INDUSTRYWIDE STUDIES REPORT
A WALK THROUGH SURVEY OF

ROSS LABORATORIES
(Division of Abbott Laboratories)
625 Cleveland Avenue
Columbus, Ohio 43216

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16. Abstract (Limit: 200 words)

A walk through survey was conducted at Ross Laboratories, a Division of Abbott Laboratories (SIC-2023, SIC-3069), Columbus, Ohio in August, 1985. The purpose of the survey was to determine the feasibility of including the facility in a NIOSH industry wide mortality/industrial hygiene survey of ethylene-oxide (75218). The facility produced infant formula and infant related products, including nipples. The nipples were sterilized with a 12 percent ethylene-oxide/88 percent freon mixture until 1982. After that time, sterilization was performed off site by an independent company. Limited industrial hygiene monitoring for ethylene-oxide had been performed by the company. The data indicated that ethylene-oxide exposures were limited to the room containing the sterilizers. Personnel records existed only back to 1977 to 1978. The company had a full time nurse on the first and second shifts. A physician was available on a contract basis. New employees were given preemployment physicals. Employees received annual physicals until 1982 after which they became optional. The physicals did not include any components relating to ethylene-oxide exposure. The authors conclude that the personnel records are not adequate to identify a cohort of exposed individuals at the facility. The facility will not be included in the NIOSH study.

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DISCLAIMER

Mention of companies names or products does not constitute endorsement by National Institute for Occupational Safety and Health (NIOSH).

PURPOSE:	To evaluate the industrial hygiene records, production processes, and personnel records to determine the suitability of including this facility in the NIOSH Industrywide Studies Branch mortality/industrial hygiene study of ethylene oxide (ETO).
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EMPLOYEE REPRESENTATIVES CONTACTED:	No union.
STANDARD INDUSTRIAL CLASSIFICATION:	2023 - Dairy Products, Condensed and Evaporated Milk 3069 - Fabricated Rubber Products, Not Elsewhere Classified

ABSTRACT

On August 1, 1985, a walk through survey was conducted at Ross Laboratories, a Division of Abbott Laboratories, Columbus, Ohio.

Ross produces infant formula and packages nipples. The nipples were sterilized with ETO on-site until 1982. After 1982, nipple sterilization was done by an outside firm off-site. The company had conducted some limited industrial hygiene sampling with a Miran, a direct reading instrument, and Quazi Ketchem charcoal tubes. The results indicated that the ETO exposure was limited to the room which contained the sterilizers, therefore, the number of workers exposed was quite small. Following a review of the personnel records, it was determined that the personnel records were not adequate to identify a cohort of exposed individuals, therefore, this facility will be excluded from the retrospective cohort mortality study.

INTRODUCTION

Ethylene oxide (ETO) is one of the 25 chemicals of highest production volume in the United States.[1] The major portion of ETO produced is used in the production of ethylene glycol (antifreeze) and as a chemical intermediate for polyester films, fibers, and bottles. A small fraction of ETO, less than 0.24%, has been used by the health care and medical supply industries over the past 35-40 years to sterilize heat-sensitive medical supplies.[1]

ETO, a colorless gas at standard temperature and pressure or a liquid at higher pressures, is miscible with water, ethanol, ether, and most common organic solvents. In addition, it is highly explosive when in concentrations of 3 to 100% (ETO) in air.[2] The biological warning properties are essentially useless since the (ether-like) odor threshold among individuals ranges from 300 to 1,500 parts per million (ppm) and adverse health effects may be elicited at levels much less than this.[3]

Due to the toxicity and possible carcinogenicity of ETO (see section on Toxicity), NIOSH researchers initiated an investigation in 1982 to assess the feasibility of conducting a cohort mortality study and industrial hygiene evaluation of workers exposed to ETO. Based on the data gathered during the feasibility study, it was concluded that the cohort of workers in the health care and medical supply industry, specifically those workers exposed to ETO in industrial sterilization processes, was the most adequate group to support a cohort mortality study.[4] This decision was supported by the findings of a 1977 survey conducted by National Institute for Occupational Safety and Health (NIOSH) researchers which showed that it is in this industry most of the employee exposures occur.[5,6] This survey estimated that approximately 75,000 health care workers were employed in ETO sterilization operations, with an additional 25,000 employees which may have incidental exposure resulting from inadequate engineering controls.[5,6]

This walk-through survey was conducted to determine the suitability of including Ross Laboratories (a division of Abbott Laboratories) in the industrywide mortality and industrial hygiene study of workers potentially exposed to ETO in industrial sterilization processes. The suitability of including this facility was based on data gathered in this walk-through and is discussed in the Conclusion and Recommendation section. In addition, the data gathered during the walk-through survey will be used to develop, to the extent possible, estimates of exposure to ETO by department and/or job category, level and duration of continuous and peak exposures, and calendar year within this plant. These exposure estimates will then be compiled into an exposure matrix which will be used to determine the existence of a dose response relationship with any positive association observed in the mortality study.

