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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



8EHQ-02-15198

Ladies and Gentlemen:

Subject: Notice in Accordance with Section 8(e) - Results of a Full-Scale Prenatal Developmental Toxicity Study in Wistar Rats with 6-Methylhept-5-en-2-one

BASF Corporation is submitting results of a prenatal developmental toxicity study in Wistar rats with 6-Methylhept-5-en-2-one (CAS 110-93-0) conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany. The test substance was administered by gavage to 25 time-mated female Wistar rats/group at doses of 0, 50, 200 and 1,000 mg/kg body weight on day 6 through day 19 post coitum. 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. 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) and EPA, Health Effects Test Guidelines; OPPTS 870.3700: Prenatal Developmental Toxicity Study (August 1998).

Relevant Findings:

Marked signs of maternal toxicity occurred at the high dose level. These were substantiated by adverse clinical findings like abdominal position, unsteady gait and salivation, statistically significant impairments in food consumption and decreased absolute and corrected body weight gains. Temporary salivation was still shown by some dams of the 200 mg/kg group.

Marginal signs of developmental toxicity occurred exclusively at the high dose level (1,000 mg/kg body weight/day) in the form of slightly reduced mean placental and fetal body weights and general signs of delayed ossification of the fetal skeletons. The described skeletal findings are considered as variations because they also appear spontaneously in control fetuses.

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. The Material Safety Data Sheets will be updated to reflect the results of this study. Please note that findings from a 90-day gavage study in rats with 6-Methylhept-5-en-2-one have previously been submitted to EPA under 8EHQ-02-15141.

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot

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Director, Toxicology and Product Regulations



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