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October 15, 2003

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



Contain NO CBI

Ladies and Gentlemen:

Subject: Notice in accordance with Section 8 (e) Interim Results of a Full-Scale Prenatal Developmental Toxicity Study in Wistar Rats with 2-Methyl-3(4-tert-butylphenol)-propanal

BASF Corporation is submitting preliminary results of a prenatal developmental toxicity study in Wistar rats with 2-Methyl-3(4-tert-butylphenol)-propanal (CASRN 80-54-6) 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); and 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 doses of 0(control), 5, 15, and 45 mg/kg bw-d on day 6 through day 19 post coitum (p.c.). Determinations of liver weights as well as hematocrite and clinical chemistry (enzymes including choline esterase) were included as additional parameters to substantiate potential effects of the test compound on dams. At scheduled necropsy, 22-23 females/group had implantation sites. The fetuses were assessed for external findings without knowledge of treatment groups. Soft tissue and/or skeletal (incl. cartilage) examinations are ongoing.

Relevant Results

Marked maternal toxicity occurred at the high dose level (45 mg/kg bw-d). Most salient findings were salivation after treatment, significantly reduced food consumption (by 17%) during GD 6-8, and markedly decreased absolute (75% of control) and corrected (68% of control) body weight gain. During GD 6-8, a significant loss of body weight was noted.

Clinical chemistry investigations showed increased activities of alanine aminotransferase and glutamate dehydrogenase as well as decreased activities of serum and erythrocyte choline esterase. Furthermore, increased absolute (111% of control) and body weight-adjusted (119% of control) liver weights were noted.

Mid dose (15 mg/kg bw-d) evoked slight signs of maternal toxicity such as decreased absolute (56% of control during GD 6-8) body weight gain, increased activity of alanine aminotransferase, decreased activity of serum and erythrocyte choline esterase as well as increased absolute (113% of control) and body weight-adjusted (111% of control) liver weights.

Exclusively at the high dose level (45 mg/kg bw-d), cesarean section revealed an increased postimplantation loss (15.1% vs 4.4% control) and, subsequently, a decreased number of live fetuses



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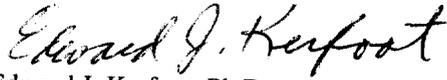
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per dam (7.4 vs 8.1 control). Slight signs of developmental toxicity occurred at 15 and 45 mg/kg bw-d in the form of statistically significantly reduced fetal body weights (92% and 80% of control, respectively).

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.

Very truly yours,

BASF CORPORATION



Edward J. Kerfoot, Ph.D.

Director, Toxicology and Product Regulations

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