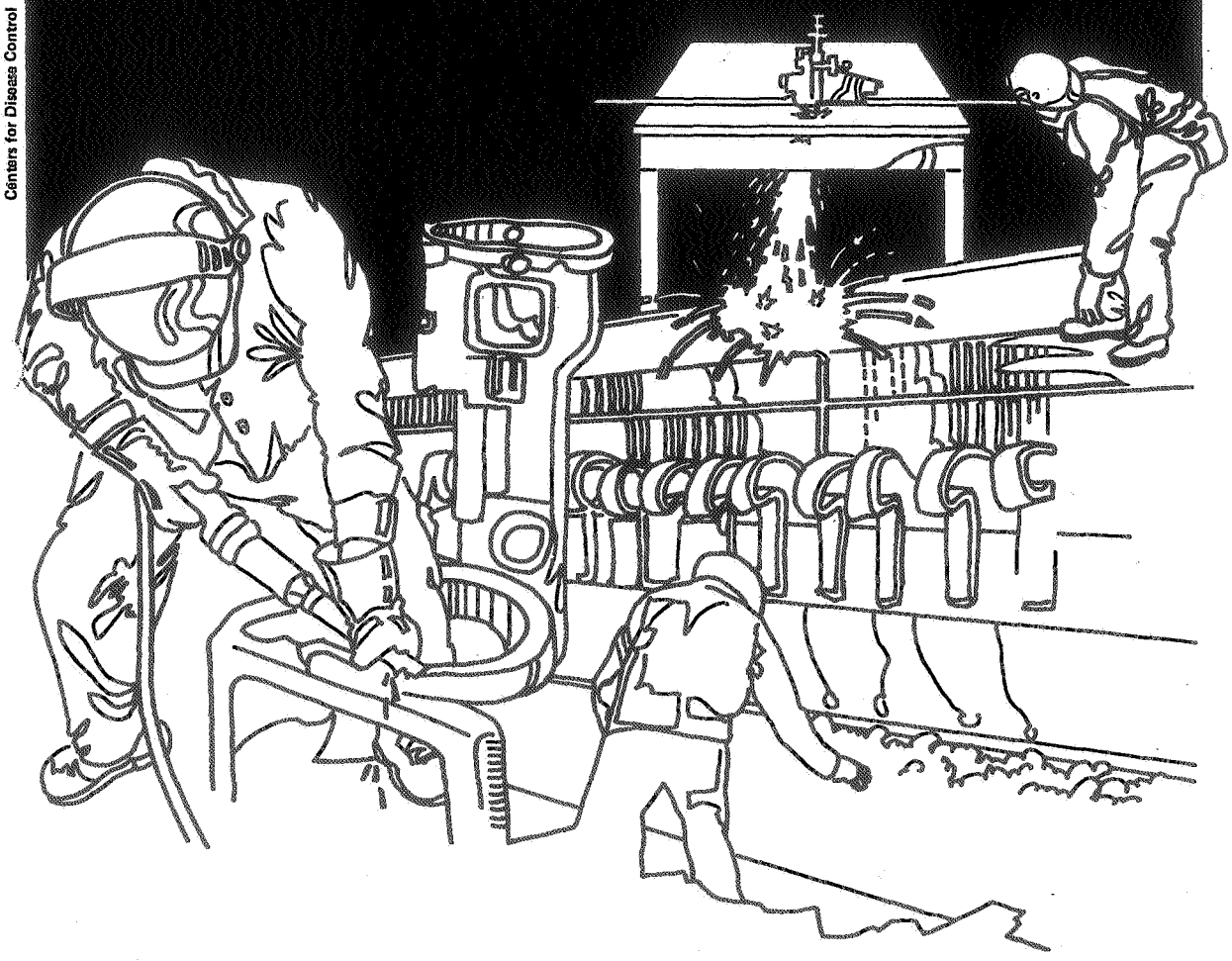
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public H... /ice
Centers for Disease Control ■ National Institute for Occupational Safet... alth

NIOSH



Health Hazard Evaluation Report

HETA 81-270-1012
LEAR SIEGLER, INC.
SAN DIEGO, CALIFORNIA

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any 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 Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

HETA 81-270-1012
DECEMBER 1981
LEAR SIEGLER, INC.
ACCURATE PRODUCTS DIVISION
SAN DIEGO, CALIFORNIA

USC CONTRACT INVESTIGATORS:
William E. Wright, M.D
John M. Peters, M.D.
Elizabeth A. Plyler, M.P.H.
NIOSH INVESTIGATOR:
Pierre L. Belanger, M.S., IH

I. SUMMARY

On April 6, 1981, the National Institute for Occupational Safety and Health (NIOSH) received a union request to investigate an apparent increased incidence of miscarriages among workers at Accurate Products Division (AP) of Lear Siegler, Inc., San Diego, California. The health hazard evaluation was conducted on June 11 and June 18, 1981, by doctors from the University of Southern California School of Medicine under contract with NIOSH. A review of previous evaluations of the plant by the California Occupational Safety and Health Administration (Cal-OSHA) inspection and follow-up suggested there might be a problem with reproductive capacity as a result of worker exposure to ethylene thiourea.

