

BASF Corporation

8EHQ-0595-13435

**BASF**

Certified Mail P 633 101 613

Return Receipt Requested 95 MAY -2 AM 9:01

**ORIGINAL**

April 25, 1995

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



8EHQ-95-13435  
INIT 05/02/95

RECEIVED  
APR 27 1995  
U.S. EPA

Ladies and Gentlemen:

Contains No CBI

Subject: Notice in Accordance with Section 8(e) of TSCA - Results of a Full-Scale Prenatal Toxicity Study with 2-Butyne-1,4-diol (CAS. No. 110-65-6).

BASF Corporation is submitting the results of a full-scale prenatal toxicity study with 2-butyne-1,4-diol, conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany. The sponsor of this study was BG Chemie, Heidelberg, Germany. Although BASF Corporation does not feel that the information presents a substantial risk to health or environment, it is being submitted under Section 8(e) of TSCA.

In the full-scale study, 2-butyne-1,4-diol was administered to 18-22 pregnant Wistar rats per group by gavage for 10 consecutive days (days 5-15 post coitum) in daily doses of 10, 40 and 80 mg/kg body weight. For comparison, a control group was dosed with the vehicle only (double distilled water).

Food consumption and body weights of the animals were recorded regularly throughout the study period. The state of health of the animals was checked daily.

On day 20 p.c., all females were sacrificed and assessed by gross pathology (including weight determinations of the unopened uterus). The fetuses were dissected from the uterus, sexed, weighed and further examined for any external, soft tissue and/or skeletal findings.

The following is a summary of the results:

At the highest dose level of 80 mg/kg body weight/day, some overt signs of maternal toxicity were observed. Food consumption was about 21% lower than in the concurrent control group. A statistically significant body weight loss occurred at the beginning of the treatment period (days 6-8 p.c.). Also, one dam died intercurrently on day 8 p.c. For this animal and another high dose dam some adverse clinical symptoms such as apathy, poor general state, vaginal hemorrhage and piloerection were reported.

The only sign of embryo-/fetotoxicity observed was a marginal, but statistically significant increase in one skeletal variation (accessory 14th rib(s)) at 80 mg/kg. No teratogenic effects were seen.



88950000219

At the low (10 mg/kg body weight/day) and the intermediate (60 mg/kg body weight/day) doses, no signs of maternal toxicity, substance-induced effects on gestational parameters or embryo/fetotoxicity (including teratogenicity) were observed.

Although the only sign of developmental toxicity in this study appeared only when overt maternal toxicity was evident, BASF Corporation understands that this reporting of these results under TSCA 8(e) is in accordance with EPA's policy.

All persons handling this product will be informed of these results via an updated Material Safety Data Sheet.

Please note that this submission does not contain confidential business information.

If you have any questions, please feel free to call me at (313) 246-6207.

Very Truly Yours,

BASF Corporation

A handwritten signature in black ink that reads "Edward J. Kerfoot". The signature is written in a cursive style with a large, prominent "E" and "K".

Edward J. Kerfoot, Ph.D.

Director, Toxicology & Product Regulations

**Best Available Copy**