

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W., WASHINGTON, D.C. 20009

TELEPHONE: (202) 328-4200
TELEX: 89617 (MCA WSH)

January 8, 1979

National Institute of Environmental Health
and Safety
Research Triangle Park, North Carolina 27709

Re: Contract NO-ES-2-2084 (continuation of
NH-NIEHS-72-2-2084)

Dear Sir or Madam:

The Manufacturing Chemists Association, pursuant to 5 U.S.C. § 552 and 45 C.F.R. Part 5, hereby requests a copy of a contract entered into between Midwest Research Institute (MRI) of Kansas City, Missouri 64110 and the Environmental Branch of the National Institute of Environmental Health and Safety. The MRI contract covered carcinogenicity studies of vinyl chloride (VC) and vinylidene chloride (VDC). The MRI project number was 3612-B and the contract number was NO1-ES-2-2084 (continuation of NH-NIEHS-72-2-2084). Mr. James S. Woods was the project officer. The key people involved in the contract study for MRI's Pharmacology and Toxicology Department were as follows:

Dr. C. C. Lee, Assistant Director of Biological Sciences Division for Pharmacology and Toxicology (principal investigator for the project); Dr. Joseph M. Winston, Associate Toxicologist; Dr. William B. House, supervising the inhalation chamber operation; Dr. Paul J. Peters, Assistant to House; Dr. Jagdish C. Bhandari, Associate Pathologist; Dr. John R. Hodgson, Senior Biochemist; Mr. Jack H. Hagensen, Jr., Biologist (responsible for analytical monitoring); Mr. Thomas W. Redding, Lab Supervisor in hematology and clinical chemistries; and Mrs. Ellen R. Ellis, histologist.

The Manufacturing Chemists Association also requests all records, papers, reports, studies, documents or other methods by which information is or has been preserved concerning contract number NO1-ES-2-2084 (continuation of NH-NIEHS-72-2-2084) that contain one or more of the following data and/or information:

- (1) Historic control data on the incidence of liver angiosarcomas in the CD-1 mouse and the subcutaneous angiosarcomas in the CD rat and age at which control animals were observed to have the tumors.
- (2) Shipping slips on the animals that were used in the study. How many shipments were made and the dates of each of these shipments.
- (3) The chemical analysis of vinylidene chloride and source of the vinylidene chloride used. Information on whether or not chemical analysis was made on each one of the samples of vinylidene chloride used.
- (4) Information on generation of chamber atmospheres including:
 - a) The flow rate into the exposure chamber.
 - b) How was 55 ppm metered into the air stream.
 - c) How was the rotameter calibrated.
 - d) The size and composition of the vessel used for the VDC.
 - e) How was the vessel heated.
 - f) How was the vessel held over the weekend (at 37°C or cooled?).
 - g) Was the VDC refrigerated/stored over the weekend.
 - h) Was the VDC inhibited.
 - i) Was the moisture content in the system checked.
 - j) Procedure for shutting the system down at the end of the week run.
- (5) The starting date of the studies and the age of the animals when put on test and the age of the animals when tumors are first observed.
- (6) The number of animals (rats and mice) and the source from which they obtained these animals. An explanation of how these animals were transmitted from the source to the laboratory.

- (7) The identification of the holding rooms (by number) for the groups of animals exposed to vinyl chloride and vinylidene chloride. Information should include the location and the proximity to the exposure chamber rooms.
- (8) The records on the temperature and humidity in the rooms housing these animals over the 12-month period.
- (9) The times at which the animals were taken out of the chamber after exposure and/or for cleaning. .
- (10) Information on the times at which the cages were cleaned and/or sterilized, and identification of those individuals who handled these cages.
- (11) As animals died spontaneously or were sacrificed for interim kills, were surviving animals' cages consolidated.
- (12) Animal numbers and the individual body weight, food consumption, hematological and clinical chemistry data. Daily clinical observation on each of the animals. The times at which these observations were made. Cytogenetic data obtained on each of the animals and identification of the animals used in the cytogenetic studies.
- (13) Information regarding animal accountability; this should include a statement as to whether or not extra animals were carried on through the study and if any substitutions were made during the study, and when and why.
- (14) The gross and histopathology sheets on each of the animals including the dates when performed and who performed the gross necropsy.
- (15) The method for randomization and the details of the coding of the animals.
- (16) Copies of internal and external memoranda and correspondence pertaining to the study.
- (17) Copy of the final report submitted by MRI to the National Institute of Environmental Health and Safety.

NIEHS

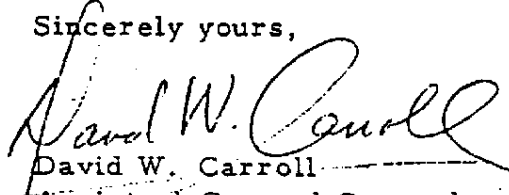
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The Manufacturing Chemists Association also requests any transcript, notes, tapes, or other methods by which a record is or has been preserved of the National Institute of Environmental Health and Safety Conference on Comparative Metabolism and Toxicity of Vinyl Chloride Related Compounds held at the National Institute of Health, Bethesda, Maryland on May 2-4, 1977.

The Manufacturing Chemists Association is a nonprofit trade association having 191 United States company members representing more than 90 percent of the production capacity of basic industrial chemicals within this country. We believe that the subject materials will be of significant value to our member companies in evaluating the September 21, 1978, Joint NIOSH/OSHA Current Intelligence Bulletin: Vinyl Halides - Carcinogenicity. In addition, we believe it would be in the best interest of the public to release the subject documents.

Sincerely yours,


David W. Carroll
Assistant General Counsel

DWC/sad

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