The NIOSH study included current workers, male and female, using a thorough reproductive history questionnaire. Forty-six (82%) of the 56 male employees were evaluated, but only 14 (30%) of them were young, of prime reproductive age, and not using contraception. None complained of sexual dysfunction. Four (8%) of 48 of their wives' pregnancies before employment at AP ended in spontaneous abortion (miscarriage), and one (11%) of 9 since employment. Eighty-one (94%) of the 86 female employees were evaluated. Of these only 11 (14%) were ever at high risk of becoming pregnant (married, of reproductive age, not surgically sterile, not using contraceptives) during the last ten years at AP. Of seven pregnancies only two resulted in spontaneous abortions, one with an identified medical problem. The 81 women had had 192 pregnancies before starting work at AP with 16% spontaneous abortions. The ratio for menstrual problems among molders compared to non-molders was 1.05, decreasing when adjustments were made for age. There was no indication that menstrual problems increased with duration of employment as a molder.

This evaluation did not find any adverse reproductive effects which could be attributed to the work environment, although the small numbers available for study prevent the possibility from being entirely ruled out. Further, because of the small number of workers and the limited availability of records this does not appear to be a good setting to be included in an industry-wide study of the problem.

On the basis of review of past studies and personal interviews, NIOSH concludes that a reproductive hazard probably does not exist for workers at Accurate Products Division, Lear Siegler, Inc., San Diego, California, although small numbers preclude a more definite conclusion. Recommendations are made to reduce respiratory and musculoskeletal complaints.

KEYWORDS: SIC 3069 (Fabricated Rubber Products, Not Elsewhere Classified), molded rubber, reproductive hazard, ethylene thiourea.

II. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) received a request on April 6, 1981, from District 50, International Association of Machinists and Aerospace Workers, to investigate an apparent increased incidence of miscarriages among workers at Accurate Products Division (AP), Lear Siegler, Inc., San Diego, California. The medical aspects of the study were performed under Professional Physicians Services Contract #210-81-5014 with the University of Southern California School of Medicine, Los Angeles (USC), as contractor. The NIOSH industrial hygienist represented NIOSH on site.

The health hazard evaluation was carried out on two days. On June 11, 1981, the evaluation team met in separate interviews with management and labor representatives. On June 18, 1981, medical evaluations consisting of interviews were performed on all available employees.

III. BACKGROUND

A. History of the Reproductive Complaint

In July 1979 California Occupational Safety and Health Administration (Cal-OSHA) responded to a complaint at AP alleging safety hazards and dermatitis. During the inspection, chemicals in the storage area were noted, one of which was ethylene thiourea (ETU). The container was labeled as a possible carcinogen and teratogen based on animal studies. Inquiries regarding reproductive problems at the plant were made by Cal-OSHA employees and in October 1979, a formal complaint to Cal-OSHA alleging five miscarriages was received. That month two RNs from the Cal-OSHA Medical Unit interviewed 56 women out of 104 at the plant. Of 11 pregnancies occurring during employment at AP, there were three normal live births, six spontaneous abortions (miscarriages), one therapeutic abortion, and one current pregnancy. Of six pregnancies that occurred in 1979, four apparently terminated in spontaneous abortions.

The results of the Cal-OSHA investigation were thought to be suggestive of but not conclusive for there being a problem with reproductive capacity at AP. Therefore, the University of California at San Diego School of Medicine and the International Association of Machinists and Aerospace Workers Union mailed a questionnaire regarding reproductive history to 304 past (since 1977) and current employees of AP. The proportion of employees responding to the questionnaire was 13% and only three pregnancies were reported during employment at AP. No conclusions regarding possible reproductive hazards could be drawn from this study. The faculty members at UCSD School of Medicine who conducted the questionnaire survey suggested to the union business representative that a health hazard evaluation be requested.

