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June 4, 2007

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

Dear Sir:

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

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.

Sincerely,

8EHQ-07 16869

Enclosures

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COMPOUND: [redacted]

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

REPORT OR STUDY NO.: [redacted]

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

This study was a modified LLNA in that it included an assessment of the irritation potential of the HDI homopolymer test substance. The study design was in accordance with OECD guideline 429. Different groups of 6 female NMRI mice were dermally exposed to concentrations of 0, 2, 10 and 50%.

The results showed an increase in the weights and cell counts of the draining lymph nodes at all concentrations tested leading the investigator to conclude that the test substance has a sensitization potential. Ear thickness and weights were also increased. This information led the investigator to conclude that the test substance has a skin sensitization potential.

The criterion for reporting dermal sensitization studies is if the results indicate the test substance to be a strong sensitizer. There is no officially recognized categorization of responses from this study type to determine what repreents a strong sensitization response. However, it is generally regarded by investigators in this field that a response with concentrations less than 1% is indicative of a strong sensitizer. The robustness of the response at 2% concentration suggests that a sensitization potential may also be expected at less than 1% concentration. Therefore, it is recommended that this study be submitted under TSCA 8(e).

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