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Contractor	BASF AKTIENGESELLSCHAFT		
Document Title	INITIAL SUBMISSION: LETTER FROM BASF CORP TO USEPA, RESULTS OF PRENATAL DEVELOPMENTAL INHALATION TOXICITY STUDY (VAPOR EXPOSURE) EXPOSURE) IN WISTAR RATS W/N-VINYL PYRROLIDONE, DATED 3/16/01		
Chemical Category	N-VINYL PYRROLIDONE		

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Ladies and Gentlemen:

Subject: Notice in Accordance with TSCA Section 8(e) – Results of a Prenatal Developmental Inhalation Toxicity Study (Vapor Exposure) in Wistar Rats with N-Vinyl Pyrrolidone (CAS No. 88-12-0) Conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany

BASF Corporation and International Specialty Products are submitting results of a prenatal developmental inhalation toxicity study (vapor exposure) in Wistar rats with N-Vinyl Pyrrolidone (CAS No. 88-12-0) conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany.

Scope of Examinations

Twenty-five mated female Wistar rats per test group were whole-body exposed to dynamic atmospheres of N-Vinyl Pyrrolidone (NVP) vapors for 6 hours per day on day 6 through day 19 post coitum (p.c., 14 exposures). The target concentrations were 4.6, 23 and 92 mg/m³ (1, 5 and 20 ppm). A concurrent control group was exposed to clean air.

The study was carried out in accordance to the following test guidelines:

- EC Commission Directive 87/302/EEC of November 18, 1987; Part B: Methods for the determination of toxicity – Teratogenicity Study (rodent and non-rodent); Official Journal of the European Communities; No. L 133, pp. 24-26 (1988)
- OECD Guideline for the Testing of Chemicals; Proposal for updating guideline No. 414 (August 1999)
- EPA, Health Effects Test Guidelines; OPPTS 870.3700 (August 1998)

The following is a summary of the most relevant results:

The inhalation exposure of pregnant Wistar rats to vapors of the test substance elicited overt maternal toxicity at the intermediate and high concentration. Maternal toxicity was substantiated by clinical signs of upper respiratory and digestive tract irritation and statistically significant changes in body weight data (decreased body weight, body weight gain, corrected body weight gain, carcass weight).

There were no substance-induced, concentration-related influences on the gestational parameters.

Signs of prenatal developmental toxicity occurred at the high concentration in the form of slightly reduced fetal body weights and an increased incidence of skeletal variations (i.e., delays in fetal skeletal maturation and an increased frequency of wavy ribs). No signs of prenatal developmental toxicity were noted at the low and intermediate concentrations (4.6 and 23 mg/m³ (1 and 5 ppm). There were no substance-induced indications of teratogenicity at any concentration.

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Although substance-related signs of prenatal developmental toxicity occurred only at a clearly maternally toxic concentration, BASF Corporation and International Specialty Products understand that the reporting of the study results are in accordance with EPA's policy.

If you have any questions, please call me at 734-324-6207.

Very truly yours,

BASF CORPORATION



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

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