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August 3, 2009

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8EHQ-0809-17605A

Document Control Officer 8(e) Coordinator
U. S. Environmental Protection Agency – East
Confidential Business Information Center
Mail Code: 7407M
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Subject: TSCA 8(e) Submission



DCN:(88090000329s)

Dear Sir:

In accordance with TSCA 8(e) requirements, [REDACTED] is submitting Local Lymph Node Assay in Mice (LLNA/IMDS).

The purpose of the study was to assess the dermal sensitization potential for the test substance.

The information submitted in this study is considered "Confidential Business Information". A sanitized, as well as a confidential version, is being submitted.

Please contact me if you have any questions.

Company Sanitized

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COMPOUND: [REDACTED] (Amine)

STUDY TITLE: Local Lymph Node Assay in Mice (LLNA/IMDS)

REPORT OR STUDY NO.: Study [REDACTED], Report [REDACTED]

The purpose of the study was to assess the dermal sensitization potential for the test substance. This study was a modified Local Lymph Node Assay (LLNA) in that it included an assessment of the irritation potential of the test substance. The study design was in accordance with OECD Guideline 429 and EPA OPPTS 870.2600. Different groups of 6 female NMRI mice were dermally exposed to 0 (vehicle control), 2, 10, or 50% solutions of the test substance in acetone:olive oil (4:1). Endpoints included cell counts and weights of draining lymph nodes, ear weights, and ear swelling.

A significant increase was found for weight and cell counts of the draining lymph node at the mid and high doses indicating a dermal sensitization potential. Ear swelling and ear weight were also increased at the mid and high doses indicating an irritation potential. The study investigator concluded that the test substance showed a moderate sensitization potential.