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Bayer MaterialScience



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**CONTAINS TSCA CONFIDENTIAL
BUSINESS INFORMATION**

November 22, 2010

8EHQ-1110-18196A



By Certified Mail

DCN:8811000080s

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428 Attn: Section 8(e)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue. N.W.
Washington, DC 20460

Subject: TSCA § 8(e)
Test Substance: Condensation products of isononylphenol, diethanolamine and formaldehyde in TCPP

Dear Sir or Madam:

Bayer MaterialScience LLC (the “*Company*”) is submitting a Local Lymph Node Assay in Mice (LLNA/IMDS) of the Test Substance, which the Company imports, processes, and distributes in the United States.

The Company is submitting these data in accordance with our understanding of EPA’s interpretation of the requirements of TSCA § 8(e) as expressed in agency guidance. However, the Company has not determined whether these data actually disclose a substantial risk of injury to health or the environment associated with the chemical substance or mixture.

This submission contains TSCA confidential business information (“*CBI*”). Accordingly, the Company is providing both original and redacted versions of this submission to EPA, along with the attached justification of the Company’s CBI claims. In keeping with recent guidance from EPA, the Company is not claiming the chemical identity as CBI.

Company Sanitized

Please contact me if you have any questions.

Sincerely,

Attachment

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TEST SUBSTANCE: **Condensation products of isononylphenol, diethanolamine and formaldehyde in TCPP**

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

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 cell proliferation was measured by cell counts rather than radioactive labeling and the assay included an assessment of the irritation potential of the test substance. The study design was in accordance with OECD Guidelines 429 and 406, as well as EPA OPPTS 870.2600. Different groups of 6 female NMRI mice were dermally exposed to 0 (vehicle control), 4, 20, or 100% solutions of the test substance in acetone/olive oil. Endpoints included cell counts and weights of draining lymph nodes, ear weights, and ear swelling.

Compared to vehicle-treated controls, weights of draining lymph nodes and cell counts were statistically significantly increased in all treated groups. In addition, the "positive level" index of 1.4 was exceeded for cell counts in all treated groups (ratio of mean for treated group to vehicle control). The study director concluded that a sensitizing potential was observed with this test substance under the conditions of this assay.