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SilSense® A-21 Silicone Toxicology Studies

CTFA / INCI Name: PEG-7 Amodimethicone

The toxicology studies summarized below were performed on polymers with chemical compositions representative of SilSense® A-21 silicone. Therefore, this toxicology data is expected to be predictive of the toxicity of the commercial grades of SilSense A-21 silicone.

Acute Oral Toxicity

The acute oral toxicity was evaluated in rats using a test material as a 50 % w/v solution in water according to FHSLA, 16 CFR 1500.3. Five male and five female rats were administered a single dose of 5,000 mg/kg via gavage, which is the equivalent 2,500 mg/kg of SilSense A-21 silicone, a dry product. The animals were housed individually and observed for mortality and clinical signs of toxicity for 14 days following exposure. No evidence of toxicity was observed. Based on these results, the acute oral LD_{50} of SilSense A-21 silicone is predicted to be greater than 2,500 mg/kg.

Skin Irritation

The skin irritation of the undiluted test material was evaluated in rabbits according to OECD Guideline No. 404, 1992; Method B4 of Commission Directive 92/69/EEC. The test material (0.5 ml) was applied to the intact skin on the backs of three animals under a semi-occlusive dressing. Four hours after the application of the test material, the patches were removed, and the test material was gently removed from the skin. The test sites were evaluated one hour after removal of the patches and at 24, 48, and 72 hours. The test material produced a primary irritation index score of 0.0 and was classified as non-irritating.

Eye Irritation

The eye irritation of the undiluted test material was evaluated in rabbits according to OECD Guideline No. 405, 1987; Method B5 of Commission Directive 92/69/EEC. The test material (0.1 ml) was placed in the conjunctival sac of the one eye of each of three animals. The other eye served as an untreated control. The eyes were evaluated 1, 24, 48, and 72 hours following treatment. The test material produced a maximum mean score of 13 out of 110 and was classified as mildly irritating.

Skin Sensitization

The skin sensitization potential of a number of samples of the test material was evaluated in the mouse using the Local Lymph Node Assay based on the guidelines described in OECD, Section 4, Health Effects, No. 429 (Draft), Paris Cedex, 2000, EC, Council Directive 67/548/EEC, Annex IV C, B.42 (Draft), June 2001 and ICCVAM, NIH publication, No. 99-4494, February 1999. Groups of four mice were treated with the test material at concentrations of 0%, 5% and 50% w/v in propylene glycol (25 µl/ear) by daily application to the dorsal surface of each ear for three consecutive days. Five days following the first topical application, all mice were injected with 25 µl of phosphate buffered saline containing 3H-methyl thymidine via tail vein giving a total dose of 20 µCi to each mouse. A single cell suspension of pooled lymph node cells was prepared by mechanical disaggregation through stainless steel gauze (125µm diameter). The cells were washed and centrifuged, precipitated, and re-centrifuged at 4°C, and then were measured for ^{3}HTdr incorporation. Based on the initial results, additional groups of animals were

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treated with test substance concentrations of 35% and 50%, a repeat dose. Solutions of 5%, 10% and 25% alpha-hexylcinnamic aldehyde in acetone:corn oil (4:1 v/v) were used as the positive control.

Slight erythema was noted at the two top doses. The majority of lymph nodes were enlarged. No other macroscopic abnormalities of the lymph nodes were noted. The stimulation index (SI) for the test substance was determined to be between 0.59 and 2.86. Because the SI value at 50% was below the criteria for a positive response (test/control ratio > 3), the test substance was determined not to cause a sensitization response under the conditions of this test.