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Submitting Organization
N-METHYLPYRROLIDONE PROD GROUP

Contractor

Document Title
INITIAL SUBMISSION: LETTER FROM N-METHYLPYRROLIDONE PROD GROUP TO USEPA RE: ORAL FEEDING REPRODUCTIVE TOXICITY STUDY ON N-METHYLPYRROLIDONE, DATED 10/10/1997

Chemical Category
N-METHYLPYRROLIDONE

NMP

N-METHYLPYRROLIDONE PRODUCERS GROUP, INC.

701 PENNSYLVANIA AVENUE, N.W., SUITE 900, WASHINGTON, D.C. 20004 • (202) 434-7373 • FAX (202) 434-7400

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October 10, 1997

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Office of Pollution Prevention and Toxics
United States Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

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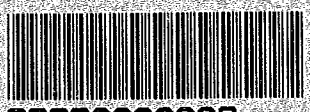
Re: TSCA 8(e) Submission On N-Methylpyrrolidone
Oral Feeding Reproductive Toxicity Study

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-Methyl-pyrrolidone, CAS Registry Number 872-50-4, pursuant to an Enforceable Consent Agreement under TSCA Section 4, 58 Fed. Reg. 61814 (Nov. 23, 1993). In addition to those studies, the NMP Producers Group is also sponsoring two 2-generation reproductive toxicity studies in Sprague-Dawley rats and in Wistar rats. The study in Wistar rats is 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, and the study in Sprague-Dawley rats is being carried out at Hungtingdon Life Sciences, East Millstone, N.J. In both studies, NMP is being administered to 25 rats per sex at dietary concentrations of 0; 50; 160; and 500 mg/kg/day.

The Agency has previously been informed of embryolethality (and fetal mortality) in Sprague-Dawley rats, NMRI mice and New Zealand White rabbits following oral administration of NMP at doses of 500 mg/kg/day and greater, during reproduction and toxicology studies. Preliminary data have demonstrated similar responses in the present studies. Although the effect has been reported previously at these doses by this route of administration in Sprague-Dawley



rats, the NMP Producers Group believe that those data may be reportable under TSCA Section 8(e) because the effect has not been previously reported in the Wistar strain of rats.

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

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

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