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ARISTECH



8EHQ-94-13083
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ORIGINAL

January 13, 1995

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Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460
ATTN: 8(e)Coordinator

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Re: Aristech Submission 8EHQ-0794-13083



89950000096

Dear Sir:

This letter is a follow-up to the July 13, 1994 TSCA Section 8(e) submission (8EHQ-0794-13083) of Aristech Chemical Corporation regarding rodent oncogenicity testing of Di(isononyl)phthalate. In the 8EHQ-0794-13083 submission, Aristech Chemical Corporation reported that at the terminal sacrifice of a lifetime feeding study with rats the test material, Di(isononyl)phthalate, appeared to produce an increased incidence of liver masses in the high-dose male rats but not in female rats. At the time of the report to the Agency, histopathological analysis of the liver masses had not been completed. Microscopic analysis of the tissues from rats killed at study termination is now available. Test material-related changes were reported for the livers of the high-dose rats and the kidneys of the mid-, high-, and recovery-dose animals. The liver changes consisted of increased cytoplasmic eosinophilia in both sexes of rat: 81% incidence in males and females and hepatocellular enlargement, 87.5% in males, 78% in females. Spongiosis hepatitis was observed in male rats but not female rats at 33% and 56% in the mid- and high-dose survivors, respectively, as compared to 2% incidence in the control males. Hepatocellular neoplasms occurred with the following frequency in the terminal sacrifice animals:

2/2/95

	<u>DOSE GROUP (ppm in diet)</u>					
	0	500	1500	6000	12000	12000 Rec'y
MALES						
Hepato-cellular Adenoma	2/41	2/35	1/39	4/36	8/32	4/29
Hepato-cellular Carcinoma	1/41	0/35	0/39	1/36	9/32	1/29
FEMALES						
Hepato-cellular Adenoma	0/42	0/38	0/40	1/38	0/37	0/34
Hepato-cellular Carcinoma	1/42	0/38	0/40	1/38	3/37	1/34

no details in renal lesions

Mineralization of the renal papilla and pigment in tubule cells was observed in a dose-related fashion that increased in incidence and severity in male rats. The kidney findings were observed in the presence and absence of spontaneously occurring leukemia.

It should be emphasized that the results presented in this letter are for animals surviving to study termination (week 104 of treatment). Microscopic analyses of the tissues for all animals in the study (early deaths) are not available at this time. Likewise, statistical analysis has not been performed on the results presented herein. An unaudited draft study report is expected within the next several weeks. Additional pertinent findings or information contained in that report will be forwarded to the Agency.

If there are questions about this follow-up letter or about any aspect of the Aristech Chemical Corporation toxicology research on Di(isononyl)phthalate, please do not hesitate to contact me directly. I can be phoned at 412-433-7686.

Sincerely,

John R. Bankston
Supervisor
Product Regulation