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8EHQ-10-18000	<b>88100000329</b>	6/15/10

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8EHQ-0610-18000A

June 14, 2010



**Via Federal Express**

United States Environmental Protection Agency - East  
Attn: TSCA Section 8(e)  
Room 6428  
1201 Constitution Avenue, NW  
Washington, DC 20004

**Subject:** Notice in Accordance with Section 8(e): Results of a Reproduction/Developmental Toxicity Screening Test in Wistar Rats with TDA-vicinals (ortho-TDA); [50% of 4-methyl-o-phenyldiamine (CAS No. 496-72-0), 45% of toluol-2,3-diamine (CAS No. 2687-25-4), 1% of 4-methyl-m-phenyldiamine (CAS No. 95-80-7)]

Dear Sir/Madam:

BASF Corporation is submitting results of an OECD 421 Reproduction/Developmental Toxicity Screening Test in Wistar Rats [CrI:WI(HAN)] with TDA-vicinals (ortho-TDA); [50% of 4-methyl-o-phenyldiamine (CAS No. 496-72-0), 45% of toluol-2,3-diamine (CAS No. 2687-25-4), 1% of 4-methyl-m-phenyldiamine (CAS No. 95-80-7)], conducted by BASF SE, Ludwigshafen, Germany.

The aim of this study was to obtain information on the possible effects of TDA-vicinals (ortho-TDA) on the integrity and performance of the male and female reproductive systems including gonadal function, mating behavior, conception, gestation and parturition.

The study was carried out with reference to the requirements of the following guidelines:

- OECD Guidelines for Testing of Chemicals; No. 421, Reproduction/ Developmental Toxicity Screening Test (27 Jul 1995)
- EPA, Health Effects Test Guidelines; OPPTS 870.3550: Reproduction/ Developmental Toxicity Screening Test (Jul 2000)

The dose levels were 0; 10, 50 and 250 mg/kg body weight/day (gavage). All animals were observed daily for any clinical signs during the study period.

After a 14-day pre mating period, the male and female parental animals were mated overnight in a 1:1 ratio until evidence of copulation (vaginal smear). The day on which sperm was detected was referred to as gestation day (GD) 0 and the following day as GD 1. All parental males were sacrificed and examined after the end of the administration period (at least 28 days). The parental

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females were allowed to deliver and rear their pups until postnatal day (PND) 4. On PND 4, all pups were sacrificed and examined.

**The following is a summary of the most relevant results:**

Test group 3 (250 mg/kg body weight/day):

*Males:*

- Reduced activity after treatment in up to 10 of 10 animals
- Eyelid halfclosure after treatment in up to 10 of 10 animals
- Salivation after treatment in up to 10 of 10 animals
- Piloerection in up to 5 of 10 animals
- Decreased food consumption during premating
- Lower body weight gain during the entire study period
- Decreased number of spermatids/g testis
- Decreased terminal body weights at necropsy

*Dams:*

- Eyelid halfclosure after treatment in up to 6 of 10 animals during premating, gestation and lactation
- Salivation after treatment in up to 7 of 10 animals during premating, gestation and lactation
- Decreased mean food consumption during premating and between GD 7-14
- Lower mean body weights during premating and gestation
- Lower body weight gain during premating and gestation
- Decreased number of implantation sites, i.e. 8.6 vs. 14.1 (control)
- Increased postimplantation loss (27.4%)
- Decreased number of delivered pups, i.e. 7.9 vs. 13.6 (control)
- Insufficient maternal care in 1 of 8 animals during lactation
- Increased pup mortality, i.e. decreased viability index of 91%
- Decreased terminal body weights at necropsy



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Test group 2 (50 mg/kg body weight/day):

*Males:*

- Eyelid halfclosure after treatment in up to 1 of 10 animals
- Salivation after treatment in up to 6 of 10 animals
- Piloerection in up to 1 of 10 animals

*Dams:*

- Salivation after treatment in up to 4 of 10 animals
- Decreased mean food consumption during second study week (prematuring)

Test group 1 (10 mg/kg body weight/day):

*Males:*

- No treatment-related findings were observed.

*Dams:*

- No treatment-related findings were observed.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please call Janet Cerra at (973) 245-6693.

Sincerely,

*Janet Cerra*

Janet Cerra  
Product Regulatory Center of Expertise  
North America

/jc

1077th Letter.doc

From: Origin ID: LKKA (973) 245-6693  
 Janet Cerra  
 BASF  
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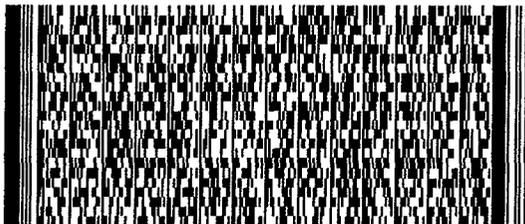
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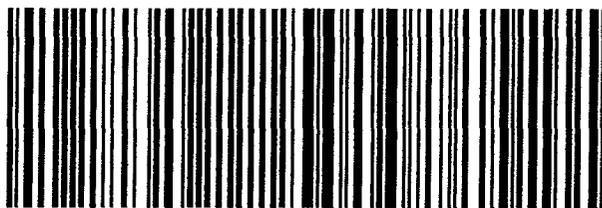


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