



The Chemical Company

Helping Make
Products Better™

RECEIVED
OPPT CBIC

Fed Express 7915 0336 6796

04 DEC 23 AM 9:32

December 15, 2005 *SA*



Document Processing Center
EPA East (Mail Code 7407M)
Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

CONTAINS NO CB1

8EHQ-1204-15882

RECEIVED
OPPT CBIC
2005 JAN 14 AM 9:39

Subject: Notice in accordance with Section 8 (e): Results of a Full-Scale Prenatal Developmental Toxicity in Wistar Rats with N-Ethyl-2-pyrrolidone, (CAS No. 2687-91-4)

Ladies and Gentlemen:

BASF Corporation and ISP Technologies Inc. are submitting results of a prenatal developmental toxicity study in Wistar rats with N-Ethyl-2-pyrrolidone, (CAS No. 2687-91-4) conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany.

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

- EC Commission Directive 87/302/EEC of Nov. 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 (January 2001)
- EPA, Health Effects Test Guidelines; OPPTS 870.3700: Prenatal Developmental Toxicity Study (August 1998)

The test substance was applied dermally to 25 presumed pregnant female Wistar rats/group (6 hours/day) to the intact shaven dorsal skin using semi-occlusive dressing at doses of 0; 200; 400 and 800 mg/kg body weight/day on day 6 through day 19 post coitum (p.c.). At scheduled necropsy, 21 - 24 females/group had implantation sites. The fetuses were assessed for external, soft tissue and/or skeletal (incl. cartilage) findings without knowledge of treatment group.



BASF Corporation
1609 Biddle Avenue
Wyandotte, MI 48192-3729
Tel: (734) 324-6000
www.basf.com/usa

281778



The Chemical Company

The following is a summary of the most relevant results:

Marked maternal toxicity occurred at the high dose level (800 mg/kg). Most salient findings were significantly reduced food consumption (by 10%) during GD 6-19, and markedly decreased absolute (78% of control) and corrected (57% of control) body weight gain. During GD 6-8 a significant loss of body weight was noted.

Mid dose (400 mg/kg) still evoked slight signs of maternal toxicity such as significantly decreased food consumption with body weight loss on GD 6-8 and lowered corrected body weight gain (79% of control).

Slight signs of developmental toxicity occurred exclusively at 800 mg/kg body weight/day in the form of statistically significantly reduced mean placental and fetal body weights (83% and 89% of control, respectively) and an increased rate of fetuses with skeletal variations (delays/minor disturbances in ossification, predominantly of skull and sternebrae; supernumerary 14th ribs).

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy. BASF Corporation will be updating and communicating the hazard information on its MSDS.

Lastly, please note that our Corporate Headquarters are now located at Florham Park, NJ and not Mt. Olive, NJ. I request you to send all correspondence related to the TSCA 8 (e) submissions to the Wyandotte, MI address listed below:

Attn: Sree L. Jasti, Ph.D.
BASF Corporation
1609 Biddle Ave
Wyandotte, MI 48192-3799

Please do not send any correspondence to either the new Florham Park, NJ address or the old Mt. Olive, NJ address. If you have any questions please call Dr. Sree Jasti at 734-324-5107. Thank you for your consideration.

Sincerely,

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

Enc.

433rd Mtg Santz'd Letter.doc

BASF Corporation
1609 Biddle Avenue
Wyandotte, MI 48192-3729
Tel: (734) 324-6000
www.basf.com/usa