TOX-048
Edition: January 30, 2004
Previous Editions: July 9, 2003, October 24, 2003
Original: January 14, 2003

SilSense® PE-100 Silicone Toxicology Studies

CTFA / INCI Name: Dimethicone PEG-8 Phosphate

The toxicology studies summarized below were performed on test materials with chemical compositions representative of SilSense® PE-100 silicone. Therefore, the toxicology data below is expected to be predictive of the toxicity of the commercial grades of SilSense PE-100 silicone.

Oral Toxicity

The acute oral toxicity of the test material was evaluated undiluted in rabbits according to FHSLA, 16 CFR 1500.3. A group of 10 animals (5 male and 5 females) were given a single dose of 5000 gm/kg by gavage and then were observed for 14 days. No deaths or signs of systemic toxicity were noted. The oral LD_{50} was determined to be greater than 5000 mg/kg.

Skin Irritation

The skin irritation potential of the test material was evaluated undiluted in rabbits according to FHSLA, 16 CFR 1500.41. The test material (0.5g) was applied to the intact and abraded skin on the backs of six animals. The dose was held in contact with the skin under a semi-occlusive binder for an exposure period of twenty-four hours. Following the exposure period, the binder was removed, and the remaining test article was wiped from the skin using tap water and paper towels. The test sites were subsequently examined and scored for dermal irritation at 24 and 72 hours following patch removal.

Under the test conditions, the test material did not cause any skin irritation (Primary Irritation Index 0.0).

Eye Irritation

The eye irritation potential of the test material was evaluated undiluted according to FHSLA 16 CFR 1500.42. A standard amount of the test material (0.1ml) was instilled into the conjunctival sac of one eye of each of six rabbits while the other eye served as a control. The eyes were not washed after instillation. The eyes were evaluated at 24, 48, and 72 hours after administration.

Under the test conditions, the test material (undiluted) did not produce any eye irritation (maximum mean score = 0.0 out of 110) and was considered non-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, 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 5%, 10%, 50%, and 100% 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

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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. Solutions of 5%, 10% and 25% of alpha-hexylcinnamic aldehyde in acetone:corn oil (4:1 v/v) were used as the positive control.

Slight erythema was noted on the treated ears of the animals in the main study. However, it is not expected that this level of irritation would lead to significant stimulation of the lymph nodes. All lymph nodes were enlarged. The largest nodes were seen in the highest dose group. No other macroscopic abnormalities of the lymph nodes were noted. The stimulation index (SI) for the test substance was determined to be 2.1, 1.1, 7.6 and 19.3 at 5%, 10%, 50%, and 100%, respectively. Because this SI value 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. The estimate of the EC3 (the lowest concentration at which a positive response is expected to result under the conditions of this assay) was calculated as 21.7%. Under the current proposed classification scheme the neat material may be considered a moderate sensitizer (Class 3) while under the OECD harmonized classification system it is considered a sensitizer (Category 2). Furthermore, based on these results it was concluded that the neat material should be labeled as: may cause sensitization by skin contact (R43).

Comedogenicity Assay

The comedogenicity of the test material was evaluated in three albino rabbits. The test material (0.5 ml) was applied to the internal base of one ear of each animal while 0.5 ml of acetylated lanolin alcohol was applied to the other, serving as the positive control. Both the test material and the positive control were administered once a day for ten days. The ears were then evaluated on a scoring scale of 0 (No visible follicular hyperkeratosis) to 5 (Severe lesions). One animal exhibited a score of 1 on days 9 and 10 for the test material. All other animals were free of any changes. Scores of 3 to 4 in the animals were observed for the positive control indicating that the assay was functioning. Based on these results the test material was regarded as non-comedogenic.