

INDUSTRYWIDE STUDIES REPORT OF
WALK-THROUGH SURVEY

PROJECT NUMBER: P:84:12

MICRO-BIOTROL
1437 W. 37th Street
Chicago, Illinois 60609

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DATE OF SURVEY:
August 13-14, 1984

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Industrial Hygiene Section
Industrywide Studies Branch
Division of Surveillance, Hazard Evaluations and Field Studies
National Institute for Occupational Safety and Health
Centers for Disease Control
Cincinnati, Ohio

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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:

None

STANDARD INDUSTRIAL

CLASSIFICATION OF PLANT:

2099 - Food Preparations, Not Elsewhere Classified

ABSTRACT

On August 13-14, 1984, a walk-through survey was conducted at Micro-Biotrol Company, a division of Griffith Laboratories USA, Incorporated and Griffith Labs USA, Incorporated in Chicago, Illinois, to evaluate industrial hygiene and personnel records, production processes, and document historic use of ethylene oxide (ETO) as part of an industrywide study of mortality associated with an occupational exposure to ETO.

Griffith Labs ETO treatment department was founded in the early 1930's, to treat Griffith products (primarily spices and spice blends). Treatment with 100% or 12/88 ETO was conducted on an intermittent basis with 1 to 3 vessels from the early 1930s through the 1940s. In the early 1940s, the operation expanded considerably and ETO treatment was conducted on a full-time basis. Griffiths ETO treatment department also offered its services to other companies on a contract basis. Contract ETO treatment is Micro-Biotrol's, chief service today.

The Griffith Labs, Chicago facility, houses the Micro-Biotrol, Incorporated Chicago treatment operation, Griffith Design and Equipment Company (since 1975), and Griffith Labs processing (spice grinding). Micro-Biotrol and Griffith Labs corporate headquarters, and Griffith spice blending and packaging moved to Alsip, Illinois, a suburb of Chicago, in 1975. Micro-Biotrol's Chicago treatment operations are planning to move to Willowbrook, Illinois in mid 1985.

Some industrial hygiene sampling for ETO has been conducted by either the company or a consulting service. The levels are less than 50 ppm for all jobs sampled, however, one job has a 8 hr TWA exposure as high as 24 ppm.

This plant meets the three eligibility requirements as defined in the protocol and therefore, should be included in the study. These requirements are: 1) the plant must contribute at least 200 person-years to the high exposure group, or 400 person years total, 2) the plant must have adequate personnel records or other records that can be used for identifying past and present workers exposed to ETO, and 3) the plant must not have any serious confounding exposure to a known leukemogen.

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 Micro-Biotrol-Chicago plant 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

Griffith Labs ETO Treatment Department was established in Chicago, Illinois, as part of Griffith Laboratories, in the early 1930's, to treat Griffith products (primarily spices and spice blends). Micro-Biotrol became a separate sales division under Griffith Labs in 1970. In 1979, Micro-Biotrol became a separate operating division. Griffith Labs Chicago, is a large complex of many buildings, with Micro Biotrol-Chicago plant primarily located in 4 of them (B-1 and B-2 first floor, sterilizers and pre-tempering; C, storage; and G, offices and lunchroom, see Appendix I). Building B-1 contains Griffith Labs Nu-Spice (a registered trade mark) process on the second floor. Building D, which is shared with Griffith Labs, is used for shipping. Building E currently houses Griffith Labs' hydrolysate process and maintenance. Prior to 1971, Building E and C housed the GD&E production area. The first floor of Building F is warehouse area. The upper floors house mustard grinding and the offices for Griffith Design and Equipment Company (GD&E), a department of Griffith Labs, USA which produces food processing equipment. GD&E moved into the building in 1975. Building F is warehouse on the first floor. Building H contains the hydrolysate process on the second floor. Building I was used as a warehouse between 1971 and 1975. Building I housed Griffith Design and Equipment production areas after 1975. Griffith's corporate and Micro-Biotrol Sales and Company headquarters were also located in this complex until 1975, when they were relocated to a new facility in Alsip, Illinois a suburb of Chicago. In 1975, Griffith Labs spice blending and packaging operation also moved to Alsip.

