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SHARRONN E. ETTER
DIRECTOR, REGULATORY AFFAIRS AND PRODUCT SAFETY DEPARTMENT

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Document Control Office (7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Room G-099
Attn: TSCA Section 8(e) Coordinator
1200 Pennsylvania Avenue, NW
Washington, DC 20460

CONTAINS NO CBI

8EHQ-04-15589

Date: **June 11, 2004**

Reference: TSCA Section 8(e) Notification of Substantial Risk:
Dimethoxy(methyl)[N-phenylaminomethyl] silane CAS No. 17890-10-7

Dear Sir or Madam:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), as interpreted in the Statement of Interpretation and Enforcement Policy (40 FR 11110, 16 March 1978), Wacker Chemical Corporation is submitting the following information concerning the results of an *In Vitro* Mammalian Chromosome Aberration Test.

Chemical Substance:

CA Name: **Dimethoxy(methyl)[N-phenylaminomethyl] silane**
CAS No. **17890-10-7**
Trade Name: GENIOSIL® XL 972

Manufacturer: Wacker-Chemie GmbH

Hanns Seidel-Platz 4
81737, Munich Germany

The material is manufactured in Burghausen, Germany

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Completed Study:

In Vitro Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with Silane 449025 VP (GENIOSIL® XL 972).

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Summary:

During the described *In Vitro* Chromosome Aberration Test and under the experimental conditions as stated in the report, Silane 449025 VP (GENIOSIL® XL 972) did induce structural chromosome aberrations in the V79 Chinese hamster cell line with metabolic activation. Therefore, Silane 449025 VP was considered to be clastogenic.

Details:

Study Design:

In order to investigate the potential of Silane 449025VP to induce structural chromosome aberrations in V79 cells of the Chinese hamster an *in vitro* a chromosome aberration assay was performed.
The chromosomes were prepared 20 hours after the start of treatment with the test material.
The treatment interval was 4 hours with and without metabolic activation (Experiment I) and 4 hours with and 20 hours without metabolic activation (Experiment II). Two parallel cultures were set up. One hundred (100) metaphases were scored per culture for structural chromosomal aberrations. The following concentrations were evaluated:

Experiment I:

Without metabolic activation: 300, 400 and 500 µg/ml

With metabolic activation: 50, 100 and 250 µg/ml

Experiment II:

Without metabolic activation: 100, 200 and 300 µg/ml

With metabolic activation: 50, 200, 300 and 400 µg/ml

Findings:

A reduction of the mitotic index was observed with and without metabolic activation in all experiments. In experiment I without metabolic activation the test material did not increase the frequency of the cells with aberrations when compared to the concurrent negative controls. The values found were in the range of the concurrent control values or with 5.5 % aberrant cells which was only slightly above the historical negative control values of BSL BIOSERVICE (0 - 4.5 % aberrant cells). With metabolic activation, a distinct increase of aberrant cells up to values of 17.5% when compared to the negative controls was detected.

Under modified conditions in experiment II, an increase in aberrant cells was observed up to values of 23.5 % with metabolic activation compared to the negative controls. Without metabolic activation, no biologically relevant increase in aberrant cells was detected.

In both experiments with and without metabolic activation, no increase in the frequencies of polyploid cells was found after treatment with the test material when compared to the controls.

EMS (600 resp. 900 µg/ml) and CPA (0.83 µg/ml) were used as positive controls. These materials showed a distinct and biologically relevant increase of cells with structural chromosome aberrations above the historical control level.

Actions:

This material is a research and development material and has only been sampled to a limited number of Industrial customers who have been made aware of the toxicity. The MSDS and label reflect the potential toxicity hazard. Wacker has also made the decision to no longer promote this material and the product will no longer be available from Wacker. Wacker Chemical Corporation will provide EPA a copy of the final report when it is received.

If you have any questions please contact Sharronn E. Etter at the numbers and address above.

Sincerely,

Sharronn E. Etter

Sharronn E. Etter
Director Regulatory Affairs, Product Safety and Site Security and Safety