TOX-046
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SilSense® Q-Plus Silicone Toxicology Studies

CTFA / INCI Name: Silicone Quaternium-8

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

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 0.6 and was classified as mildly 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 26.7 out of 110 and was classified as moderately irritating.

Skin Sensitization (Preliminary Draft Report)

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 a concentrations of 0%, 0.5%, 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. A 10% solution of alpha-hexylcinnamic aldehyde in propylene glycol was used as the positive control.

Very slight erythema was noted in one animal in the highest dose group. All 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 1.20, 1.30, and 3.62 at 0.5%, 5%, and 50%, respectively. Because the SI value at 50% was above the criteria for a positive response (test/control ratio > 3), the test substance was determined to cause a sensitization response under the conditions of this test. Using linear interpolation the estimated EC3 was calculated as 47%, which is the lowest concentration at which a positive response is expected to result under the conditions of this assay. Under the current proposed classification scheme the EC3 indicates that the neat material should be considered a mild sensitizer. Furthermore, based on these results it was concluded that the neat material should be labeled as: may cause sensitization by skin contact (R43).

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