Treatment with 100% ETO or a 12/88 mixture of ETO and freon was conducted on an intermittent basis with 1-3 vessels (Number 7, 360 ft³, Number 2, 58 ft³; Number ?, about 60 ft³) from the early 1930s through the 1940s. In the 1950s, the treatment operations were transferred from the original location on the fourth floor of Building A to the first floor of Building B-2 where it was located at the time of this survey. In the early 1940s ETO treatment had become a full-time operation which by 1951 had necessitated the addition of two additional vessels (number X, about 150 ft³; number 8, 259 ft³). Vessels 4,5,6-279 ft³ each and vessel number 1, 375 ft³ were added between 1951 and 1961 in Bld. B-2. Vessel number 1 was removed in 1962. Vessel number 7 and number ? were removed prior to 1962. Small experimental vessel was also installed near vessel 4. In 1970, a new vessel 1 (660 ft³, Bld. B-2) was added. Vessel 3 (660 ft³, Bld. B-1) was installed in 1972, and vessel 9 (660 ft³, Bld. B-1) was added in 1976. Vessel 2 was removed in 1982, leaving Micro-Biotrol-Chicago plant, which became part of a separate operating division from Griffith Laboratories USA in 1979, with 8 vessels. The company's estimated use of ETO for the last year (1983) was 110,364 pounds. Approximately 90% of the merchandise received is treated with 100% ETO or a 12/88 mixture of ETO and freon, the remaining 10% is treated with 100% propylene oxide.

Micro-Biotrol-Chicago plant is anticipating a complete relocation of its treatment operations to Willow Brook, Illinois, by mid 1985.

DESCRIPTION OF THE WORKFORCE

A randomly selected sample of the personnel files of current and former employees was reviewed. Information on year of birth, sex, the year of first exposure, and the year exposure ceased was recorded for workers considered to be potentially exposed to ETO. In order to be considered potentially exposed in this review, a worker must have been employed for at least 3 months in an area or job which has potential ETO exposure (see Definition of Exposure Section). Records from the Micro-Biotrol-Chicago plant, Griffith Labs-Chicago, and Alsip operations were included in the review. Although it is anticipated that the other Chicago operations have workers who are or have been potentially exposed to ETO, it is likely that the number of workers involved would be quite small and thus records from these operations were not included in this review.

In Table 1, the results from this review are presented. All of the workers identified as being potentially exposed to ETO were males. Overall, this group is fairly young with an average year of birth ranging from 1920 to 1949. The duration of exposure at this facility seems to be relatively long, with an average that ranges between about 4 to 9 years. Overall it is estimated, based upon this sample, that there are 290 workers at this facility, who would contribute approximately 3748 person-years to the study. This estimate is probably extremely conservative, since the definition of who is exposed and would be included in the study has greatly expanded since the time of this record review. In particular, most of the Griffith-Chicago operations were not considered to have potential for exposure to ETO, however, since this review, environmental monitoring data has been obtained which suggest that all Griffith operations in the Chicago plant are and have been potentially exposed to ETO. These estimates are also low because they do not include workers from other Griffith operations, who may have been exposed.

DESCRIPTION OF PROCESS

Micro-Biotrol-Chicago plant is a contract treatment facility which treats approximately 90% of the merchandise received with ETO (100% or 12/88). Propylene oxide (100%) is used on the remaining 10%. Once the merchandise is received by Micro-Biotrol, it is palletized. Most of the merchandise is placed in a pretempering room, which is at atmospheric pressure and elevated, in respect to the surrounding rooms to a predetermined temperature and relative humidity, for twelve (12)-twenty-four (24) hours. The preconditioned merchandise is then placed directly in the vessel without being repackaged. The merchandise which was not preconditioned, is also placed directly in the vessel without being repackaged, and the vessel is closed. At the time of this survey, a 3-6 hour treatment cycle is run on about 80% of the product. The remaining 20% of the product is treated for 6-12 hours. The type of gas used (100% ETO, 12/88 ETO/freon or propylene oxide) and the total cycle time are dependent on the type of product being treated.

At the end of the treatment cycle, a vacuum is drawn on the chamber before the chamber is allowed to return to atmospheric pressure. The seal on the

chamber is broken, and the door is opened a few inches. The employees are instructed to leave the area for five minutes before unloading the vessel. The treated product is taken directly to shipping/warehouse (Bld. D), where the product off-gases or aerates for 24 hours to 3 days before it is shipped back to the manufacturer. The shipping/warehouse area is located in one contiguous area on the same floor. There are no separate quarantine or aeration areas.

