

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CINCINNATI, OHIO 45226

HEALTH HAZARD EVALUATION DETERMINATION
REPORT NO. HE 77-111-501

ALLIED CHEMICAL CORPORATION
DANVILLE, ILLINOIS

June 1978

I. TOXICITY DETERMINATION

It has been determined on the basis of medical evidence collected February 22-24, 1978, that a health hazard may be present at Allied Chemical Company, Danville, Illinois. The present percentage of workers with one abnormal kidney function test (serum creatinine) is considered by the NIOSH physician to be excessive and is the basis for the positive toxicity determination. Other observations of potential concern are the indications of the rates of at least one abnormal liver function test in packagers and laboratory technicians. Because of the small number of workers studied, firm conclusions on these values cannot be made. It was also noted that there were no indications of excessive birth defects or spontaneous abortions to the offspring of the Allied workers.

The Allied workers were evaluated by a history questionnaire, physical evaluation, and biological testing for non-specific signs attributable to fluorocarbons, vinyl chloride, carbon tetrachloride and acid toxicity. There were insufficient control volunteers, so this evaluation is based on comparison of medical tests between departments and levels of exposures. Stating that a medical hazard may be present is, therefore, based on the NIOSH physician's analysis and indicates need for further surveillance by Allied Chemical Company.

The time-weighted average air concentrations for monochlorodifluoromethane (G-22) measured on December 13, 1977 ranged from 13 ppm to 46 ppm. The current threshold limit value (TLV) for monochlorodifluoromethane is 1,000 ppm.

II. DISTRIBUTION AND AVAILABILITY OF DETERMINATION REPORT

Copies of this Determination Report are currently available upon request from NIOSH, Division of Technical Service, Information and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from NIOSH, Publication Office, at the Cincinnati address. Copies of this report have been sent to:

- a) Allied Chemical Corporation, Danville, Illinois
- b) Authorized Representative of Employees - Local 617
- c) International Chemical Workers Union, Akron, Ohio
- d) U.S. Department of Labor - Region V
- e) NIOSH - Region V

For the purpose of informing the approximately "45" affected employees, the employer shall promptly "post" for a period of 30 calendar days, the Determination Report in a prominent place(s) near where exposed employees work.

III. INTRODUCTION

Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6), authorizes the Secretary of Health, Education, and Welfare, following a written request by an employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The National Institute for Occupational Safety and Health received such a request from an authorized representative of the International Chemical Workers Union regarding employees exposure to chlorofluorocarbons. The hazard evaluation request was submitted in a response to an Allied Chemical Company notice dated March 17, 1977, stating that a health hazard existed from exposure to fluorocarbon-22(monochlorodifluoromethane). The notice stated that fluorocarbon 22, (G-22), might cause potential mutagenic, carcinogenic or mildly teratogenic effects as based on laboratory testing. The company's action was to remove women employees "from cylinder filling operations where fluorocarbon-22 exposure was likely to occur".

IV. HEALTH HAZARD EVALUATION

A. Conditions of Use

Allied Chemical, Specialty Chemicals Division, Danville, Illinois is involved with the production and packaging of fluorocarbons (Genetron[®]) G-11 (trichlorofluoromethane) and G-12 (dichlorodifluoromethane) or the blending of these substances with other materials. Blending and packaging of other fluorocarbons such as G-22 (monochlorodifluoromethane) is also performed.

G-11 and G-12 are produced at the plant in a totally enclosed, continuous processing system. Carbon tetrachloride and hydrogen fluoride, the raw materials, are fed into the reactor with a catalyst. G-11 is distilled off the first strip column and G-12 is recovered from the second distillation tower. Hydrogen chloride, a by-product, is recovered and sold as hydrochloric acid. The entire process is located out-of-doors with the process operators being housed in an adjacent building. Two or three operators are present each shift.

The G-11 and G-12 products are transferred from storage to a variety of containers for shipment. Tank trucks and railroad tank cars are loaded out-of-doors adjacent to the tank farm area. Containers, varying from 15 lb. cylinders to 1 ton cylinders, are filled indoors in the packaging building.

Genetron[®] 22 is brought to the Danville plant in bulk tank cars. It is then repackaged into 15, 25, and 50 pounds jugs and into tank cars. Some 150 pound cylinders and ton cylinders are also filled for shipping. These filling operations also take place in the packaging building. The fluorocarbons and container sizes being filled are dependent on customer demand. Approximately 10 to 14 employees are involved in the packaging operations, with 4 additional workers engaged in the tank farm operations.

The plant also employs from 6 to 8 individuals in the laboratory. The laboratory personnel are in and out of the laboratory collecting process and shipment samples for analyses.

B. Evaluation Methods

An initial environmental-medical survey was conducted at Allied Chemical in Danville on December 12-13, 1977. On December 13, environmental air samples for G-22 and G-11 were collected on large charcoal tubes (200/400 mg/tube) at a flow rate of 50 cc/minute. The samples were then maintained at dry ice temperature until being analyzed by gas chromatographic procedures.

During the initial survey, twenty-two employees were interviewed briefly for symptoms. The breakdown of jobs and complaints asked all initial survey interviewees included any complaints of palpitations of the heart. No workers complained of this symptom.

The principal medical survey was conducted on February 22-24, 1978. This evaluation was conducted by two NIOSH physicians and a NIOSH laboratory technician. The opening conference was attended by the NIOSH personnel, the Allied Chemical Company, Danville, Illinois Plant Manager, the Allied Chemical Company Assistant Medical Director for the Specialty Chemicals Division, the Allied Chemical Company, Danville Plant Personnel and Safety Director, an International Chemical Workers Union Industrial Hygienist, and an International Chemical Workers Union Local Representative. The Allied Corporate Medical Representative, the Allied Chemical Company, Danville Personnel Director, the International Chemical Workers Union Local Representative, and the International Chemical Workers Union Industrial Hygienist, and the NIOSH Physicians met with all workers divided in small groups to introduce the workers to the NIOSH personnel and to explain the scope of the medical study. The NIOSH physician felt that the company and union representatives at these group meetings were very cooperative in encouraging worker participation in the study. During the course of the study, each participating worker met with the NIOSH physician in private where informed consent was obtained and history and physical evaluations were conducted.

