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8EHQ-0305-15946

March 7, 2005

TSCA Confidential Business Information Center (7407M)  
EPA East – Room 6428 Attn: Section 8(e)  
U.S. Environmental Protection Agency  
1201 Constitution Avenue, NW  
Washington, DC 20004-3302

**CONTAINS NO OBI**

Attention: TSCA Section 8(e) Coordinator  
Re: Terephthalic Acid (CAS Number 100-21-0)  
Via: Courier Service



Dear Sir or Madame:

The American Chemistry Council's Terephthalates Panel<sup>1</sup> submits this letter report pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA) to inform the Environmental Protection Agency (EPA) of the results of a study titled "Terephthalic Acid: Multigeneration Reproduction Toxicity Study in Rats."

In this study the effect of dietary administration of terephthalic acid (at levels of 0, 1,000, 5,000, or 20,000 ppm in the diet) on the propagation of two generations of Alpk:APfSD (Wistar derived) rats was investigated. The fertility and reproductive performance of each generation of parental animals and the clinical condition, survival and growth of their offspring were assessed according to established guidelines (OECD Test Guideline 416, TSCA guidelines at 40 CFR 799.9380, EPA OPPTS harmonized test guidelines 870.3800 and Directive 67/548/EEC). Relevant (treatment related) findings were limited to a decrease in body weight, predominantly in animals receiving 20,000 ppm, at most stages of the study, both macroscopic and microscopic effects on the bladder (F0 and F1 adults) only at the highest dose tested, minimal or slight renal papillary necrosis in a few animals in the 20,000 ppm group (F0 and F1 adults) along with a decrease in kidney weight at all doses (F0 and F1 adults and F1 and F2 pups). Dietary administration of 20,000 ppm terephthalic acid for two successive generations did not result in any effects on reproductive performance. No gross or microscopic changes were seen in the reproductive system that could be related to test article administration. Most, if not all, of the effects reported here have been previously reported in a number of different reports including but not limited to:

<sup>1</sup> The members of the Terephthalates Panel are BP Amoco Chemicals and Eastman Chemical Company.

284196

- 1) Chin, T.Y., Tyl, R.W., Popp, J.A., and Heck, H.d'A. (1981) Chemical urolithiasis. 1. Characteristics of bladder stone induction by terephthalic acid and dimethyl terephthalate in weanling Fischer-344 rats. *Toxicology and Applied Pharmacology* 58, 307-321;
- 2) Chemical Industry Institute of Toxicology. (1982) A ninety-day study of terephthalic acid (CAS No. 100-21-0) induced urolithiasis and reproduction performance in Wistar and CD Rats. CIIT Docket No. 11622;
- 3) Chemical Industry Institute of Toxicology. (1983) Chronic Dietary Administration of Terephthalic Acid. Final report. CIIT Docket No. 20124; Chemical Industry Institute of Toxicology, Research Triangle Park, NC; and
- 4) Gross, J. (1974) The effects of Prolonged Feeding of Terephthalic Acid (TPA) to Rats, Project FG-Is-175. United States Department of Agriculture, Agricultural Research Services, Washington D.C.

The initial interpretation of the study results by the study sponsor and by the laboratory that conducted the study did not indicate there were any observed effects that supported notification of your office. However, in the process of preparing a manuscript of this study for publication, an alternative interpretation of the study results was submitted by a contractor to the Terephthalates Panel on February 9, 2005. Although the submission is to be processed in accordance with EPA's procedures for TSCA 8(e) to discharge any Section 8(e) responsibilities that may exist, the Terephthalates Panel has made no determination on whether the information included herein actually presents "a substantial risk of injury to health or the environment" as defined by relevant guidance.

The Panel will forward the final narrative report under separate cover to EPA shortly. To protect publication and other rights, this final narrative report will be submitted to EPA as confidential business information in accordance with EPA's requirements for protecting the same. In addition, once the referenced manuscript is published, the Panel will provide a copy to EPA.

If you have any questions, please contact Dr. Has Shah, Manager, Terephthalate Panel, at (703) 741-5637 or via e-mail at [has\\_shah@americanchemistry.com](mailto:has_shah@americanchemistry.com).

Sincerely,



Ted Waugh  
Counsel, CHEMSTAR