Griffith Laboratories, USA, which is also located in this same building complex, grinds spices (primarily mustard) in Building F, and produces hydrolyzed protein in Buildings E and H. GD&E Company, a department of Griffith Labs USA, moved into its current location in Building F in 1975. The GD&E production area has been located in Building I since 1975 and in Buildings E and G prior to 1971.

In 1977, Griffith Laboratories Patti Pro (a registered trademark) department, which produced a protein filler for food products, was disbanded. This department was located upstairs in Building B-1.

DESCRIPTION OF PAST EXPOSURES

The interior of this facility has changed little since the original construction of the building around the turn of the century. The company has introduced few modifications to the facility, or changes in work practices which would reduce employee exposure to ETO.

Facility

General

The entire production area has general dilution ventilation. The general flow of air, in the western end of the complex where Micro-Biotrol is located, is through the shipping doors, in Building D toward the back or South of the complex (Building C). The air tends to be pulled up to and through the second floor of Buildings B-1 and B-2 due to this general dilution ventilation system. This air, which may have contained large amounts of ETO, may have been able to infiltrate the entire upper floors of this complex. Several areas of the complex are on separate heating, ventilation and air conditioning (H-Vac) systems, however, reentrainment of ETO, which had been exhausted to the outside, may be a serious problem in this facility.

There has been some relocation of departments within the complex. Most of these changes are discussed in the Description of Facility section. These changes are also outlined in Table II. GD&E offices moved into the complex (Building F) in 1975. Prior to the disbanding of the patti pro (a registered trademark) department (Building B-1, upstairs) in 1977, vinyl strip curtains were installed between the patty pro and maintenance area. The patty-pro area was not utilized at the time of this survey. The GD&E production was located in Building E and G prior to 1971. In 1975, GD&E production moved into Building I.

The company reports no major accidents or leaks involving ETO, however, employees did report occasionally smelling ETO when a tank was changed

(every 2-3 days) or when a vessel was opened (daily). These reports imply that the ambient levels of ETO may have ranged between 300 and 1500 ppm.⁶ The mean odor threshold concentration is 700 ppm.⁶

Treatment Vessels

There are no devoted exhaust ventilation systems for the treatment vessels. Each vessel is equipped with a gas recirculation system, however. Each unit was equipped with a remote water/vacuum pump and water/gas separator in 1973. These pumps are located in Building C. Before 1973, a steam evacuator was used to pull the ETO out of the chamber. The ETO and steam passed through a water gas separator before the steam entered the drain. The drainage system is completely enclosed from the sterilizer to the sewer.

Gassing Stations

The gassing stations, which are located near the treatment vessels, were separated in 1981 from the rest of the area by vinyl strip curtains. A ventilation duct, with a slot opening, is located at the floor toward the rear of the station, and runs the length of the station. This ventilation system is probably ineffective, as ETO does not fall to the ground as had previously been believed. The vessel operator is responsible for charging the vessels with ETO using a semi-automatic system, which was installed in 1976. Prior to that time, a worker had to open the valve of the gas cylinder, which was placed on a scale, and monitor the volume of gas going into the chamber.

Pretempering Room

Vinyl strip curtains were installed in the pretempering room (Building B-1, south end) in 1979. The curtains on the south end of the room serve as the door to Building C.

Aeration Area

There are no dedicated areas of the warehouse for aeration or degassing of treated product, therefore uncontrolled ETO diffusion from the product occurs; adding to the overall ambient ETO levels.

Work Practices

In 1983, the company instituted a standard operating procedure (SOP), which required vessel operators to break the seal on a vessel after it had returned to atmospheric pressure (following the last vacuum and air wash), and wait in an adjacent area for 10-15 minutes. Prior to this time, the employee would enter the vessel almost immediately (about 5 minutes) after it had returned to atmospheric pressure.

Maintenance people are assigned to an area on an as-needed basis. All service (sanitation, maintenance, quality assurance) occurs on the day shift.

DESCRIPTION OF MEDICAL, INDUSTRIAL
HYGIENE AND SAFETY PROGRAMS

Medical

The company gives all employees pre-employment physicals at a near-by clinic. There are no follow-up physicals. The company does not maintain a nurse on staff, however, first-aid kits are available.