The two NIOSH physicians evaluated forty-three (43) employees or past (laid-off females) employees. The laid-off females evaluated were allowed to participate on company property with the company consent. The occupational and demographic breakdown of participating workers in the medical survey is given in Table 2 and 3. One worker with one month in the packaging plant after 8 years in the production area was included among the production personnel. The company attempted to elicit cooperation from male office personnel to act as controls, however, only two persons volunteered.

The questionnaire included demographic questions, work history, and past medical history. The past medical history was aimed at determining past symptoms related to work, past illnesses, and possible variables which might affect laboratory test results. The physical examination was an evaluation of exposed skin surfaces for chemical burns, auscultation of the heart for murmurs, premature contractions, or other characteristic arrhythmia patterns and palpation of the abdomen for liver enlargement. In male employees, a reproductive evaluation included palpation of testicles and scrotal structures.

The laboratory tests performed were serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvate transaminase (SGPT), alkaline phosphatase, serum creatinine, blood urea nitrogen (BUN), and complete blood count (CBC) on all participants. A semen analysis was performed on participant workers who volunteered a specimen. The SGOT, SGPT, alkaline phosphatase, serum creatinine, and BUN were drawn by venipuncture, the blood allowed to coagulate, and the serum transferred to transfer tubes. The CBC was drawn by venipuncture into an anticoagulant tube and drops of blood were taken for slide smear production. The sperm counts were obtained by giving each participating worker a sterile urine container to take home. The worker was to produce the specimen by masturbation after forty-eight (48) hours of sexual abstinence. The specimen was to be produced just prior to leaving for work and was brought to the NIOSH laboratory technician. These semen specimens were transferred to a transfer containers, except for three drops to make microscopic slide specimens. These slides were allowed to air dry. All specimens except for the sperm slides were kept cool and transported to Medical Diagnostic Services-Ohio Valley in Cincinnati, Ohio for laboratory analysis on February 24, 1978. The semen slides were mailed to Dr. John MacLeod, Ph.D., at Cornell Medical College for cytological evaluation.

C. Evaluation Criteria

1. Physiological effects

Fluorocarbons

Discussions of the freons can be grouped because all are similar in structure and toxicologic effects. Fluorocarbons-11 and 12 will be used as representative of the freons since these are two of the most common, and they are the types produced at the Allied Chemical Company, Danville, Illinois facility. A specific discussion of some of the reproductive effects of fluorocarbons-22 will follow.

The industrial and commercial use of fluorocarbons began in the 1920's with the development of mechanical refrigeration. The fluorocarbons were found to be useful because of their non-flammability, necessary temperature-pressure relationships, and the belief of low toxicity. The use of the fluorocarbons continued to expand with the use of aerosol sprays in the food and cosmetic industries. Fluorocarbons-11, 12, and 22 are all primarily refrigerants, however 11 and 12 are also used as propellants. Fluorocarbon 22's use as a propellant has been discontinued after its mutagenic potential was discovered.

Exposures to the fluorocarbons in the workplace are primarily by inhalation. One of the initial effects is in the central nervous system with depression, euphoria, dizziness and light headedness.² Some fluorocarbons have been used as anesthetic agents. Halothane, one of the most commonly used anesthetics in the United States is an example. In laboratory animals, tremors, loss of posture, loss of equilibrium, and incoordination have been produced by various fluorocarbons, including 11, 12, 22.³

Cardiovascular toxicity has been of concern recently. In March 1973, Azar et. al exposed dogs to fluorocarbon 11 and 12 and were able to sensitize the dogs' hearts,⁴ making the heart muscle more responsive to stimulation and increasing the chance of beating irregularly. Human exposure to cardiac sensitization has been in two situations. First, fluorocarbon containing agents have been used in abuse situations to produce an euphoria effect. Bass summarized 110 "sudden sniffing deaths" during the 1960's in JAMA, June 22, 1970.⁵ Reinhardt et. al also reported 65 deaths due to abuse situations. In their work they sensitized laboratory animals to fluorocarbons with epinephrine and could produce ventricular fibrillation.⁶ This may explain some cases of sudden death in the past where fluorocarbons were used as a carrying vehicle for sympathomimetic agents (ie. epinephrine) in asthmatic patients.⁷

It must be remembered that uses of fluorocarbons as anesthetics and in abuse situations create very high concentrations of the gas, most likely much higher than the concentrations produced in the workplace. This does not mean that care should not be taken to prevent exposure as much as possible. Extra care should be made to prevent high concentrations, poor ventilation exposure to persons with histories of premature ventricular contractions of taking cardiac stimulating drugs. Literature by Speizer et. al. reported an increasing incidence of palpitations by history and premature heart beats by EKG in young healthy pathology residents exposed to fluorocarbon-22 as a freezing agent.⁸ This is certainly not an abuse situation and indicated that cardiac toxicities may be evident in lower concentrations than those abuse situations indicated above.

The final organ systems which may be subject to toxic effects as a result of exposure are noted in a paper presented by Trochimowicz et. al. at the 16th annual meeting of the Society of Toxicology in 1977.⁹ In the abstract of the paper, as presented by the Society, rats exposed to fluorocarbon-21 with fluorocarbon-31 with 1% hydrogen "produced moderate damage to kidneys, adrenals, testes, epididymis, and hemopoietic tissues." They considered that the addition of hydrogen made the agents more toxic than fluorocarbons alone.

