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**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

September 19, 1994 (Revision 1)



COMPANY SANITIZED

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
TSCA 8(e) Coordinator
401 M. Street, SW
Washington, DC 20460

RE: Toxic Substance Control Act - Section 8(e) Substantial Risk Report

Dear Sir/Madam:

As required by Section 8(e) of the Toxic Substance Control Act (TSCA), the following notification of substantial risk is being submitted to the Administrator:

1. **Name of Contact Person:** [Confidential]
Title: [Confidential]
Telephone Number: [Confidential]
2. **Company Name:** [Confidential]
Address: [Confidential]
3. **Name of Chemical:** d-Allose
CAS Number: 2595-97-3
4. **Summary of Adverse Effects:**

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A 28-day oral toxicity laboratory study on rats involving repeated doses of 3.1 gr/kg/day and 5.1 gr/kg/day of a research material, d-allose, has resulted in adverse effects on blood, specifically granulocytopenia and reduced platelet counts, at both dosage levels.

To summarize the study, the research material or deionized water (as a control) was administered to 30 male and 30 female rats by gavage once daily for 28 days at dosage levels of 3.1 gr. material/kg/day and 5.1 gr. material/kg/day. The control animals received deionized water at a dosage volume comparable to the test animals. At study termination, all animals were euthanized, and thorough post-mortem examinations were conducted on the primary study group of animals.

Hematological studies showed a marked decrease in segmented neutrophils which were dose-related and associated with a marked reduction in mature myeloid cells

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in the bone marrow smears. Platelets also showed a dose-related reduction in numbers in both sexes. There was no apparent effect on the erythroid series.

There were no test article-related effects on survival, appearance, body weights, food consumption or water consumption. There were no treatment related findings at necropsy or on histopathological examination of the designated organs.

Pursuant to 40 CFR Section 2.203(b) and Section 14 of the Toxic Substances Control Act, we have [bracketed] certain portions of this notification which we consider confidential. We claim that disclosure of this information to others would cause substantial harm to our competitive position and that this information is exempt from disclosure to others under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4). We have also submitted a second copy of the notification for EPA public files which has excised all confidential information.

[Confidential]

If you have any questions regarding this submission please contact me.

Sincerely,

[Confidential]