

BASF Corporation

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Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution and Toxics
U. S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

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Ladies and Gentlemen:

Subject: Notice in Accordance with TSCA Section 8(e) – Results of a carcinogenicity study in Wistar rats with Bis-(hydroxylammonium)-sulfate [CAS 10039-54-0] conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany

Bis-(hydroxylammonium)-sulfate was administered to groups of 50 male and 50 female Wistar rats in drinking water at concentrations of 0, 5, 20 and 80 ppm for 24 months (main groups) and to 10 animals per sex and dose for 12 months (satellite groups). The study was carried out according to the following test guidelines: 87/302/EEC, OECD 451, U.S. EPA 40CFR § 798-3300 and Japan/MAFF.

Summary of Findings:

The following is a summary of the non-neoplastic findings at the end of the 24 months of treatment: At the 80 ppm concentration, there were clear signs of hemolytic anemia and compensatory reactions in both sexes; increased mean absolute and relative spleen weights in females and a higher degree of hemosiderin storage in both sexes; increased number of males and females with angiomatous hyperplasia in the spleen with a higher degree in females; and congested vessels in the spleen in both sexes. At the 20 ppm concentration, a higher degree of hemosiderin storage in the spleen of females was observed. No treatment related findings were observed in the 5 ppm concentration.

The following table shows the incidence of neoplastic findings in the spleen:

| Drinking Water Concentration (ppm) | Males | | | | Females | | | |
|------------------------------------|-------|---|----|----|---------|---|----|----|
| | 0 | 5 | 20 | 80 | 0 | 5 | 20 | 80 |
| Hemangiosarcomas | 4 | 7 | 9 | 8 | 2 | 1 | 1 | 3 |
| Hemangiomas | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 4 |

The 5 ppm drinking water concentration equated to dose levels of 0.2 and 0.4 mg/kg body weight/day for males and females, respectively. The material safety data sheet will be updated to reflect these test results and notification is being provided to customers.

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot/mk

Edward J. Kerfoot, Ph.D.

Director, Toxicology and Product Regulations



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