% and 101% for the 100% and 25% concentration respectively after the exposure period. The mean relative tissue viability values of the negative and positive controls were valid and met the acceptability criteria. Under the experimental conditions, this substance was considered to be non-irritant using the EPISKIN Standard Model.

Eye Irritation

The irritation potential of the test material was evaluated using the Bovine Corneal Opacity and Permeability test (BCOP test) as indicated in the OECD Guideline No. 429, 2009. The test material was administered at concentrations of 100% as supplied and 25% dilution in phosphate buffered saline (PBS). Eye irritation is expressed as irritancy score after the exposure period to the test substance.

Triplicate corneas were treated with 750 µl of the test item, or negative control, or positive control and exposed for 10 ± 1 minutes at 32 ± 1 °C. After the exposure period, the epithelium was washed at least 3 times with Eagle's Minimum Essential Medium (cMEM). Corneas were incubated for 120 ± 10 minutes at 32°C. After incubation, mean opacity measurements and mean permeability measurements were obtained. Mean opacity and mean permeability measurements were used to calculate an *in vitro* irritancy score. A test substance with a calculated *in vitro* irritancy score greater than 55.1 is defined as corrosive or a severe irritant. Mean *in vitro* scores for the test substance were 3.2 and 0.3 (100% as supplied and 25% in PBS) respectively. This test substance was considered to be non-irritant in the Bovine Corneal Opacity and Permeability test.

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Skin Sensitization

The skin sensitization of the test material was evaluated in the mouse using the Local Lymph Node Assay as indicated in the OECD Guideline No. 429, 2008; Method B.42 of Commission Directive 2008/440/EC. Groups of five mice were treated with the test material at concentrations of 25, 50% v/v in DMF or 100% v/v as supplied by daily application to the dorsal surface of each ear for three consecutive days. Six days following the first topical application, all mice were injected with 250 µl ^{3}H-methyl thymidine (^{3}HTdR: 112 µCi/mL) via tail vein giving a total dose of approximately 20 µCi ^{3}HTdR to each mouse. Cell suspension of individual lymph node cells was prepared by gentle mechanical disaggregation through nylon mesh. After completing centrifuging and washing steps, the precipitates were incubated overnight at 2-8°C, were re-centrifuged, and measured for ^{3}HTdR incorporation. The mean stimulation index (SI) for the test substance was determined to be 1.98 (25%), 2.79 (50%), and 2.31 (100%) respectively. Based on this information it was concluded that the test material is not a skin sensitizer when tested up to the highest applicable concentration of 100% as supplied.