UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM JUL 27 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Henry Jacoby, PM-21
Registration Division (TS 767C)

THRU: Christine Chaisson, Ph.D.
Toxicology Division (TS-769C)

SUBJECT: Subchronic Inhalation Testing Protocol for Vapam (EPA no. 476-859) using technical Sodium N-methyldicarbamate (SNMDC), Caswell # 780.

Request

This protocol was submitted with a letter of June 22, 1982 from Ralph L. Riggs, Senior Regulatory Affairs Supervisor, Stauffer Chemical Company. The letter indicated that the intent of the study was to provide data for determining the industrial hygiene value for exposures to Vapam Technical. Occupational exposure standards are determined by the Occupational Safety and Health Administration rather than by EPA. A phone call on July 26 to Dr. Bruce Stuart, Alternate Study Director and Manager of Inhalation Toxicology at Stauffer, indicated that the study was also to be used in a future EPA registrations of the product.

Conclusion

The Toxicology Branch has no objection to the proposed protocol. The protocol is well documented meets well the current guidelines. It goes beyond these by providing information on preventing exposures of the laboratory personnel to SNMDC while carrying out the study.

Protocol

This study calls for the use of Sprage-Dawley rats (18/sex/exposure group) to be exposed to concentrations of SNMDC technical (32.7% AI) 6 hours per day, 5 days per week over a 90 day period. Group 1 will serve as an air control, while groups 2 to 4 will be exposed to

concentrations of 6.0, 32.0 and 160 mg SNMDC/cu.m. of air. The exposures will be carried out in standard dynamic air chambers under standard conditions of air flow, temperature and humidity. Exhaust chamber air is to be filtered and passed through activated charcoal filters before exhausted into the atmosphere. The test atmosphere will be generated with the use of a collison nebulizers and particle charges neutralized using Kr85 discharge tubes.

Upon generation, the test agent decomposes to methyl isothiocyanate and hydrogen sulfide. Chamber air concentrations will be determined for SNMDC indirectly by measuring sodium and/or methyl isothiocyanate (infrared adsorption). These samples will be obtained by passing air into gas sampling traps which trap both the particulate and the vapor phase of the test material. Particle size determinations will be made using high volume casscade impactors.

The animals will be observed twice daily and examined for masses and weighed weekly. Pretest, interim (at 6 weeks) and termination hematology and clinical chemistry studies, including choline esterase determinations (6 animals/sex/period) (apparently to be preformed on different animals each time) will be carried out. Ophthalmological examinations will be carried out pretest and at the end of the exposure period. Post mortem examinations will include the expected gross necropsy, organ weighings and histopathology. In addition, the lungs will be perfused with netural formalin prior to histopathological preparation.

The protocol describes also safety precautions to be used when loading and unloading the chamber generator, generator malfunction, and spill cleanup. This involves the use of full-face MSA Ultra-Twin respirator with MSA GMA-H cartridges to guard against inhalation exposures and protective and impermeable protective clothing and gloves.

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TS-769C: SBG: 557-1511: Rm 824 CM2: July 27, 1982