Cal-OSHA sampled for ETU in 1979 and 1980. Sampling included workers' breathing zone, wipe samples, bulk samples, and urine samples. Breathing zone sampling showed a TWA for ETU of .096 ug/m^3 for an extrusion operator and a TWA of .198 ug/m^3 for a press operator.* Wipe sampling showed 1.0 + .04 ug/cm^2 in the molding and extrusion areas and higher levels (5 to 7 ug/cm^2) in the mill and stock areas. Bulk samples of residue at the Banbury showed approximately 8 to 10 micrograms of ETU present per gram of material sampled (8 to 10 parts per million, ppm). Analysis for ETU in urine was done on workers apparently exposed to ETU, on unexposed workers, and on non-plant controls. There was no significant difference in urinary levels of ETU among the three groups.

B. Plant Description

Accurate Products is one of 47 divisions of Lear Siegler, Inc. The division was founded in 1937 as Royal Industries and later became part of Lear Siegler, Inc. The division has been at its current site since 1967 and borders on residential and light industrial areas.

The products manufactured at AP are small rubber washers, bushings, gaskets, grommets, hoses and tubes, and diaphragms. These items are produced in a variety of sizes and shapes and are used in the auto and aircraft industries, among others. The division is described by management as a non-innovative commercial manufacturer that bids jobs and follows customer requirements. Natural and synthetic rubbers are used. Among the elastomers used at this plant about two-thirds is styrene-butadiene copolymer. The remainder includes polychloroprene (neoprene), ethylene-propylene-diene terpolymers (EPDT), butadiene-acrylonitrile copolymer (NBR), natural rubber (NR), polyvinyl chloride, and silicone elastomers. Most of the ETU is used in manufacturing parts from ethylene-propylene-diene terpolymers (EPDT). Until October 1978 powdered ETU was used. Since then "encapsulated" ETU has replaced the powdered form. By weight, these EPDT elastomers account for approximately two percent of the elastomers used. There are three distinct product lines in the plant: small molded parts, extrusion department, and truck brake diaphragms. Mixing, milling, and storage areas are in one section of the building. Molding, extrusion, and truck brake diaphragm operations are in a separate part of the building. Areas for finishing, packing, and shipping are adjacent to the molding and extrusion operations.

---

* Although no standards for airborne ETU exist, NIOSH has recommended handling ETU in the powder form (but not the "encapsulated" form) as a possible human carcinogen.[1] It has been shown to be carcinogenic and teratogenic in laboratory animals. Laboratory methods are sensitive to as low as 30 ug/m^3 TWA using a low volume pump by the NIOSH recommended procedures. Cal-OSHA used high volume pumps to detect these low levels.

The process begins with formulation of rubber and additives in a banbury mixer, with subsequent milling and introduction of additives to produce a homogeneous sheet of desired thickness of rubber. For the small parts molding, the rubber sheet is cut into 12 inch by 12 inch by 3/8 inch slabs and these slabs are taken to the molding department. The slabs are placed in metal mold forms (plates) where they undergo a transfer molding process. Strips of rubber sheets of similar formulation to the small parts rubber are used in the extrusion process and some final milling is done in this department as well as in the basic milling area. Rolls of pre-milled rubber stock, purchased from a supplier, are cut to size for use in the truck brake diaphragm molding process. Chemicals used in this plant are the traditional rubber additives that include some mutagens and teratogens. Ventilation in the plant is achieved by open doors, banks of windows, and roof exhaust fans, except for the banburys which also have slot exhaust at the gates.

It appeared that the small parts molding area had the greatest potential for exposure to reproductive hazards: the 30 transfer molding presses operate at 340°F and are opened every 2-1/2 to 3-1/2 minutes; manual punch out of the molds is done near the presses; and more than half the female employees work in this operation. The extrusion operation is carried out at lower temperature (110°F), has fewer people exposed, and curing is done in two large ovens which are run for several hours at 150°F. The diaphragm molding area includes six presses which are opened every 11-12 minutes and are run at greater than 300°F.

C. Description of Work Force

The number of employees varies from 100 to 190 depending on the work load. Turnover of employees is approximately six to ten percent per year. At the time of this study there were 142 production and maintenance employees. The small parts molding was working three shifts, truck brake diaphragm was working two shifts, and the extrusion department and banbury mixers were working one shift only.

Approximately 60% of the work force was female, about 1/3 was Spanish surname, and a small percentage was Asian. There were no non-English speaking people among the currently employees.

D. Records Available

1. Industrial Hygiene: There are no routine industrial hygiene sampling records available. Occasionally Cal-OSHA has done sampling, and extensive sampling was done trying to identify areas of contamination with ethylene thiourea during the Cal-OSHA 1979 investigation.

2. Personnel Records: Personnel records of employees and their work records are available for the past three years only. Some records are available prior to that time, but are in storage and apparently are incomplete.