The authority and responsibility for conducting and reporting on field studies in industry was given to NIOSH under the Occupational Safety and Health Act of 1970 (set forth by the 91st Congress, S.9123, Public Law 91-596). Section 20(a)7 states that NIOSH shall conduct and publish industrywide studies of the effects of chronic low level exposure to

industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in the aging adult.

DESCRIPTION OF FACILITY

Ross Laboratories, a Division of Abbott Laboratories, began operations in Columbus, Ohio as part of Moore's and Ross Dietetic Laboratories in the early 1920's. Ross was purchased by Abbott in 1966. Ross, which produces infant formula and packages nipples, is located in several buildings at one site. ETO usage occurred from 1966 until 1982 when it was discontinued. The only product that was sterilized with ETO were the nipples in plastic blister packs. The sterilizers were always at the same location within the complex. The quarantine area for the sterilized goods was adjacent to the sterilizers. There is a cafeteria on-site where the employees eat and/or take their breaks from work.

DESCRIPTION OF WORKFORCE

The current employment at the plant is approximately 520, of whom approximately 70 are exempt management, while the rest are hourly employees. Approximately 71% of the workforce is male. Approximately 80% of the workforce is white. The average age of the hourly workforce is 41. Turnover is approximately 6% a year.

DESCRIPTION OF PROCESS

Ross Laboratories, a division of Abbott Laboratories, markets many infant related products, including nipples. The nipples were sterilized on-site with a gas mixture of 12% Ethylene Oxide (ETO) and 88% Freon (12/88) until 1982. After that time, the sterilization was done off-site by an independent company.

The nipples were placed in blister packs, and the packs were machine sealed in the blister pack area. The sealed packs were palletized and transported to the sterilizer area, which was located adjacent to the blister area. Biological Indicator strips (BIs) were placed in and around the cases by the sterilizer operators, and the pallets were loaded into the sterilizers. The product was in the sterilizer for about 5.5 hours, with an exposure time of about 4 hours. At the end of the cycle, the vessel was flushed with two air washes. The sterilizer operator then removed the product and the BIs. The BIs were taken to the Microbiology area by the Microbiology personnel. The product was taken to the warehouse, where it aerated for about 30 days. After that time, the product was shipped from the facility.

DESCRIPTION OF PAST EXPOSURES

There have been several procedural changes since 1977 which should have reduced employee exposure to ETO. The major changes were:

March, 1977

1. Cylinders were no longer vented to the work area to determine the amount of ETO in the cylinder.
2. The vacuum discharge to the sewers was enclosed.

April, 1977
1. Product was taken directly to the aeration area of the warehouse after it was removed from the sterilizer.

September, 1977
1. The air drain to the main water outlet was sealed.
2. The final vacuum was changed to allow two air changes instead of one.

May, 1978
1. A bulk ETO tank replaced individual ETO cylinders.

September, 1978
1. Ceiling fans were installed in the warehouse and the sterilizer area.

June, 1980
1. A hood was installed in the microbiology area.

April, 1982
1. The use of ETO was discontinued.

DESCRIPTION OF MEDICAL. INDUSTRIAL HYGIENE AND SAFETY PROGRAMS

Medical Program

Ross Laboratories has a full-time nurse on the first and second shift. There is a physician available on a contract basis. Every employee is given a pre-employment physical. Employees received annual physicals until 1982, after which time they became optional. There were no special components of the physical relating to ETO exposure.

Industrial Hygiene and Safety

Ross has had an industrial hygiene and safety program for many years. In 1981, the day to day responsibility for the industrial hygiene and safety programs was transferred from the corporate level to the plant. The first industrial hygiene sampling (grab samples with bags analyzed by gas chromatography) for ETO was conducted by the analytical chemistry section of Ross Labs in 1977. These samples were collected in the general sterilizer area, including the control panel and printer area, the aeration area of the warehouse, and the elevator area. These samples may not have been an accurate evaluation of exposure in these areas, due to use of an inappropriate sampling protocol, however, they could probably have been used to indicate extent of exposure to ETO. The corporate industrial hygienist used Quazi Ketchem tubes to collect breathing zone height general area samples (1978-1980) as well as personal breathing zone samples on the

sterilizer operators and fork lift drivers (1980-1981). These samples were analyzed by the corporate industrial hygiene laboratory.

