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December 21, 2005 *BEHQ-1205-16340*

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Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington DC 20460-0001



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Subject: Notice in accordance with Section 8 (e): Results of an OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar rats with 2-Butene-1,4-diol

Ladies and Gentlemen:

BASF Corporation and ISP Technologies, Inc. are submitting results of an OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar rats (strain CrIGxBriHan:WI) with 2-Butene-1,4-diol, CAS No. 110-64-5. The test substance is an ICCA/HPV compound.

Scope of examinations:

The study was carried out in accordance with the requirements of the following guidelines:

- OECD Guidelines for Testing of Chemicals, Guideline 422,
- EPA, Health Effects Test Guidelines OPPTS 870.3650

The test substance was administered as an aqueous solution by oral gavage to groups of 10 male and 10 female Wistar rats (F0 animals) at doses of 20, 60 and 200 mg/kg body weight/day. Two weeks after the beginning of treatment, the F0 animals were mated to produce a litter (F1). Pregnant females were allowed to litter and the offspring were brought-up until postnatal day 4. The males were treated for 29 days (approx. 2 weeks pre-mating, 2 weeks mating and post mating). In females treatment was performed during pre-mating, mating and gestation through day 4 after delivery (approx. 7 weeks).

The following is a summary of the most relevant results:

The gavage administration of 200 mg/kg body weight/day 2-Butene-1,4-diol to male and female Wistar rats caused distinct systemic toxicity such as salivation, markedly reduced

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (800) 526-1072
www.basf.com/usa



MR 291155



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food consumption and retarded body weight development, liver enzyme induction, storage of alpha 2u protein and mild impairment of motor activity in the males as well as mild anemia in the females. Whereas the cohabitation, fertility and integrity of the reproductive organs of both male and female rats were not affected, a substantially impaired pre- and postnatal development of the offspring was observed at this overtly maternally toxic dose. Developmental toxicity became obvious by an increased postimplantation loss, lower average litter size and markedly impaired postnatal viability of offspring.

A dose of 60 mg/kg of body weight/day still evoked liver enzyme induction in both genders, storage of alpha 2u protein in males and mild anemia in females but had no influence on reproduction and development of offspring.

No treatment related effects were observed in the 20 mg/kg bw/day dose group.

BASF Corporation and ISP Technologies, Inc. understand that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please send all correspondence related to the TSCA 8 (e) submissions to the Wyandotte, MI address listed below.

If you have any questions please call Dr. Sree Jasti at 734-324-5107. Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Sree Jasti".

Sree L. Jasti, Ph.D.
Product Regulatory Center of Excellence
BASF Corporation
1609 Biddle Avenue
Wyandotte MI 48192-3899

Enc.

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BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (800) 526-1072
www.basf.com/usa