



N-METHYLPYRROLIDONE PRODUCERS GROUP, INC.

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September 16, 1997

Contains No CBI

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BY HAND

TSCA Non-Confidential Information Center (7407)  
Attention: Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
United States Environmental Protection Agency  
401 M Street S.W.  
Washington, D.C. 20460

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Re: TSCA 8(e) Submission On N-Methylpyrrolidone  
Oral Feeding 18-Month Carcinogenicity Study

The N-Methylpyrrolidone (NMP) Producers Group, Inc. submits this information pursuant to Section 8(e) of the Toxic Substances Control Act and the EPA's Statement of Interpretation and Enforcement Policy, 43 Fed. Reg. 11110 (March 16, 1978). This submission is made on behalf of the member companies of the NMP Producers Group: ARCO Chemical Company, BASF Corporation, and ISP Management Company, Inc. We do not believe that the data discussed below demonstrate that NMP presents a significant risk to human health or to the environment. However, the NMP Producers are aware of the Agency's interest in receiving toxicological information as soon as possible and we are therefore submitting the following information.

The NMP Producers Group is sponsoring a series of health effects tests on N-Methylpyrrolidone, CAS Registry Number 872-50-4, pursuant to an Enforceable Consent Agreement under TSCA Section 4, 58 Fed. Reg. 61814 (Nov. 23, 1993). One of those tests is an oral (feeding) 18-month carcinogenicity study in B6C3F1 mice being carried out, pursuant to contract with the NMP Producers Group, in the laboratory of the Department of Toxicology of BASF Aktiengesellschaft (AG), Ludwigshafen, Germany. In this study, NMP was administered to 50 B6C3F1 mice per sex at dietary concentrations of 0, 600, 1,200, and 7,200 ppm for 18 months. These values correspond to a mean daily test substance intake of 0, 99, 192, and 1,210 mg/kg body weight in males and 0, 128, 249, and 1,584 mg/kg body weight in females, respectively.

The following table summarizes the number and percent incidence of mice with macroscopically observable liver masses following final sacrifice.

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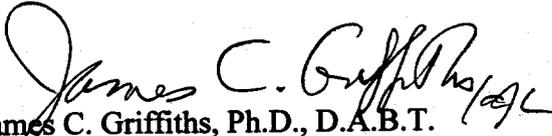
Page 2

Sex	Male				Female			
	0	600	1,200	7,200	0	600	1,200	7,200
Dose level (ppm)								
Mice with Liver Masses	10/50 (20%)	3/50 (6%)	8/50 (16%)	18/50 (36%)	2/50 (4%)	4/50 (8%)	2/50 (4%)	16/50 (32%)

The data listed above do not demonstrate a clear dose-response relationship and their significance are unknown. Although the laboratory does not maintain historical control data on macroscopically observed liver masses, some perspective on the potential significance of these data may be provided by the laboratory's historical control data for histologically diagnosed liver neoplasia in B6C3F1 male (8 - 60 percent) and female (0 - 25 percent) mice. The observation that the percent incidence of macroscopically observed liver masses in high-dose females exceeds the historical control range for histologically diagnosed liver neoplasia in female mice is a potentially significant finding. These and other results will be fully detailed in a final report at the scheduled completion of the study in August, 1999.

The NMP Producers Group will supplement this submission as additional information becomes available. In the interim, please do not hesitate to contact me at (973) 628-4087 if you have any questions about this submission.

Very truly yours,

  
James C. Griffiths, Ph.D., D.A.B.T.  
Chair, Toxicology Committee