Industrial Hygiene

Micro-Biotrol does not have an in-house industrial hygiene program. A consulting firm, however, has provided the safety and industrial hygiene services over the past 10 years. In 1980, some sampling for ETO was conducted by the consulting firm with charcoal tubes. In 1983, Micro-Biotrol required ETO monitoring every 3 months with 3M badges and every 2 months with an organic vapor analyzer (OVA). The passive monitoring data, which is summarized in Table III, reveals that while exposures in all job titles listed were less than the previous standard of 50 ppm (8-hour TWA) many of these exposures would exceed the existing standard of 1 ppm. In addition, reported values may be low, as there is a trend toward decreased recovery and sampling capacity for increased exposure time at high concentrations when using passive monitors. The vessel operators are the highest exposure group with 8 hr TWA ranging from 1-24 ppm with an average exposure of 8.5 ppm. The lowest exposure group is GD&E office with an average exposure of 0.3 ppm (8 hr TWA) and a range of 0.5-0.5. The company did not have a respirator program at the time of this survey.

Safety

The company requires the use of hard hats and safety shoes by all employees. Safety glasses are required on an as-needed basis. There is a safety committee composed of management and worker representatives.

DESCRIPTION OF RECORD SYSTEMS

Current Employees

Personnel records for current Corporate (Griffith Labs and Micro-Biotrol Headquarter) and Alsip employees (Griffith Labs and Micro-Biotrol) are filed at the Alsip facility. The Chicago facility maintains personnel files for both Chicago Griffith and Micro-Biotrols current employees. These files contain application forms, preemployment physical exam reports, and wage, salary and transfer records. Demographic information (i.e. date of birth, sex) needed for the study could be obtained from the application forms. The wage, salary and transfer records are filed each time there is a change in position or salary, and could therefore be used for creating detailed occupational histories.

'Rate Change Cards' are maintained on file for all current Griffith and Micro-Biotrol employees at the Alsip facility. These cards contain most of the information required for the study including: date of birth, social security number, detailed work histories, and current address. These cards also indicate which facility an individual is currently working at. Since all of this information is located on one piece of paper, these cards would

provide a far more convenient source of information for the study than the personnel files described above.

At the time of this survey there were a total of 454 active employees working in the various Griffith operations in the Chicago area. Following is a breakdown of the approximate number of active employees for each of the Chicago divisions: Griffith Corporate - 183 employees, Griffith Chicago plant - 54 employees, Alsip plant - 172 employees, Griffith Labs Incorporated - 17 employees, Griffith Design and Equipment - 11 employees, Micro-Biotrol Corporate - 7 employees, and Micro-Biotrol Chicago plant - 10 employees.

Former Employees

Rate cards and personnel files for former employees are interfiled together and stored at a warehouse. These records are identical to the ones described above for active employees and are also separated by the Griffith divisions. Unfortunately it seems that these files do not contain records for workers terminated prior to sometime in the mid 1960s.

There are a total of approximately 1739 personnel records for former employees from the various Griffith operations in the Chicago area.

The file drawer for Micro-Biotrol Chicago, contains only 5 individual files. The small number of records in this file is due to the fact that Micro-Biotrol became a separate operating division from Griffith in 1979, and only a small number of workers have begun employment with Micro-Biotrol-Chicago plant since then. For Griffith Labs Chicago there were 5 file drawers containing 1350 personnel files for all former employees. For the Alsip Plant there were 2 file drawers containing approximately 295 personnel files for all former employees. Personnel files for Griffith Corporate and Griffith Labs Incorporated were filed together in one drawer containing approximately 51 records of all former employees. For Griffith Design and Engineering there was one drawer containing approximately 38 personnel files for all former employees.

Other Record Systems

The personnel office maintains an index card system, which contains a card for every employee that has been employed by Griffith Labs since about 1960. These cards contain the following information: name, social security number, first and last date employed, birthdate, department number and address. These records do not contain detailed work histories. There are a total of about 4700 of these cards on file.

The payroll department has quarterly earnings reports prepared for IRS back to 1964. They also have a few payroll records from earlier time periods, although these are spotty at best.

In summary, personnel records exist which can be used to identify current workers, and workers terminated since the mid 1960s who have been potentially exposed to ETO. These records contain adequate demographic and occupational history information for the purposes of the mortality study.

DEFINITION OF EXPOSURE

Currently only employees from Micro-Biotrol-Chicago plant, Griffith Chicago plant, and Griffith Design and Equipment have a potential for ETO exposure and would be included in the study. Prior to the construction of the Alsip facility in 1975 all of these workers were located at the Chicago facility and were potentially exposed to ETO and would be included in the study.

