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June 24, 2014

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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW Room 6428
Washington, DC 20004
Attn: 8(e) Coordinator

CBIC Control Number
360734

Dear Sir/Madam:

Reaction product of decanoic acid, 12-hydroxystearic acid and 1,2-ethandiamine

A Magnusson-Kligman test was conducted with guinea pigs to determine the potential for the test substance to invoke dermal skin sensitization reactions. The study was conducted using four stages; preliminary irritation screens, a two-stage induction phase, and a challenge phase as described below. Preliminary irritation testing was performed on 12 animals to determine appropriate concentrations of the test substance that could be used for both intradermal and topical induction as well as topical challenge. An emulsion of 50% v/v Freund's Adjuvant Complete in distilled water was used during the intradermal injection screening and the injection induction phases. This emulsion was thoroughly mixed using a stir plate and is referred to throughout the report as an emulsion of Freund's Adjuvant Complete. The first induction phase involved six intradermal injections into the suprascapular area of each of 20 guinea pigs. These doses were comprised of pairs of injections of the test substance in mineral oil (3% w/w), the test substance (3% w/w) combined with an emulsion of Freund's Adjuvant Complete, as well as an emulsion of Freund's Adjuvant Complete alone. A sham control group (ten animals) was maintained under the same environmental conditions and received injections of mineral oil, mineral oil (50% w/w) combined with an emulsion of Freund's Adjuvant Complete, as well as an emulsion of Freund's Adjuvant Complete alone. Approximately 24 and 48 hours after the injections, all sites were evaluated for an irritation response (erythema). Approximately one week later, the second phase of induction was conducted. The test substance as a 60% w/w mixture in mineral oil (test group) or (100%) mineral oil (test vehicle control group) was applied topically for a period of 48 hours to the area encompassing the intradermal injection sites. Approximately one hour after the topical induction patches were removed, all animals were scored for erythema. Approximately two weeks later, a primary challenge consisting of three occluded applications was conducted on each animal. One Hill Top Chamber containing 0.5 mL of 100% mineral oil was applied to a naive site on the right middle flank of each animal. The remaining two Hill Top Chambers containing 0.5 grams of the HNIC (Highest Non-Irritating Concentration, determined in the preliminary irritation screen to be a 60% w/w mixture in mineral oil) of the test substance and 0.5 mL of a 33% dilution of the HNIC (20% w/w mixture in mineral oil) were positioned on two naive sites on the left front and rear flank, respectively, for approximately 24 hours. The test vehicle control group was also treated with the test substance and test vehicle (as described above) at challenge. Approximately 24 and 48 hours after challenge patch removal, all animals were scored for a sensitization response (erythema).

Based on the results of this study, the test substance is considered to be an extreme contact skin sensitizer. The positive response observed in the historical positive control validation study with alpha-Hexylcinnamaldehyde, ≥ 95% (HCA) validates the test system used in this study.

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