The toxic properties of fluorocarbon-22 in relation to reproductive effects, specifically mutagenic and teratogenic events, are important. In November 1976, the E.I. DuPont DeNemours and Company contacted the Director of NIOSH concerning fluorocarbon-22.¹⁰ They stated that fluorocarbon-22 had been found to be weakly mutagenic in a 72-hour Ames test. The 6-hour Ames test had been negative. At this time the use of fluorocarbon-22 as a propellant was discontinued. In February, 1977, an Allied Chemical Company sponsored project by Litton Biometrics confirmed that fluorocarbon-22 exhibited mutagenic activity to Salmonellae strains TA 1532 and G-46. In this same study mutagenic events were not found in liver tissue homogenates prepared from Sprague-Dawley rat.¹¹ In April, 1977, a second Allied Chemical Company sponsored project by Litton Biometrics reported that cytogenetic analysis of bone marrow of ten males rats exposed to 10,000 ppm of fluorocarbons-22 for 6 hours "did not differ from control rats...".¹² Therefore, two studies showed mild mutagenic events in bacterial cells and two studies showed cytogenic changes in mammalian cells exposed to fluorocarbon-22 of varying doses in each study.

Teratogenic studies have been performed by the E.I. DuPont DeNemours and Company and verbal results were provided by a representative of the Freon Products Laboratory. In their 1st and 2nd teratology studies Charles River rats were exposed during gestational days 6-15 at doses as low as 500 ppm and sacrificed at day 21. Examination showed a "small number of animals" with anophthalmia and microphthalmia (abnormal underdevelopment or lack of development of the eyes). Analysis of the information was determined by DuPont to be "barely statistically significant." There are currently long term studies in progress, but no results are available at this time.¹³

Vinyl Chloride

The purpose of this section is to inform persons with past exposure of their relative risk of vinyl chloride exposure. The chemical is no longer present in the Danville facility, so a risk to new or non-exposed workers is not present.

Until several years ago, the toxic properties of vinyl chloride went unrecognized. The belief that there were no toxic effects led to its consideration as a surgical anesthetic at one time and its use as a propellant. The largest use of vinyl chloride was in the plastics industry. With the growth of that industry, larger amounts of vinyl chloride are being used. In the early 1960's, some studies began to show toxic effects. Torkelson et. al. in 1961 found vinyl chloride to have the capacity to cause liver and kidney injury.¹⁴ In 1967, Harris and Adams¹⁵ reported Acroosteolysis (a degeneration process of the bones) in autoclave cleaners in the vinyl chloride and polymerization process. In May, 1970 at the Tenth International Cancer Congress Vignola et. al. reported indications of liver cancer in laboratory animals.¹⁶

This period in the late 60's resulted in growing evidence of liver injury in vinyl chloride workers. A report from Russia¹⁷ of a condition called "chronic epithelial hepatitis" was reported; and liver fibrosis, enlarged spleen, and portal hypertension were reported from Germany.¹⁸ In January, 1974, a manufacturer of polyvinyl chloride informed NIOSH of the death of three workers due to a cancer of the liver called angiosarcoma.¹⁹ Since that time other cases have been found.²⁰

NIOSH recommendations for medical screening is generally directed towards those workers exposed in the manufacture of polyvinyl chloride. These guidelines recommend annual liver function testing for persons exposed for less than 10 years. If abnormalities are detected, more frequent screening is suggested with a repeat test in 2-4 week, and if abnormal function tests persist after 3 months an individualized medical workup is suggested.²¹

CARBON TETRACHLORIDE

Carbon tetrachloride is a volatile colorless liquid with multiple industrial uses. It is considered as a prime representative of the class of halogenated hydrocarbons. It has excellent solvent properties and is non-flammable, which allowed its wide use as a cleaning solvent and a fire extinguisher element for many years. Recently, less toxic materials are being used to replace carbon tetrachloride for uses where large human exposures would result. Industrially, carbon tetrachloride is still in wide use as a solvent and as a reactant to produce other chemicals. Dr. J. Arena in his book entitled Poisoning states that "over half the carbon tetrachloride produced in the United States is used in the manufacture of other chemicals such as freon propellants and refrigerants."²²

Toxic effects of carbon tetrachloride may be produced by inhalation, ingestion, or skin absorption. The greatest number of poisonings are secondary to inhalation of the chemical in poorly ventilated areas. The toxic properties immediately are drowsiness, sluggishness, nausea, vomiting, dizziness and headache. Carbon tetrachloride may affect many systems including the cardiovascular, neurologic, renal, and hepatic systems. The cardiovascular system may be affected by respiratory failure and ventricular arrhythmias (irregular fluttering of the heart muscle causing a loss of the pumping action). This may result in sudden death. Ventricular arrhythmias may be more frequent when using heart stimulants such as epinephrine. This is very important to persons taking this drug as an inhalant for asthma.²³ Neurologic symptoms are drowsiness, dizziness, and euphoria. Severe exposures may result in coma and death.²⁴ Kidney and liver failure are the most common causes of death in the severely intoxicated persons. Minor degrees of liver and kidney damage may also occur over time with smaller exposures.²⁵

Carbon tetrachloride is considered a potential cause of liver cancer. Since 1941 multiple studies have shown the potential of carbon tetrachloride to induce tumors in laboratory animals.²⁶ The NIOSH criteria document on carbon tetrachloride has also reviewed two studies attempting to investigate mutagenic and teratogenic effects of carbon tetrachloride.²⁷ Neither study showed anatomical abnormalities by gross examination of fetuses of laboratory animals exposed to carbon tetrachloride.

Prevention of exposure is the best method of protection. Occasionally, other chemicals may be substituted, such as for its uses as a solvent. Where carbon tetrachloride is used, personal work practices are important to reduce exposure. Alcohol can also intensify the toxic effects of carbon tetrachloride, so the use of alcohol before exposure is especially hazardous (in addition to the obvious safety hazard of on-the-job alcohol intoxication). Where carbon tetrachloride is used, the workers' kidney and liver functions should be monitored. An additional safety hazard is that carbon tetrachloride will decompose upon heating to phosgene, a strong respiratory irritant.

