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Attention: 8(e) Coordinator
U. S. Environmental Protection Agency
Document Control Officer
Office of Pollution Prevention and Toxic Substances, 7407
1200 Pennsylvania Avenue, NW
Washington, DC 20460



Ladies and Gentlemen:

Subject: Notice in accordance with Section 8(e) - Results of a Full-Scale Prenatal Developmental Toxicity Study in Wistar Rats with Bis-(2-propylheptyl)phthalate

BASF Corporation is submitting preliminary results of a prenatal developmental toxicity study in Wistar rats with Bis-(2-propylheptyl)phthalate (CASRN 53306-54-0) 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 November 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 administered to 25 presumed pregnant female Wistar rats/group via oral gavage at dosages of 0 (control), 40, 200 and 1000 mg/kg body weight/day on day 6 through day 19 post coitum (p.c.). At scheduled necropsy, 17 - 25 females/group had implantation sites. The fetuses were assessed for external, soft tissue and/or skeletal (incl. cartilage) findings without knowledge of treatment group.

Summary of Relevant Results:

Marked maternal toxicity occurred at high dose level (1000 mg/kg). Most salient findings were insufficient care of fur, significantly reduced food consumption (by 32%) during GD 6-10, and markedly decreased corrected (70% of control) body weight gain. During GD 6-8, a significant loss of body weight was noted. At gross necropsy, 2 high dose females with hydrometra were found.

Cesarean section revealed an increased postimplantation loss (23.1% vs. 6.2% control, almost all early resorptions) exclusively at high dose level (1000 mg/kg body weight/day). Only 17/20 high dose dams had viable fetuses; in 3 dams, only resorptions were found in the uterus (2.2% vs. 0.5% control).

Marginal signs of developmental toxicity occurred at 1000 mg/kg body weight/day in the form of a statistically significantly increased incidence of fetal soft tissue variations (dilated renal pelvis) which was just outside the historical control data.

Although the findings are not considered to present a substantial risk to human health or the environment, BASF Corporation understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy. Please note that BASF Corporation does not currently commercially manufacture, process or distribute this chemical in the United States.

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot
Edward J. Kerfoot, Ph.D.

Director, Toxicology and Product Regulations

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