



8EHQ-0902-15196

Acetophenone Task Force

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TSCA Section 8(e) Coordinator
Document Control Officer (MC-7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001



8EHQ-02-15196

Re: Toxic Substances Control Act -- Section 8(e)

Dear TSCA Section 8(e) Coordinator:

The Acetophenone Task Force (ATF), c/o Mr. William J. Moffatt, JLM Chemicals, Inc., 3350 West 131st Street, Blue Island, Illinois 60406-2365, submits to the U.S. Environmental Protection Agency (EPA), pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), preliminary results of an Organization for Economic Cooperation and Development (OECD) 422 Combined Repeated Dose Toxicity Study and Reproduction/Developmental Screening Study in Sprague-Dawley Rats with Acetophenone (CAS No. 98-86-2). Although the ATF is submitting these results under TSCA Section 8(e), the ATF has not confirmed that they satisfy the Section 8(e) criteria for "substantial risk information," nor has the ATF determined whether the results are corroborative of "well-established adverse effects."

ATF is comprised of the following companies: JLM Chemicals, Inc., and Aceto Corporation. The study was conducted as part of the OECD Screening Information Data Set (SIDS) Program. The nature of the study and the adverse effects being reported are summarized below.

- Methods:** The study was carried out in accordance with the requirements of OECD Guidelines for Testing of Chemicals, Guideline 422 and EPA, Health Effects Test Guidelines, OPPTS 870.3550. For the toxicity phase, the test substance was administered once daily for a minimum of 28 days via oral gavage to 4 groups of 10 male and 5 female rats at 0, 75, 225, and 750 milligrams per kilograms per day (mg/kg/day) of acetophenone. For the



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milligrams per kilograms per day (mg/kg/day) of acetophenone. For the reproduction/developmental phase, dosage levels were administered once daily for a minimum of 14 days through day 3 of lactation via oral gavage to 4 groups of 10 female rats at 0, 75, 225, and 750 mg/kg/day of acetophenone.

- **Preliminary Results:** There was no mortality observed in any of the adult animals. Preliminary results of this screening study indicate that effects were observed in the 225 and 750 mg/kg/day groups. These effects included urine stains and predose and postdose salivation in the 225 mg/kg/day group, and urine stains, hair loss, predose and postdose salivation, and postdose wobbly gait in the 750 mg/kg/day group. There was one incidence of postdose salivation in the females in the 225 mg/kg/day group. Transient body weight change losses were measured in the 750 mg/kg/day group males from days 0 through 3. No other significant body weight changes were noted. The forearm grip strength and motor activity of the males in the 750 mg/kg/day group were decreased on day 29. No other meaningful differences were noted in the functional observation battery. Transient food consumption decreases were noted in males and females in the 750 mg/kg/day group from days 0 through 3. While there were other slight decreases in food consumption periodically throughout the study, none was statistically significant. There were no toxicologically meaningful findings in the hematology or coagulation parameters. The clinical chemistry findings revealed the mean total protein, calcium, and cholesterol for males in the 750 mg/kg/day group and the cholesterol for females in the 750 mg/kg/day group were statistically elevated. The pup necropsy data revealed one stillborn pup in the 750 mg/kg/day group with a cleft palate. No gross necropsy findings were noted in stillborn pups from any other treated groups. Necropsies on pups found dead between lactation days 0 and 4 revealed scabbing, desquamation, and dermal hypoplasia in the 750 mg/kg/day group. No remarkable necropsy findings were noted in pups found dead from any other treated groups. At the scheduled pup necropsy (lactation day 4), findings included scabbing and desquamation in both the 225 and 750 mg/kg/day groups. No remarkable pup necropsy findings were noted in the 75 mg/kg/day group at study termination. The parental female reproductive indices were not remarkable among treated and control groups. The live birth and day 4 viability indices were statistically lower in the 750 mg/kg/day group. In addition, the mean pup weight at days 1 and 4 were statistically lower in the 750 mg/kg/day group. Lastly, the number of stillborns was statistically increased in the 750 mg/kg/day group.

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Any subsequent information regarding this chemical from this study that is considered to present a substantial risk to human health or the environment under TSCA Section 8(e) will be submitted to EPA.

If you have any questions, please contact Lynn L. Bergeson, legal counsel to the ATF, by telephone at (202) 557-3801, or by e-mail at lbergeson@lawbc.com.

Sincerely,

ACETOPHENONE TASK FORCE

By: William J. Moffatt
William J. Moffatt
Chair

cc: Acetophenone Task Force (via e-mail)