Hydrofluoric and Hydrochloric Acids

Hydrofluoric and hydrochloric acids are both strong irritants but hydrofluoric acid does have some systemic toxic effects. Both acids can be volatilized to a gas, so exposures are primarily by inhalation. Irritation and burns to eyes and skin, and respiratory irritation are the results of contact. Dermatologic burns up to third degree may be produced.

Irritation of respiratory tract produces pulmonary edema (fluid in the lungs) resulting in death in some cases.²⁸

Some cases of bone and ligament sclerosis have also been reported to workers involved in HF production and preparation for many years.²⁹

Avoidance of inhalation of vapors and direct skin and eye contact are protective.

2. Environmental Standards

The current American Conference of Governmental Industrial Hygienist (ACGIH) threshold limit values (TLV's) for F-22 and F-11 are 1000 ppm. This refers to an 8-hour time weighted average exposure to which it is believed workers may be repeatedly exposed, day after day, for a working lifetime with no adverse effects. In the case of G-22, as stated previously, current studies indicate a possible teratogenic response in rats and may require revision of the present TLV.

D. Results

On the initial walk-through survey of the Danville facility the area seemed clean and well monitored. There were adequate sanitation facilities for washing and toilets. Showers were provided by the Company. The workers did, however, store and eat lunches at their workplace. First aid facilities consisted of a room containing a cot, a chair for removal of foreign bodies in the eye, antiseptic solutions, bandages, and oxygen. There is no nurse in the plant, and first aid is to be provided by trained workers and supervisors. Accident victims are to be transported by a local ambulance to an emergency room approximately twenty minutes away.

The company medical program was described as consisting of a pre-employment evaluation and periodic evaluations. The evaluations are performed by either of two local physicians and the medical records are kept by those physicians. For the last 21 years, the content of the evaluations has been directed by the Allied Corporate Medical Department. The pre-employment evaluation consists of a history and physical examination, chest X-ray, lower back X-ray, CBC, pulmonary function studies, audiogram and urine analysis. Through 1977, no liver or kidney function tests were performed, however, a new corporate policy to begin in 1978 requires an EKG and multiple blood tests, including liver and kidney function tests, on the pre-employment evaluation. A special surveillance of 12 persons for liver function was being performed prior to 1978 because of a past exposure to vinyl chloride. The periodic evaluation given every two years includes a history and physical examination, chest X-ray and EKG for employees over forty years of age. As of 1978, they will begin to repeat all tests on the periodic evaluation that are given on the pre-employment evaluation.

The results of the medical questionnaire administered on the follow-up survey are shown in Table 5. Many of these symptoms or disease histories have explanations other than work-related. The two lung diseases are past tuberculosis and frequent upper respiratory infections. The heart disease is a past myocardial infarction. There is one other person, as indicated, who was told by his physician that his EKG was mildly abnormal but the abnormality was not significant. The three cases of jaundice are in persons with a past history of hepatitis. The reported kidney diseases are a case of frequent urinary tract infection in a female and a structural abnormality of the urinary tract in one man. One case of hematuria was secondary to trauma. The reported sensation loss was also secondary to trauma. The symptoms listed of concern are the coughing at work, shortness of breath, palpitations, tremors and paresthesias. These reported complaints can all be toxic symptoms of chemicals present in the workplace. They are also common complaints in the general population.

A separate reproductive questionnaire was administered. Of the 36 males participating, two complained of decreased libido associated with age and one of decreased muscle size. No males noted change in facial or body hair or increased breast development. Of the five females participating, none noted changes in menstrual cycles during their employment at Allied Chemical Company, other than during pregnancy. The number of births, birth defects, spontaneous abortions and still births were recorded. Of the 36 males field workers, 35 have fathered children. Of the five female employees or past employees interviewed all have born children. The results are in Table 6.

Physical examinations as described above were performed. The only positive findings were one worker with a chemical burn on the leg reported to be secondary to xylene, one heart murmur of which the worker had prior knowledge, one worker with multiple extra systoles, and one patient with an enlarged liver. The worker with the enlarged liver had normal liver function tests. Testicular sizes were measured in all but one male participant. One person had one testis which was considered atrophic, and two workers had testes considered mildly soft in consistency to the evaluating physician. The person with the atrophic testis had a low sperm count. One of the persons with decreased consistency had a normal sperm count and the other did not submit a specimen.

The results of the blood tests are listed in Table 7. The CBC results were distorted by degeneration of white blood cells, so only the hemoglobin and hematocrit results were considered accurate. Seven persons had at least one abnormal liver function test, fifteen had at least one abnormal kidney function test. All kidney function abnormalities were serum creatinines. The BUN values were all within the laboratory's normal range. Four workers had a lowered hemoglobin or hematocrit. The sperm counts of the twelve volunteers are listed in Table 8. The cytological evaluation of these semen specimens were submitted to Dr. John MacLeod, Ph.D., Assistant Professor Emeritus of Cornell Medical College. Three of the twelve specimens had some degree of atypical cells. Two specimens had a high degree of tapering of cell. One specimen had obvious microcephalia.

The result of the environmental samples collected on December 13, 1977 are given in Table 17. The time-weighted average (TWA) air concentration for G-22 ranged from 13 ppm to 46 ppm. The samples collected for G-11 had a TWA of 5 ppm. All sample concentrations are well below the current TLV's of 1000 ppm. However, at the present time, the safe exposure level to G-22 remains questionable. (Environmental sampling was limited to measuring G-22 exposure as exposure to the other materials discussed in this report no longer were present or had previously been well documented and found to be considerably below existing standards.)