3. Union Records: The union has a seniority list that has name and address of all union members from 1977 to present.

4. Medical Records: Outside physicians are used for injuries and compensation claims. There is no program of pre-employment or routine physicals.

IV. MEDICAL EVALUATION

Although the initial complaint to Cal-OSHA was related to the presence of ETU in the workplace, ETU is only one of several possible exposures to mutagens or teratogens in the plant. Chloroprene, thiram, Ziram, Cumate, ethyl tellurac radform, captan, and n, 1-3 dimethylbutyl-n-phenylenediamine, are also used in the workplace. The molding area appeared to be where exposure was likely to be greatest to all these substances. A random sample of the female employees were interviewed from the molding area as they seemed most likely to have health hazards related to reproduction. Ten employees were selected from the first and second shifts. Of these ten, six were not at risk for having reproductive problems because of using birth control pills or being surgically sterilized. Of the four remaining, two had miscarriages while employed as molders, one reported that she was unable to conceive while employeed as a molder, and one became pregnant as a molder, stopped work because of bleeding and delivered a normal child at term. As a result of this sample it was decided that a thorough reproductive history of all current employees should be done. On the second day of the health hazard evaluation with the support of the management and union, an attempt was made to interview all male and female employees listed on the company and union rolls. Telephone contact was attempted for those employees absent or on leave.

V. RESULTS AND DISCUSSION

A. Reproductive Problems

1. Male Employees: Forty-six (82%) of the 56 male employees were evaluated. No men complained of unexplained inability to conceive or difficulty with sexual function while employed by AP. Before employment at AP four of 48 of their wives' pregnancies (8%) ended in spontaneous abortion. During employment at AP one of nine of their wives' pregnancies (11%) ended in spontaneous abortion. Only 14 of the 46 men were young, of prime reproductive age, and not using contraception.

2. Female Employees: Eighty-one (94%) of the 86 female employees were evaluated. There was no unusual occurrence of difficulty conceiving while employed at AP. The 81 women had 192 pregnancies with 16% spontaneous abortions before work at AP. However, only 11 women were ever at high risk of becoming pregnant (married, of reproductive age, not surgically sterile, not using contraceptives) during employment at AP over the past ten years. These women had seven pregnancies resulting in three normal births, two spontaneous abortions, and two induced abortions. One of the two women who had a spontaneous abortion was diagnosed as requiring a uterine suspension to maintain pregnancy. There were 14 young, never married women currently

employed. The rate ratio for menstrual problems among molders compared to non-molders was 1.05 and decreased when adjustments were made for age. There was no indication that menstrual problems increased with duration of employment as a molder.

B. Respiratory Complaints

During the walk-through survey, two of the investigators experienced acute upper respiratory tract discomfort while observing the small parts molding operation. There was a blue haze in the air over the molding area. These conditions were similar to those in curing operations associated with adverse respiratory effects that one of the investigators had previously studied.[2,3] During the medical evaluation several employees had chronic respiratory symptoms and thought that this was a bigger problem than reproductive hazards.

Cal-OSHA performed an industrial hygiene evaluation of the small parts molding area in 1977 because of respiratory complaints. Their focus was to determine if any substances in the blue haze were above allowable concentrations. In one part of their evaluation charcoal tubes held in the breathing zone and pumps and impingers worn by one worker at a very smoky station were used. Detector tubes showed no CO or NO_2. Eight hour TWAs in parts per million were calculated for HCl (less than 0.60), formaldehyde (less than 0.03), methyl ethyl ketone (less than 0.1), acetone (less than 0.2), and toluene (less than 0.1). A sample of talc showed no fibers. A laboratory analysis was done on one of the formulations used in small parts molding: heated viton rubber (vinyllidine fluoride and hexafluoropropylene copolymer) and shell oil 99S. The liquid condensate contained mostly water with very low levels of acetone, benzaldehyde, many hydrocarbons (alkanes, cycloalkanes, olefines, and several oxygenates). The condensate was low in aromatics, contained no chlorine, evolved HCl at temperatures greater than 250°C, and had a pH of approximately four. The shell 99S oil alone heated to 320° produced a white smoke that caused throat and eye irritation for laboratory personnel. The smoke was collected in a charcoal tube and showed no peaks on gas chromatograph. On the basis of their investigation, Cal-OSHA did not issue a citation related to respiratory hazards.

However, it appears from this visit that respiratory complaints may still be prevalent and that there may be some combination of exposure or effect of pH and chemical exposure that is producing at least acute respiratory symptoms. Work shift decrements in pulmonary function could be studied to assess adverse acute effects of these combined exposures on respiratory function. However, the number of people possibly affected who would participate in a respiratory evaluation may be small.

