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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 OECD 421 Reproduction/
Developmental Toxicity Screening Test in Wistar rats with Zinc (1,2,3-propanetriolato
(2)-O1,O2) homopolymer stereoisomer (CAS No. 87189-25-1)

Dear Sir/Madam:

BASF Corporation is submitting results of a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar rats [CrI:WI(HAN)] with Zinc (1,2,3-propanetriolato (2)-O1,O2) homopolymer stereoisomer (CAS No. 87189-25-1), conducted by BASF SE, Ludwigshafen, Germany. The substance is used as an additive (nucleating agent) in polypropylene.

The aim of this study was to obtain information on the possible effects of the substance 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; 100, 300 and 1000 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 surviving parental males were sacrificed and examined after the end of the administration period (at least 28 days). The parental females were allowed to deliver and rear their pups until postnatal day (PND) 4. On PND 4, all pups were sacrificed and examined.

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The following is a summary of the most relevant results:

Test group 3 (1000 mg/kg body weight/day):

Males:

- Salivation after treatment in up to 4 of 10 animals
- Poor general state in 2 of 10 animals
- Decreased food consumption during the first study week
- Lower body weights during the entire study period

Dams:

- Three of 10 animals were found dead during gestation period
- Sacrifice of 1 of 10 animals, which was unable to deliver (palpable fetuses in abdomen)
- Piloerection in up to 4 of 10 animals during gestation and 3 of 10 animals during lactation
- Poor general state in 4 of 10 animals during gestation and 3 of 10 animals during lactation
- Decreased food consumption during the entire study period
- Lower body weights during gestation and lactation
- Lower body weight gain during entire study period
- Increased postimplantation loss (31.3%)
- Three dams with complete litter loss
- Decreased live birth index of 72% (28% stillborn)
- Insufficient maternal care in 1 of 6 animals during lactation
- Increased pup mortality, i.e. decreased viability index of 62%
- Decreased pup weights

There were no test substance related adverse effects at 300 and 100 mg/kg body weight/day.

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

Product Regulatory Center of Expertise, North America

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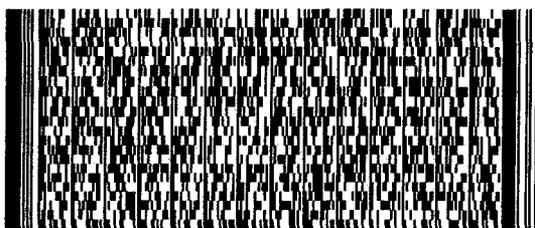
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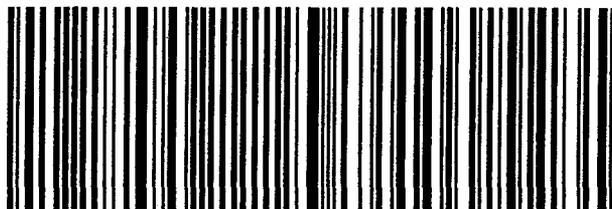


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