(Values presented by Tracor Gitco consultants indicated the TWA concentrations for G-11 ranged from 6 ppm to 21 ppm, G-12 from 0.9 ppm to 43 ppm and carbon tetrachloride concentrations ranged from 0.5 ppm to 1.1 ppm.)

E. Discussion

On medical analysis of the questionnaire data completed by field workers who had symptomatic complaints, those complaints were considered of major importance if they were characteristic of any the chemical studied. It is impossible, in this study to determine if the complaints of each persons are occupationally related.

The data concerning children of workers were reviewed by noting the children of those workers prior to and after first exposure to Allied Chemical Company. The total number of children, birth defect and spontaneous abortions are roughly comparable and show no indications of increased birth defects or spontaneous abortions in the offspring of Allied Chemical workers. This data cannot be compared as is to determine fertility as comparison must be made comparing birth and pregnancy rates. The total number of pregnancies conceived is relatively small, so firm conclusions about potential mutagenic activity in the studied chemicals cannot be derived from this study. All one can justifiably conclude is that there is no indication of increased birth defects or spontaneous abortions in the group studied.

There were few positive physical findings. The presence of a chemical burn on only one worker was probably remarkable considering the large amounts of acid used in the plant.

There were multiple abnormal laboratory blood values. Since there were insufficient control persons, statistical analysis of the data, as initially planned, was not possible. The data was analyzed by comparing abnormal laboratory values rates for each department vs. the remainder of the plant; and by comparing abnormal laboratory value rates for workers with the exposure to a common chemical or chemical group with workers claiming no exposure to that chemical or chemical group. Divisions by positive exposure to chemical or chemical group were (1) fluorocarbon-22, (2) all other fluorocarbons, (3) vinyl chloride, and (4) carbon tetrachloride. A single worker is a member of his Department for analysis of that department, and in the analysis of other departments he will be among the group of non-members of that department. For example, an individual packager will be in the group of packagers, non-maintenance, non-production operators, non-tank farm persons, and non-laboratory technicals. In the analysis of each chemical, each worker may be in that positive chemical exposure group for each chemical depending on his work history. These values are listed in Tables 9 thru 14.

The liver function test data (Tables 9 and 10) have two interesting points. The most significant is that half of the laboratory workers tested have at least one abnormal liver function test and the mean SGPT value is only one unit from the upper limit of normal. This may be explained by the small number of persons available for testing. The other interesting point was in the packaging department. Here more workers were tested and the packagers have over twice the abnormal liver function test rate than those persons in other department.

The most impressive finding was in the kidney function testing. (Tables 11 and 12). Since all the field workers claimed exposure to some fluorocarbons, this group, might be considered representing all plant field worker. Thirty-nine (39) percent of this group had an abnormal serum creatinine. The departments varied from twenty-five percent to fifty-five percent of the persons having an abnormal serum creatinine. It was the impression of the NIOSH physician that this was a very high percentage of the population to have an abnormal result. It was noteworthy that all persons had a normal BUN, however, the serum creatinine is more specific for kidney abnormalities and this also assumes that the analyzing laboratory is reliable and made no consistent error that would account for the elevated serum creatinine values. It would, however, be expected that the BUN values should also be elevated.

The hematologic values (Tables 13 and 14) indicate lowered hemoglobin or hematocrit values as abnormalities. There was one person with a very slight elevated hematocrit which is not considered abnormal in these tables. These results did not indicate any group as elevated as compared to the other groups listed.

In the analysis of the sperm counts a graphic analysis may be made in comparison 9,000 sperm count values reported to NIOSH by Dr. John MacLeod³⁰ and the work of Nelson and Bunge.³¹ Figure I is a graph of the accumulative percent of persons participating vs. sperm count in the ranges indicated for the twelve workers and the two studies indicated above. Dr. MacLeod's work as reported to NIOSH were given as a percent of the 1,000 workers with a sperm count range for each of 9 years. These nine means for each group were averaged to determine a single percentage value for each sperm count range. The values graphed in Figure I are indicated in Table 15. The graph of Allied Chemical Workers tends to follow the graph of Dr. MacLeod studies, especially in the range of potential abnormality (>40 million cells/ml). The graph of the Nelson and Bunge³¹ study has a higher percentages of persons in the low sperm count range than MacLeod or the Allied Chemical workers.

The cellular component of the testis reacts somewhat non-specifically to stress, by releasing sperm cells that are underdeveloped or overdeveloped. Without having a previous specimen on the individuals it is impossible at this time to determine if the atypical cells seen in the three normal cytological readings are a genetic characteristic for that person or a non-specific reaction to stress. To aid in evaluation, Dr. MacLeod enclosed mean cell types count from 5000 semen evaluations from persons seen for the first time between 1972 and 1977. This information is provided in Table 16. The mean number of cells in each study appears similar.

F. Conclusions

- 1) The present percent of the workers with one abnormal kidney function test (serum creatinine) is considered by the NIOSH physician to be excessive and is the basis for the positive toxicity determination for the population studied. These abnormalities do not tend to segregate into any specific department.
- 2) Other observations of potential concern are the indications of the rates of at least one abnormal liver function test in packagers and laboratory technicians. One may not make firm conclusions on these values because of the small number of workers studied. These test should be scrutinized in the future when performed by the company in their periodic evaluations.
- 3) There are no indications of excessive birth defects or spontaneous abortions to the offspring of Allied Chemical workers.
- 4) Chemicals considered to be mutagenic may affect the genetic material of both male and female employees. The risk is theoretically present in both males and females. Chemicals considered to be teratogenic by laboratory studies may affect a developing fetus and females of reproductive potential should be withheld from exposure. The tests performed on F-22 at this time are inconclusive in determining the full mutagenic or teratogenic risk to humans.

