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June 29, 2009

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

8EHQ-0609-17582A



Dear Sir:

In accordance with TSCA 8(e) requirements, [REDACTED] is submitting Micronucleus Test on the male Mouse.

The purpose of the study was to evaluate the genotoxic (clastogenic) potential of the test substance [REDACTED]

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.

DCN: (88090000306s)



**Company Sanitized**

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**COMPOUND:** [REDACTED] Aziridine

**STUDY TITLE:** Micronucleus test on the male mouse

**REPORT OR STUDY NO.:** [REDACTED]

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The purpose of these two studies was to evaluate the genotoxic (clastogenic) potential of the test substance ([REDACTED]). The studies were performed in accordance with OECD Guideline 474. In the first study, groups of male NMRI mice received two intraperitoneal (i.p.) injections of 1.25, 2.5, or 5 mg/kg of the test substance separated by 24 hours. In the second study, male mice received two i.p. injections of 80 mg/kg separated by 24 hours. The femoral bone marrow of all groups was prepared 24 hours after the last dose. Normally the bone marrow erythrocytes are not nucleated. An increased incidence of micronucleated erythrocytes compared to negative controls indicates that the test substance may cause chromosome breaks or spindle disorders in these cells.

Mice in all groups in the first study showed signs of toxicity after two injections, including spasm, extension spasm, and difficulty breathing. The same signs were reported in the negative controls. Therefore the spasms do not appear to indicate substance-related effects on the nervous system. The ratio of polychromatic to normochromatic erythrocytes was not altered in these groups. The number of micronuclei was increased in positive controls

Similar clinical signs were reported in the second study with 80 mg/kg and 3 of 7 mice died. The incidence of micronucleated erythrocytes showed an increase in this study. The authors concluded that "this finding demonstrates relevant systemic exposure of the males to [REDACTED]" and that there "was an indication of a clastogenic effect".

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