Respirators for ETO were never used by any personnel at this facility.

DESCRIPTION OF PERSONNEL RECORDS

Approximately 430 active hourly records were arranged alphabetically, as were approximately 70 active salaried records. A search of the personnel records, in both the personnel office area and the records storage area, revealed that the records for terminated hourly employees existed only back to 1977-78. Given that the requirements for the first portion of the mortality study is that exposure must have occurred prior to 1/1/78, the nonexistence of the hourly terminated records prior to 1977-78 means that few person-years would be available at this plant.

Furthermore, sterilization occurred in the assembly of blister-packs which was an isolated area within a large facility with many buildings. The blister pack operation was a sub-department, part of department 890, the Finishing Department. Finishing A and Finishing B were also sub-departments in the Finishing Department, but were located in different buildings and did not involve exposure. However, personnel records since the early 1970's list only the overall department number, and do not permit the identification of sub-department. Hence, from personnel records it would be impossible to tell whether an individual who worked in department 890 was exposed, after approximately 1971-72.

Given these limitations in the records system, no sampling of personnel records was conducted, and it was concluded that the personnel records were inadequate to identify a cohort of exposed individuals.

TOXICITY

Evidence from animal studies suggests that ETO may have carcinogenic properties.[7,8] A group of ETO manufacturers sponsored a study at the Bushy Run Research Center in which male and female Fischer 344 rats were exposed to ETO at airborne concentrations of 10, 33, or 100 parts per million (ppm) for 6 hours per day, 5 days per week for two years.[7] Two other groups of animals served as controls. Initially, there were 120 animals of each sex, in each exposure group. The researchers observed a statistically significant increase in the incidence of mononuclear cell leukemia among the female rats, and peritoneal mesothelioma among the male rats exposed to ETO. The increase in leukemia incidence was found to increase linearly as a function of ETO exposure. An elevation in incidence of brain cancers (glial type) was also observed in the rats exposed to ETO.

NIOSH researchers have recently reported on the results from an animal experiment which corroborated the findings of the Bushy Run Study.[8] Male Fischer 344 rats were exposed to ETO for 7 hours/day, 5 days/week for 2 years at airborne concentrations of 0, 50, or 100 ppm. There were 80 rats in each exposure group. Increases in the incidence of mononuclear leukemia,

peritoneal mesothelioma, and cerebral gliomas were observed among the ETO exposed rats, relative to nonexposed controls.

Only a few epidemiologic studies have examined the potential human carcinogenicity of ETO.[9-11] Hogstedt, et al, conducted a retrospective cohort mortality study of a group of workers in a Swedish chemical factory that had previously been included in a hematologic investigation.[9] This facility produced ETO via the chlorohydrin process in which, in addition to ETO, there was potential exposure to ethylene, ethylene chlorohydrin, ethylene dichloride, and small amounts of bis(2-chloro-ethyl) ether. Among 89 "full-time" exposed workers, a statistically significant (p less than .01) excess of leukemia mortality was observed (2 observed versus 0.14 expected). In addition, a statistically significant (p less than .01) excess of stomach cancer was observed (3 observed versus 0.4 expected). Because of the mixed exposures, these findings could not be attributed to ETO; however, ethylene oxide and ethylene dichloride were the prime suspects.

Morgan, et al, conducted a retrospective cohort mortality study of workers involved in the production of ETO at a Texaco Facility.[10] A total of 850 workers were included in the study, of which 767 were potentially exposed to ETO. No ETO was detected in most samples taken in the production area, and all measurements in this area were below 10 ppm. No cases of leukemia were observed in this study; however, the authors estimated that the lowest relative risk that they had a high probability of detecting (80% power) was 10.5.

Hogstedt also reported on three cases of leukemia that occurred in a small group of workers at a Swedish company.[11] The company used a mixture of 50% ETO and 50% methyl formate to sterilize hospital equipment. The 8-hour TWA exposure for ETO at this facility was estimated at 20 ppm. According to national statistics, only 0.2 deaths due to leukemia were expected in this cohort. One of the cases was exposed to benzene, a known leukemogen, and it was speculated that the combined exposure of ETO and methyl formate might produce a special risk.