G. Recommendations

- 1) The planned changes in the Allied Chemical Company, medical program should be implemented to include liver and kidney function tests as soon as possible. Since cardiac arrhythmias are potential side effects of fluorocarbons, the planned use of electrocardiograms should be implemented as soon as possible. Once established, the kidney function tests should be reviewed to confirm or refute the elevated serum creatinine values since a concurrent elevation in the BUN values was not noted.
- 2) The company should continue to search for all workers previously exposed to vinyl chloride and evaluate their liver function at least annually.
- 3) Educate workers to the potential hazards and toxic symptoms of the chemicals in the plant so that they may be better aware of their health effects.

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TABLE 1

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Job Descriptions and Symptomatic Complaints Registered on Initial Survey

<u>DEPARTMENT</u>	<u>NUMBER OF PERSONS IN EACH DEPARTMENT INTERVIEWED</u>
Laboratory Technican	4
Packager	9
Production Operator	2
Maintenance	3
Tank Farm	3

<u>COMPLAINT</u>	<u>NUMBER OF PERSONS EXPRESSING EACH COMPLAINT</u>
Euphoria (light headed)	6
Headache	5
Dizziness	8
Syncope (fainting)	1
Nausea	5
Short of Breath	5
Chest Pains	4
Sneezing	1
Acid Burns	2

TABLE 2

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111Demographic Data of Medical Survey
Sex and Job Description of Participants

	Present Field Employees	Controls	Past Employees	Total
Males	36	2	0	38
Females	<u>2</u>	<u>0</u>	<u>3</u>	<u>5</u>
TOTAL	38	2	3	43
Packaging Plant	10	0	2	12
Production Operators	11	0	0	11
Laboratory Technicians	4	0	0	4
Tank Farm	4	0	0	4
Maintenance	9	0	1	10
Office Personnel	<u>0</u>	<u>3</u>	<u>0</u>	<u>3</u>
TOTAL	38	3	3	43

TABLE 3

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Demographic Information of Medical Survey
Age of Present Field Employees

	N=	Mean Age (yrs)	Age Range (yrs)	Mean Yrs. at Allied	Range Yrs. at Allied
Packaging Plant	10	37	28-53	11	1-23
Production Operators	11	47	29-61	17	7-22
Laboratory Technicians	4	33	29-38	7	5-12
Tank Farm	4	36	28-49	14	7-26
Maintenance	8	53	45-64	23	15-40

TABLE 4
ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Participation Rate of Present Field Employees

	<u>Total Employees</u>	<u>Evaluated</u>	<u>Percent</u>
Packaging	14	10	71.43
Production	11	11	100.00
Maintenance	15	8	53.33
Tank Farm	5	4	80.00
Laboratory	<u>7</u>	<u>4</u>	<u>57.14</u>
TOTAL	52	37	71.15

TABLE 5

ALLIED CHEMICAL COMPANY
Danville, Illinois,
HE 77-111

Medical Histories of 38 Survey Participants

	<u>Number of Persons Expressing Complaint</u>	<u>Percent Positive</u>
<u>RESPIRATORY</u>		
History of Lung Diseases	2	5
Difficult Breathing or Shortness of Breath	2	5
Cough at work or afterwork	3	8
Wheezing at work or afterwork	0	0
Emphysema	0	0
<u>ART</u>		
History of Heart Disease other than specifically discussed below	1	3
Diagnosed Hypertension	5	13
Abnormal EKG	1	3
Palpitations	1	3
Cyanosis	0	0
History of Murmur	1	3
<u>GI AND LIVER</u>		
History of Liver Disease other than Hepatitis	0	0
History of Hepatitis	3	8
History of Jaundice	3	8
Orange Colored Urine	0	0
Nausea or Vomiting at work	5	13

TABLE 5 con't

	<u>Number of Persons Expressing Complaint</u>	<u>Percent Positive</u>
<u>RENAL</u>		
History of Kidney Disease	2	5
History of Blood in Urine	2	5
Tea Colored Urine	0	0
<u>NEUROLOGICAL</u>		
Sensation Loss	1	3
Tremors	3	8
Paralysis	0	0
Paresthesias	4	11

TABLE 6

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Children, Children's Birth Defects, Abortions and Still births of Workers at Allied Chemical Company

A. Males Fathering Children (N=36)	Before Working at Allied	During or After Working at Allied
Total Children	51	48
Children with birth defects	3	2
Spontaneous abortions	7	6
Stillbirths	0	0
B. Females Bearing Children (N=5)		
Total Children	7	5
Children with birth defects	0	0
Spontaneous abortions	1	0
Stillbirths	0	0

TABLE 7

ALLIED CHEMICAL COMPANY
 Danville, Illinois
 HE 77-111

Blood Test Laboratory Values (male workers)

Case #	SGPT	SGOT	Alkaline Phos.	BUN	Creatinine	Hemoglobin	Hematocrit
Normals	3-23 IU/ml	7-40 mU/ml	30-115 mU/ml	10-26 mg/dl	.5-1.3 mg/dl	Males 14-18 g/dl	42-52 %
1	19	29	129	17	1.2	15.4	45.0
2	24	41	81	12	1.3	16.0	47.1
3	10	33	51	13	1.4	16.3	48.9
4	11	21	63	13	1.4	16.4	48.7
5	17	30	96	21	0.9	16.2	47.6
6	8	19	40	13	1.4	14.6	44.0
7	18	32	61	9	1.1	14.8	44.0
8	10	18	69	14	1.2	14.2	41.9
9	18	33	57	16	1.4	14.0	41.8
10	12	14	44	21	1.5	15.9	47.3
11	16	21	91	16	1.4	14.5	42.8
12	18	23	66	12	1.5	16.5	47.7
13	17	30	62	15	1.5	15.5	44.1
14	8	27	78	19	1.2	15.9	47.1
15	21	30	82	9	1.1	17.2	50.6
16	16	28	49	14	1.2	15.0	44.3
17	11	28	65	16	1.6	18.2	53.5
18	10	15	45	10	1.7	14.7	44.1
19	23	27	66	14	1.6	17.1	50.2
20	13	22	59	12	1.6	14.3	44.4

