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Document Title	INITIAL SUBMISSION: LETTER FROM BASF CORP TO USEPA, SUMMARY OF PRELIM RESULTS OF PRENATAL DEVELOPMENTAL TOXICITY STUDY IN RABBITS WITH PYRAZOLE, [], DATED 01/18/00 (SANITIZED)		
Chemical Category	PYRAZOLE (CONFIDENTIAL)		

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

8EHQ-00-14641 Company Sanitized
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Ladies and Gentlemen:

Notice in Accordance to TSCA Section 8(e) - Preliminary results of a full-scale prenatal developmental toxicity study in Himalayan Rabbits with Pyrazole.

BASF Corporation is submitting preliminary results of a full-scale prenatal developmental toxicity study in Himalayan rabbits with Pyrazole, conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany. Shipments totaling approximately 4.6 kilograms active ingredient have been shipped to the U.S. since 1998.

This range finding study was carried out in accordance with:

- EC Commission Directive 87/302/EEC of November 18, 1987, Official Journal of the European Communities, No. L 133 (1988)
- OECD Guidelines for Testing of Chemicals, Proposal for Updating Guideline 414, Prenatal Developmental Toxicity (Draft Document August 1999)
- U.S. EPA, Health Effects Test Guidelines, OPPTS 870.3700; Prenatal Developmental Toxicity Study (August 1998)
- Japan/MAFF: Testing Guidelines for Toxicology Studies: Teratogenicity Study (1985)

The test substance was administered by gavage to 25 pregnant female Himalayan rabbits/group at doses of 0, 50, 150 and 450 mg/kg body weight on day 7 through day 28 post insemination. 22 - 25 females/group had live fetuses at scheduled necropsy. The fetuses were assessed now for external and soft tissue findings without knowledge of treatment group.

Following is a summary of the most relevant results:

Main signs of maternal toxicity were substantiated by significant reductions in food consumption (high dose only) and dose-dependent impairments in body weight gain (from the lowest dose onward). Moreover, 3 out of the 25 pregnant animals of the high dose group aborted before scheduled necropsy.

Signs of developmental toxicity occurred at all 3 dose levels predominantly in the form of increased malformation rates, with no clear dose-response relationship. They consisted of malformations of the urinary tract and associated organs (i.e. agenesis of the kidneys and ureters; malpositioned kidneys, misshapen kidneys) at incidences outside the background control range. A variety of other external or soft tissue malformations (i.e. cleft palate and various malformations of the cardiovascular system) were seen in single fetuses predominantly of the of the substance-treated groups.

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.

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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, Ph.D.
Director, Toxicology and Product Regulations

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