C. Musculoskeletal Complaints

Complaints related to tendonitis in the molding area were one of the subjects of the Cal-OSHA inspection of Accurate Products in August 1979. Recommendations were apparently made by Cal-OSHA

regarding handling and opening of molds. An exercise program including arm strengthening exercises was organized by the company nurse. Power tools are available for opening molding, but the employees appear to favor using screwdrivers to pry the molds open. During this medical evaluation several employees complained of the lifting and prying requirements. Cal-OSHA may follow-up this problem. There are apparently insufficient medical data to advise general limiting of work of pregnant women in this environment.

VI. CONCLUSIONS

This evaluation cannot entirely rule out the possibility of adverse effects of chemical exposure on reproduction at AP because it was unable to assess reproductive effects in those who had left employment at AP. The small number of pregnancies among current female employees and among wives of male employees probably reflects the small number of women-years at risk of pregnancy rather than reduced fertility resulting from chemical exposure. There was no apparent excess of miscarriages among current employes at AP and there was no excess of menstrual irregularity related to exposure in small parts molding. Among the current male and female employees at AP there were no adverse reproductive effects related to workplace exposure that could be detected by ascertainment of reproductive history. However, the small numbers of men and women at risk for adverse reproductive effects limits the strength of these conclusions. In addition, AP does not appear to provide a good setting for future epidemiologic study of reproductive hazards in the rubber industry because of the small number of employees at risk and the limitation of available records for assembling a cohort for retrospective study.

Although ETU is not the only potential carcinogen-teratogen present, using ETU in the "encapsulated" form should reduce any hazard from it to minimal levels.[1]

Respiratory and musculoskeletal complaints were present and have been addressed by Cal-OSHA. These may deserve further evaluation if the recommendations are followed and do not improve the situation.

VII. RECOMMENDATIONS

1. The ventilation in the small parts molding area should be reviewed. If indicated, improvements could be expected to reduce respiratory irritation.

2. Workers feeling they have a problem with lifting and/or prying should consider modifying work practices to better utilize available mechanical aids and exercise programs.

VIII. REFERENCES

1. Special Occupational Hazard Review with Control Recommendations for Ethylene Thiourea. DHEW (NIOSH) Publication No. 79-109 (1978).

2. Fine LJ, Peters JM: Respiratory morbidity in rubber workers, I. Prevalence of respiratory symptoms and disease in curing workers. Archives of Environmental Health 31:5-9, 1976.

3. Fine LJ, Peters, JM: Respiratory morbidity in rubber workers, II. Pulmonary function in curing workers. Archives of Environmental Health 31:10-14, 1976.

IX. AUTHORSHIP AND ACKNOWLEDGMENTS

Report Prepared By:

William E. Wright, M.D.
Assistant Professor of Occupational Health
University of Southern California
School of Medicine
Los Angeles, California

Theodore W. Thoburn, M.D.
NIOSH Project Officer
Medical Officer
NIOSH, Region VIII
Denver, Colorado

Evaluation Assistance:

John M. Peters, M.D.
Professor of Occupational Health
University of Southern California
School of Medicine
Los Angeles, California

Elizabeth A. Plyler, M.P.H.
Research Associate
Division of Occupational Health
University of Southern California
School of Medicine
Los Angeles, California

Pierre L. Belanger, M.S.
Industrial Hygienist
NIOSH, Region IX
San Francisco, California

Originating Office:

Hazard Evaluation and Technical Assistance Branch (HETAB)
Division of Surveillance, Hazard Evaluations & Field Studies (DSHEFS)
NIOSH, Cincinnati, Ohio

Report Typed By:

Marilyn K. Schulenberg
Occupational Health Technician
NIOSH, Region VIII
Denver, Colorado

X. DISTRIBUTION AND AVAILABILITY

Copies of this report are currently available upon request from NIOSH, Division of Standard Development and Technology Transfer, Information

Resources 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, Publications Office, at the Cincinnati address.

Copies of this report have been sent to:

1. Lear Siegler, Inc.
2. International Association of Machinists and Aerospace Workers, District 50.
3. International Association of Machinists and Aerospace Workers.
4. U.S. Department of Labor/OSHA - Region IX.
5. NIOSH - Region IX.
6. California Department of Health.
7. State Designated Agency.

For the purpose of informing affected employees, a copy of this report shall be posted in a prominent place accessible to the employees for a period of 30 calendar days.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
ROBERT A. TAFT LABORATORIES
4676 COLUMBIA PARKWAY, CINCINNATI, OHIO 45226

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

Third Class Mail

POSTAGE AND FEES PAID
U.S. DEPARTMENT OF HHS
HHS 396