TABLE 7 con't

Blood Test Laboratory Values (male workers)

Case #	SGPT	SGOT	Alkaline Phos.	BUN	Creatinine	Hemoglobin	Hematocrit
Normals	3-23 IU/ml	7-40 mU/ml	30-115 mU/ml	10-26 mg/dl	.5-1.3 mg/dl	Males 14-18 g/dl	42-52 %
21	24	50	60	25	1.3	14.8	44.1
22	20	26	46	15	1.0	14.7	41.8
23	17	29	70	22	1.3	16.6	46.4
24	11	30	60	18	1.1	16.0	45.1
25	43	55	70	12	0.9	16.4	46.8
26	19	22	40	15	1.0	17.9	50.2
27	11	27	48	16	1.0	14.0	40.9
	15	26	72	13	1.4	16.3	46.1
29	12	21	52	26	1.4	15.6	44.5
30	16	29	62	13	1.1	16.8	46.4
31	12	19	69	11	1.0	15.8	44.0
32	15	23	61	21	1.0	15.6	45.1
33	18	24	54	11	1.2	16.6	47.6
34	17	21	59	10	1.1	17.9	50.7
35	15	31	28	24	1.7	15.6	44.9
36	16	23	59	9	1.3	15.0	43.1
37	12	21	39	15	1.2	15.7	45.4
38	19	32	74	18	1.3	16.3	46.7

TABLE 7 con't

Blood Test Laboratory Values (Female workers)

Case #	SGPT	SGOT	Alkaline Phos.	BUN	Creatinine	Hemoglobin	Hematocrit
Normals	3-23 IU/ml	7-40 mU/ml	30-115 mU/ml	10-26 mg/dl	.5-1.3 mg/dl	Females 12-16 g/dl	37-47 %
1	36	37	56	14	1.1	12.4	36.4
2	24	37	80	10	1.1	12.8	39.1
3	7	20	44	15	0.7	14.0	40.5
4	27	48	39	9	0.8	13.7	38.8
5	7	12	58	9	1.0	13.2	40.9

TABLE 8

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Sperm Counts on twelve (12) Volunteer Workers

	Count (cells/ml)
	12.4 million
	26.0 million
	41.0 million
	152.2 million
	167.2 million
	137.8 million
	62.2 million
	168.2 million
	109.0 million
	16.4 million
	48.2 million
	49.0 million
Mean	82.5 million
S.D.	60.3 million
Median	55.6 million

TABLE 9

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Liver Function Tests by Department (LFT)

	Packaging	Non-Packaging	Prod. Oper.	Non-Prod. Oper.	Tank Farm	Non-Tank Farm	Laboratory	Non-Lab.	Maintenance	Non-Maintenance
N=	10	28	11	27	4	34	4	34	9	29
Mean Age	37	45	47	41	35	44	33	44	53	40
Mean Yrs. @ Allied	11	17	17	15	14	16	7	16	23	13
% Abnormal LFT	20.00	7	18	15	0	15	50	9	0	1
Mean SGPT	18	16	17	17	17	17	22	16	13	18
S.D.	9.78	5.85	4.65	7.84	1.41	7.41	11.09	6.40	4.12	7.38
Mean SGOT	30	27	28	28	24	28	32	27	24	29
S.D.	13.41	6.38	7.11	9.04	4.08	8.74	6.08	8.08	5.36	8.99
Mean Alkaline Phos.	60	64	63	63	72	62	64	63	62	63
S.D.	10.50	19.98	26.07	13.99	32.63	16.92	14.61	18.46	10.93	19.75

TABLE 10
 ALLIED CHEMICAL COMPANY
 Danville, Illinois
 HE 77-111

	Liver Function Tests by Chemical or Chemical Groups							
	Fluorocarbon-22	Non-F-22	Any Fluorocarbon	Non-Fluorocarbon	Carbon Tetrachloride	Non-CCl ₄	Vinylchloride	Non-Vinylchloride
N=	37	1	38	0	28	10	25	13
Mean Age	43	-	43	-	45	38	44	41
Mean Years at Allied	15	-	15	-	17	11	17	13
% Abnormal Liver Function Test	16	-	16	-	14	20	12	15
Mean SGPT	17	-	17	-	16	18	17	17
S.D.	7.10	-	7.01	-	5.85	10.39	5.65	9.35
Mean SGOT	28	-	28	-	27	30	27	28
S.D.	8.51	-	8.43	-	6.38	12.64	7.25	10.68
Mean Alkaline Phos.	63	-	63	-	63	64	64	61
S.D.	18.17	-	17.92	-	19.30	14.26	20.30	13.08

TABLE 11
 ALLIED CHEMICAL COMPANY
 Danville, Illinois
 HE 77-111

Kidney Function Tests by Department

	Packaging	Non-Packaging	Production Oper.	Non-Prod. Oper.	Tank Farm	Non-Tank Farm	Laboratory	Non-Lab.	Maintenance	Non-Maintenance
N=	10	28	11	27	4	34	4	34	9	29
Mean Age	37	45	47	41	36	44	33	44	53	40
Mean Years at Allied	11	17	17	15	14	16	7	16	23	13
Abnormal Kidney Function Test	30	43	55	33	25	11	25	41	44	38
Mean BUN	14	16	17	14	15	15	13	15	15	15
S.D.	4.88	4.43	4.21	4.49	4.92	4.59	2.50	4.72	5.42	4.47
Serum Creatinine	1.3	1.3	1.4	1.2	1.2	1.3	1.2	1.3	1.3	1.2
S.D.	.27	.21	.22	.22	.24	.22	.17	.23	.19	.24

