

ARISTECH 

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8EHQ-91-1325
SP001 05/24/95Aristech Chemical Corporation
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Telex: 6503608865
Answer Back: 6503608865MCI UW**YENQ-0575-1325**

May 19, 1995

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

89950000204

Contains No CBIRe: Followup Information to 8EHQ-0891-1325 , Notice of Substantial Risk
Filing on 2-Ethylhexanol (2-EH), CAS No. 104-76-7

Dear Sir or Madam:

ORIGINAL

In August, 1991, Aristech Chemical Corporation submitted information from a draft report of an oncogenicity study in mice on the subject chemical. At that time the Agency requested no further information. Subsequent to the 8(e) filing, the Chemical Manufacturers Association Oxo Process Panel submitted the final report to EPA in compliance with a TSCA Section 4 test rule, reference 40 CFR Part 799.1645.

Recently, the Oxo Process Panel submitted an oncogenicity manuscript for publication in a peer-reviewed publication. Although the original study analysis reported a slight increase in the liver tumor incidence in high dose female mice, it was concluded that this finding was incidental and not biologically relevant. However, the peer reviewers asked for additional statistical information related to this endpoint. The Panel then contracted with a statistician to examine the data from the report utilizing other statistical tools. The statistician utilized the Simple Peto test, the Cochran-Armitage test, and the Peto test to evaluate the hypothesis of no statistical dose-response trend for the mouse liver tumors.

Attached is a summary table of results from this reanalysis of the study. These results indicate that using these statistical tests, there is a dose-response trend for liver tumors in male and female mice. In order to ensure compliance with the Agency's 8(e) guidance, we are submitting this followup to our original 8(e) filing of August, 1991. We have not evaluated the relevance of these results. A copy of any final determination will be supplied to the Agency.

Pending a full interpretation of the data, we maintain our original position that these observations, in themselves, do not lead to any conclusion of hazard in the normal handling and use of 2-EH.



If you have any questions regarding this matter, please contact me.

Sincerely,

A handwritten signature in black ink that reads "John R. Bankston II". The signature is written in a cursive style with a large, stylized initial "J".

John R. Bankston II
Supervisor
Product Regulation

Attachment

cc: J. J. Pottmeyer III
J. A. Santory

Submitted Via Certified Mail, Article No. Z 008 778 125

2-ETHYLHEXANOL: Oncogenicity Study
18 Month Gavage Application to B6C3F1 Mice

**Significance Levels in One-Sided Tests for
 Increasing Hepatocellular Carcinoma Response Rates with Increasing Dose**

	Tests for Trend: Not Including Time-to-Response Information		Tests for Trend: Including Time-to- Response Information
	Simple Peto Test	Cochran- Armitage Test	Peto Test
Female Mice			
Use Data at 0, 50, 200, and 750 mg/kg			
Water Control	0.01951 **	0.03852 **	0.00179 ***
Vehicle Control	0.00703 **	0.01383 **	0.00040 ***
Combined Control	0.00330 ***	0.00650 ***	0.00012 ***
Use Data at 0, 50, and 200 (Disregard Data at 750 mg/kg)			
Water Control	0.10662	0.21171	0.20126
Vehicle Control	0.02991 **	0.05897 *	0.06155 *
Combined Control	0.03143 **	0.06220 *	0.06169 *
Male Mice			
Use Data at 0, 50, 200, and 750 mg/kg			
Water Control	0.02921 **	0.05780 *	0.00447 ***
Vehicle Control	0.07111 *	0.14122	0.02032 **
Combined Control	0.04169 **	0.08276 *	0.00705 ***
Use Data at 0, 50, and 200 (Disregard Data at 750 mg/kg)			
Water Control	0.10351	0.20549	0.16681
Vehicle Control	0.25076	0.50008	0.51998
Combined Control	0.19476	0.38832	0.34442

- * Significant at the 10% Level
- ** Significant at the 05% Level
- *** Significant at the 01% Level

Sielken Inc.

Best Available Copy