ETO is also a potent alkylating agent capable of causing irreversible changes or mutations in cellular proteins and DNA in animals.[12,13] ETO is also a positive mutagen in several *in vitro* systems such as *Salmonella typhimurium*, viruses, and *Tradescantia poludosa*.[6]

Chromosomal aberrations related to ETO exposure have been observed in a number of animal studies and epidemiologic investigations.[8,13-20] Yager and Benz observed a dose related increase in sister chromatid exchanges (SCEs) among New Zealand white rabbits that were exposed via inhalation to 50 to 250 ppm of ETO.[14] NIOSH (Lynch, et al) recently reported preliminary findings in which cynomolgus monkeys were exposed to 0, 50, or 100 ppm of ETO for 7 hours per day, 5 days per week.[8] After 24 months of exposure, statistically significant increases were observed in the frequency of chromosomal aberrations (including quadriradial chromosomes) and SCEs in the peripheral lymphocytes of the 50 and 100 ppm exposed groups versus the controls.

Garry, et al, examined the occurrence of SCE in the peripheral lymphocytes of 12 ETO exposed workers and 12 nonexposed controls in a hospital sterilization facility.[15] The exposed group showed statistically significant elevations in the number of SCEs compared to the controls. Particularly high SCE frequencies were observed among 4 workers that had reported either neurologic or respiratory symptoms. The maximum peak exposure level of ETO measured at this facility was 36 ppm.

Cytogenetic abnormalities have also been observed in several studies of workers exposed to ETO. Ehrenberg, in a study of workers at a factory manufacturing and using ETO, observed a high frequency of chromosomal aberrations in 8 workers who were accidentally exposed to high concentrations of ETO. One case of leukemia was also observed among the 37 workers studied.[16]

American Hospital Supply initiated a cytogenetic survey of workers that were exposed to ETO in the sterilization of medical devices in 1978.[17,18] Seventy-five exposed workers at 9 facilities were studied, as well as 37 nonexposed workers who served as controls. Compared to controls, exposed workers were found to have statistically significant increased frequencies of SCEs and chromosomal aberrations.

In response to the findings from the American Hospital Supply study, Johnson and Johnson initiated a cytogenetic study of workers that were also exposed to ETO in the sterilization of medical products.[19,20] Approximately 50 workers not exposed to ETO were compared to 50 exposed workers at three facilities with 8-hour Time-Weighted Average (TWA) exposures to ETO of less than 1 ppm, 1-10 ppm, and 25-200 ppm, respectively. Statistically significant elevations in SCE frequency were observed in the latter two facilities, and these changes have persisted after one year. The frequency of SCEs appeared to increase in a dose response manner. Chromosomal aberrations were also elevated in the high exposure groups; however, these findings were not statistically significant.

APPLICABLE STANDARDS AND RECOMMENDED LEVELS

Prior to June 22, 1984, the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for ETO was 50 ppm as a TWA concentration for an 8-hour workshift.[21] OSHA established a new PEL of 1 ppm as an 8-hour TWA on August 21, 1984.[22] In addition, an "action level" of 0.5 ppm as an 8-hour TWA was established (by OSHA) as the level above which employers must initiate periodic employee exposure monitoring and medical surveillance. The Environmental Protection Agency (EPA) supported the OSHA PEL of 1 ppm in the Federal Register (June 22, 1984).[23]

In 1977, NIOSH recommended a ceiling level of 75 ppm as determined during a 15 minute sampling period.[6] This level, however, was set prior to the recognition of the carcinogenic potential of ETO. Based on recent findings, NIOSH recommends that ETO exposures not exceed 5 ppm for a maximum of 10 minutes per day and that exposures be controlled to less than 0.1 ppm determined as an 8-hour TWA (NIOSH Policy Statement, July 20, 1983). The American Conference of Governmental Industrial Hygienists (ACGIH) recommends

a Threshold Limit Value (TLV) of 10 ppm for an 8-hour TWA based on data available prior to 1982.[24] However, in 1982, the ACGIH issued a notice of intended change in which it was proposed that the TWA concentration be lowered to 1 ppm. This recommendation was reviewed and adopted in 1984. ACGIH has also designated ETO as an A2 carcinogen.[24] An A2 carcinogen is defined as an industrial substance suspected of having carcinogenic potential for man. This designation is based on either (1) limited epidemiologic evidence, exclusive of clinical reports of single cases, or (2) demonstration of carcinogenesis in one or more animal species by appropriate methods.

CONCLUSIONS

There are limited industrial hygiene data that could be used to construct an exposure matrix for this facility. A review of the personnel records revealed that the records were not adequate to identify a cohort of exposed individuals at this facility. It was concluded, therefore, that this facility would be excluded from the retrospective cohort mortality study.

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