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 mortality from 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 AND RECOMMENDATIONS

This plant meets the three eligibility requirements as defined in the protocol and therefore, should be included in the study. These requirements are: 1) the plant must contribute at least 200 person-years to the high exposure group, or 400 person years total, 2) the plant must have adequate personnel records or other records that can be used for identifying past and present workers exposed to ETO, and 3) the plant must not have any serious confounding exposure to a known leukemogen.

Some industrial hygiene sampling for ETO has been conducted by the company or a consulting firm. The levels are less than 8 hr TWA of 50 ppm for all jobs evaluated, however, one job has a TWA as high as 24 ppm..

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TABLE I

SUMMARY OF RESULTS FROM THE SAMPLING OF PERSONNEL RECORDS^a

DIVISION	EMPLOYMENT STATUS	TOTAL # RECORDS (#SAMPLED)	EST. %EXP	EST. #EXP	YEAR BIRTH	AVERAGE ^b		ESTIMATED PERSON-YRS ^c
						YR 1ST EXP	DUR EXP	
Micro-Biotrol 24 (Chicago) 80	Inactive	5 (5)	40	2	1944	1971	9.0	
	Active	51 (51)	20	10	1949	1975	7.8	
Griffith 2492 (Chicago) 344	Inactive	1350 (68)	13	178	1936	1969	3.7	
	Active	54 (10)	80	43	1944	1975	6.1	
Alsip Plant 658 150	Inactive	295 (30)	16	47	1933	1969	3.7	
	Active	172 (17)	6	10	1920	1968	7.0	
Totals 3748		1927 (181)		290				

a The following abbreviations are used in this table; exp for exposed or exposure, dur for duration, yr for year.

b Averages are based on data from the workers classified as being potentially exposed in this review.

c Person years were estimated by multiplying the estimated number of exposed workers times the length of time between 1983 and the average first year of exposure. For example it is estimated that there are 178 former employees that were potentially exposed to ETO at Griffith Labs. The average first year of employment for this group was 1969, and thus the average length of followup would be 14 years (1983-1969) and the estimated number of person-years is 2492 (178 x 14).

TABLE II
 MICRO BIOTROL, INCORPORATED
 CHICAGO PLANT
 AUGUST 13-14, 1984

<u>YEAR</u>	<u>EVENT</u>
Early 1930s	Griffith Labs established ETO Treatment Department, Building A.
1930s-1940s	Operated 3 vessels #7, 360 ft ³ ; #2, 58 ft ³ ; #7, about 60 ft ³ .
1950s	Moved ETO operation to Building B-2.
1951	Add 2 more vessels #X 150 ft ³ ; #8, 259 ft ³ .
1951-1961	Add 4 more vessels #4, 5, 6 - 279 ft ³ each; #1, 375 ft ³ .
1962	Remove vessel #1.
1970	Add new vessel #1, 660 ft ³ ; Micro-Biotrol becomes separate sales division under Griffith Labs
before 1971	GD&E production occupies space in Buildings E and G.
1971-1975	Building I is used as warehouse.
1973	Treatment vessels are equipped with remote water/vacuum pump and water/gas separator.
1975	GD&E production moves back into Building I.
1975	Vinyl strip curtains installed at gassing stations.
1976	GD&E office moves into Building F
1976	Add vessel 33, 660 ft ³ , add vessel #9, 660 ft ³ .
1977	Patti-Pro ^R department is disbanded.

TABLE II (continued)

MICRO BIOTROL, INCORPORATED
 CHICAGO PLANT
 AUGUST 13-14, 1984

<u>YEAR</u>	<u>EVENT</u>
1979	Micro-Biotrol becomes separate operating Division of Griffith Labs.
1979	Vinyl strip curtains installed at entrance and exit of pretempering room.
1980	Limited industrial hygiene sampling (charcoal tube) for ETO conducted by consulting firm.
1982	Remove vessel 2.
1983	SOP instituted that required vessel operators to open vessel and wait 10-15 minutes in an adjacent area before entering vessel.
1983	Micro-Biotrol establishes requirement for ETO sampling with 3M Badges every 3 month and Organic Vapor analyzer every 2 months.

