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INITIAL SUBMISSION: LETTER FROM BASF CORP TO USEPA REPORTING PRELIM RESULTS OF MODIFIED 1-GENERATION REPRODUCTION TOXICITY STUDY IN WISTAR RATS W/2-BUTYNE-1,4-DIOL, DATED 8/6/1999		
Chemical Category		
2-BUTYNE-1,4-DIOL		

A 02

INITIAL SUB-MISSION

A 03 BASF Corporation 8EHQ-0899-14529 BASF

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

Ladies and Gentlemen:

Subject: Notice in Accordance to TSCA Section 8(e) - Preliminary results of a modified one generation reproduction toxicity study in Wistar rats with a chemical intermediate (2-Butyne-1,4-diol; CAS No. 110-65-6).

88990000248

BASF Corporation is submitting the preliminary results of a modified one generation reproduction toxicity study in Wistar rats with a chemical intermediate (2-Butyne-1,4-diol; CAS No. 110-65-6). The study was conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany.

This study was carried out on the basis of the OECD Guideline 415 (May 1983) and was expanded to include examinations (estrus cycle, sperm parameters, organ weight determination in selected pups and parental animals, extended histology, signs of sexual maturation) required for two generation reproduction toxicity studies in the EPA, Health Effects Test Guideline, OPPTS 870.3800 (August 1998) and the OECD Guideline 416 (Draft Version; September 1998). The test substance was administered via the drinking water to 25 Wistar rats per sex and group at dose levels of 0; 10, 80 and 500 ppm. At least 10 weeks after beginning treatment, the F0 animals were mated to produce a litter (F1). The pups were raised up until day 21 post partum (p.p.) Thereafter the F1 weanlings with the exception of one male and one female pup/litter and all F0 adult animals were sacrificed. The selected F1 weanlings were reared until sexual maturation occurred and were killed thereafter.

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Summary

Clear dose-dependent effects on the F0 parental animals occurred at 80 ppm and above. These were substantiated by increased kidney weights (absolute and relative, both sexes), liver weights (absolute and relative, F0 females) and reduced water consumption. Additionally, impaired body weight gains were recorded in the high dose dams during premating, gestation and lactation. There were no adverse effects on reproductive performance of these rats.

Signs of developmental toxicity in the form of impaired pup body weight/body weight gains and associated reduced pup organ weights were observed at the top dose of 500 ppm. Furthermore, there was a slight but statistically significant delay in vaginal opening and preputial separation at 500 ppm. However, these delays in sexual maturation are considered to be a consequence of the delay in the pups' growth, indicated primarily by lowered body weights and retarded body weight gains.

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Although the findings are not considered to present a substantial risk to the health or the environment, BASF Corporation understands that the reporting of these results is in accordance with EPA's policy. Any reports or additional information that we receive will be forwarded to the Agency and Material Safety Data Sheets will be updated with this preliminary information.

1609 Biddle Avenue, Wyandotte, Michigan 48192 (313) 246-6100

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If you have any questions, please feel free to call me at (734) 324-6207.

Very Truly Yours,

BASF Corporation

Edward J. Kerfoot

Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations

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