

8EHQ-1196-130803

F

Aristech Chemical Corporation  
600 Grant Street  
Pittsburgh, PA 15219-2704  
412/433-2747  
Telex: 6503608865  
Answer Back: 6503608865MCI UW

ARISTECH

RECEIVED  
OPPT NCIC

96 NOV -8 PM 3: 01

November 5, 1996



8EHQ-94-13080

Contains No CBI

96 NOV 15 AM 11:34

RECEIVED  
OPPT NCIC

Document Processing Center  
OPPT (7407)  
USEPA  
401 M Street, S.W.  
Washington, D.C. 20460  
ATTN: TSCA 8(e) Coordinator

CS RAD: OPPT  
RECEIVED  
1-23-97  
Soc

re: Aristech Submission 8EHQ 0794-13080  
Preliminary Results of the Oncogenicity Study in Mice with Di(isononyl)phthalate

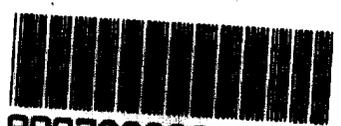
Dear Sir or Madam:

In accordance with the Toxic Substances Control Act, Aristech Chemical Corporation of Pittsburgh, Pennsylvania is submitting additional data to previously reported information regarding 2-year dietary testing of Di(isononyl)phthalate (DINP) in mice. Although we do not believe this information reasonably supports the conclusion of a substantial risk to human health or the environment, this information appears to meet reporting criteria established by the Agency.

In April, 1995, we reported preliminary results of gross pathology examinations which suggested a possible dose-related increase in liver masses in both male and female mice. In that study, **DINP was administered to male and female mice in the diet for at least 104 weeks at dose levels of 0 ppm (Group 1), 500 ppm (Group 2), 1500 ppm (Group 3), 4000 ppm (Group 4), 8000 ppm (Group 5) and 8000 ppm - Recovery (Group 6).**

In April, 1996, we reported that the unaudited results of histopathological analysis of tissue collected at the terminal sacrifice confirmed a treatment-related increase in the incidence of liver neoplasms in male and female mice. We are reporting in this letter that **the draft study identifies gross and microscopic evidence of nonneoplastic kidney effects in female mice of the high-dose group (8000 ppm). The effects consist of granular and pitted appearance accompanied by an increase in the onset of chronic progressive nephropathy in those high-dose female mice not surviving to the end of the study. This kidney effect was not seen in mice, male or female, surviving to study termination.** In addition, male mice in

Aristech Total Performance



89970000017



November 5, 1996

Page 2

groups 4, 5 and 6 killed at study termination showed a statistically significant reduction in absolute and relative testis/epididymis weight. This reduction in testis/epididymis weight was not associated with histopathological evidence of adverse testicular or epididymal was not associated with histopathological evidence of adverse testicular or epididymal effects.

A copy of the final report will be submitted to the Agency upon receipt by Aristech. If you have questions regarding this matter, please do not hesitate to contact me.

Sincerely,



John R. Bankston II

Supervisor, Product Regulation