TABLE III
 MicroBiotrol, Chicago Plant+
 Passive Monitors (3M Badges)
 Ethylene Oxide
 8 hr TWA

Micro-Biotrol

Corporate					
<u>Date</u>	<u>N@</u>	<u>\bar{X} ppm</u>	<u>Sd</u>	<u>Range ppm</u>	<u>0.5*</u>
6-83	3	1.7	1.2	1-3	0
10-83	3	0.3	0.1	< 0.5-0.5 ^o	2
3-84	5	0.25	0	< 0.5	5
9-84	6	0.6	0.3	< 0.5-1	2
<u>X</u>	17	2.1	5.9	< 0.5-3	9
Vessel Operators					
6-83	3	9.0	6.6	3-16	0
10-83	3	7.7	4.0	3-10	0
3-84	5	12.8	9.8	5-24	0
9-84	5	9.0	5.8	3-17	0
<u>X</u>	16	9.6	2.2	3-24	0
Q A Tech					
6-83	1	3	--	--	0
10-83	1	1	--	--	0
3-84	1	2	--	--	0
9-84	1	2	--	--	0
<u>X</u>	4	2	0.8	--	0
Dept. Head					
6-83	1	6	--	--	0
10-83	1	1	--	--	0
3-84	1	6	--	--	0
9-84	1	4	--	--	0
<u>X</u>	4	4.3	2.4	--	0
Office Clerk					
6-83	1	1	--	--	0
10-83	1	< 0.5 (7.5 hr)	--	--	1
3-84	1	< 0.5	--	--	1
9-84	1	0.7	--	--	0
<u>X</u>	4	0.6	0.4	--	2
Regional Manager					
6-83	1	2.0	--	--	0
10-83	1	< 0.5	--	--	1
3-84	1	0.8	--	--	0
9-84	1	0.7	--	--	0
<u>X</u>	4	0.9	0.8	--	1

<u>Date</u>	<u>N@</u>	<u>\bar{X} ppm</u>	<u>Sd</u>	<u>Range ppm</u>	<u>0.5*</u>
Warehouse Clerk					
6-83	1	5.0	--	--	0
10-83	1	2.0	--	--	0
3-84	1	3.0	--	--	0
9-84	<u>1</u>	<u>1.0</u>	<u>--</u>	<u>--</u>	<u>0</u>
\bar{X}	4	2.8	1.7	--	0
<u>GDE 9-84</u>					
Office	7	0.4	0.1	< 0.5-0.5	4
Maintenance	3	0.3	0.1	< 0.5-0.5	2
Foreman	1	0.25	--	< 0.5	1
Store Keeper	<u>1</u>	<u>0.25</u>	<u>--</u>	<u>< 0.5</u>	<u>1</u>
	12	0.3	0.1	< 0.5-0.5	8
<u>Griffith Labs 9-84</u>					
Chem Operator/ Packer	11	1.3	0.9	< 0.5-3	1
Grinder	2	0.8	0.3	0.6-1	0
Sanitor	4	1.5	0.6	1-2	0
Lift Truck	3	0.8	0.3	0.5-1	0
Supervisors	11	0.8	0.5	< 0.5-2	3
Chem Foreman	4	1.0	0.7	< 0.5-2	1
W/H Foreman	1	1	--	--	0
QA Manager	1	0.6	--	--	0
Maint Foreman/ Supervisor	3	0.6	0.4	< 0.5-1	1
Plant Manager/ Pro Supv.	3	0.6	0.5	< 0.5-1	1
Stores	1	0.25	--	--	1
Maintenance	9	0.7	0.3	< 0.5-1	3
Guard	3	0.6	0.4	< 0.5-1	1

<u>Date</u> <u>Office</u>	<u>N</u> [@]	<u>\bar{X}</u> ppm	<u>Sd</u>	<u>Range</u> ppm	<u>0.5</u> [*]
	2	0.4	0.2	< 0.5-0.5	1
Secretary	1	0.25	--	< 0.5	1
<u>\bar{X}</u> Clerk	<u>1</u>	<u>0.5</u>	<u>--</u>	<u>--</u>	<u>0</u>
	46	0.9	0.70	< 0.5-3	10

@ Number of samples collected.

* Number of samples reported less than limit of detection (0.5).

+ Data supplied by company.

o When less than 0.5 (< 0.5) was reported, 1/2 this value (0.25) was used to calculate mean.