TABLE 12

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Kidney Function Tests by Chemical or Chemical Groups

	Fluorocarbon-22	Non-F-22	Any Fluorocarbon	Non-Fluorocarbon	Carbon Tetrachloride	Non-CCl ₄	Vinylchloride	Non-Vinylchloride
N=	37	1	38	0	28	10	25	13
Mean Age	43	-	43	-	45	38	44	41
Mean Years at Allied	15	-	15	-	17	11	17	13
Abnormal Kidney Function Test	41	-	39	-	39	40	32	54
Mean BUN	15	-	15	-	15	14	15	15
S.D.	4.50	-	4.55	-	4.54	4.74	4.41	5.00
Mean Serum Creatinine	1.3	-	1.3	-	1.3	1.3	1.3	1.3
S.D.	.22	-	.22	-	.21	.26	.21	.24

FIGURE I

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Twelve (12) Sperm Specimens from Allied Chemical Company and Control Studies.

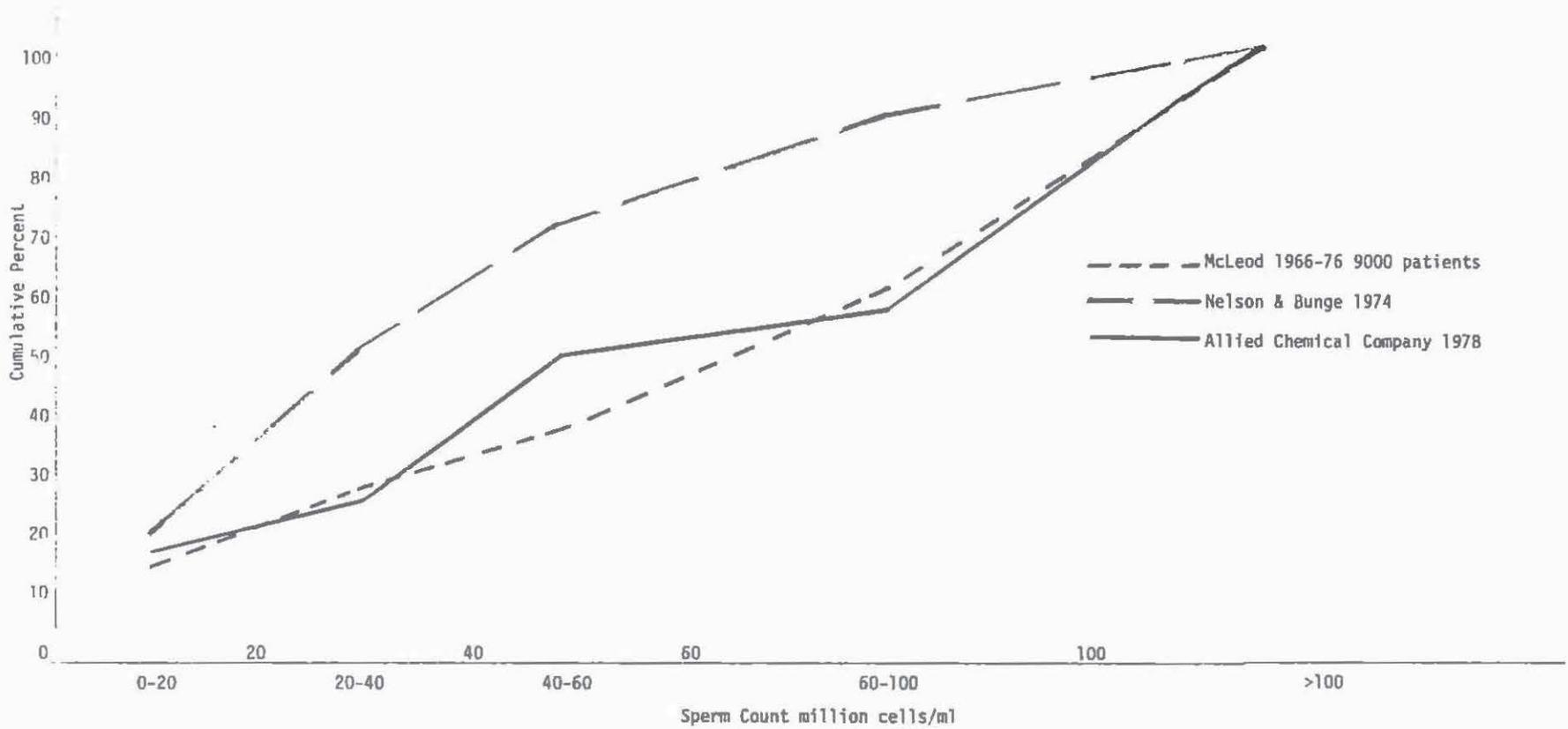


TABLE 15

ALLIED CHEMICAL COMPANY
Danville, Illinois
HE 77-111

Percent Sperm Counts (range) of Allied Chemical Workers and Control Studies

Sperm Count Range cells/ml	MacLeod ³² %	Nelson & Bunge ³³ %	Allied Chemical %
<20 million	15	20	16.7
20-40 million	11.4	30.8	8.3
40-60 million	11.8	21	25
60-100 million	25.3	21	8.3
>100 million	36.5	7.0	41.7

TABLE 16
 ALLIED CHEMICAL COMPANY
 Danville, Illinois
 HE 77-111

Sperm Morphology (mean cell type counts) of Twelve Allied Chemical Company workers and 5000 persons evaluated by Dr. MacLeod during 1972-1977.

	Oval	Large	Small	Taper	Amorphic	Bicephalic	Spermatids
5000 Evaluations Dr. MacLeod 1972-1977 %	72	1.41	8.75	8.5	8.67	1.62	2.8
Twelve Allied Chemical Workers %	78	1.33	9.6	5.83	4.35	0.83	0.6