

8EHQ-0799-14500

BASF Corporation  
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**BASF**

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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

CONTAINS NO CBI

Ladies and Gentlemen:

Notice in Accordance to TSCA Section 8(e) - Preliminary results of a range finding study in Wistar rats with 3,5-difluoroaniline (CAS registry number 372-39-4).

This substance is also known as PMN-97-648 and is subject to a Consent Order under TSCA Section 5(e).

BASF Corporation is submitting preliminary results of a range finding study for a screening study according to OECD Method No. 422 in Wistar rats with a chemical intermediate conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany.

The test substance was administered to 5 male and 5 female F0 parental Wistar rats/group at doses of 0, 50, 100 and 150 mg/kg body weight/day as an oily preparation. The application period for the F0 males lasted about 4 weeks (two weeks pre mating, during mating of 7 days at maximum and thereafter). The F0 females received the test substance preparation for about 8 weeks (two weeks pre mating, during mating, gestation until day 4 post partum (p.p.) of the last F0 female that delivered). At the end of the administration period blood samples were taken for clinical pathology from the male F0 animals and subsequently these animals were sacrificed, gross pathologically examined and different organs were weighed. The F0 females were allowed to deliver and rear their pups up to day 4 p.p. On day 4 p.p. all pups were sacrificed, externally examined, eviscerated and their organs were assessed macroscopically. After the last F0 female had delivered all F0 females were sacrificed, gross pathologically examined and different organs were weighed.

Clear dose dependent signs of parental toxicity occurred at all dose levels. These were substantiated by signs of anemia, including reduced red blood cell counts, reduced hemoglobin content and reduced hematocrit in the male F0 animals (only males examined) and associated enlarged spleens and increased spleen weight (relative and absolute) in male and female F0 rats.

Signs of developmental toxicity occurred only at the top dose of 150 mg/kg body weight/day in the form of increased pup mortality and initially reduced pup body weights (day 1 only).



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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.

No information is being claimed as confidential.

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

Very Truly Yours,

BASF Corporation

A handwritten signature in cursive script that reads "Edward J. Kerfoot".

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

cc: Ms. Geraldine Hilton  
New Chemicals Notice Management Branch  
Mail Stop 7405  
US Environmental Protection Agency  
Office of Prevention, Pesticides and Toxic Substances  
401 M Street, SW  
Washington, DC 20460