



INDUSTRYWIDE STUDIES REPORT OF  
WALK-THROUGH SURVEY OF

THE KENDALL COMPANY  
U.S. 31, W. North  
Franklin, Kentucky 42134

SURVEY CONDUCTED BY:  
Alice Greife, IHS  
Leslie Stayner, Epi II

DATE OF SURVEY:  
June 12-13, 1985

REPORT WRITTEN BY:  
Alice Greife  
Leslie Stayner

DATE OF REPORT:  
July 1, 1986

REPORT NUMBER:  
67.40

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).

**EMPLOYER REPRESENTATIVES  
CONTACTED:**

The Kendall Company  
Robert Jagger, General Manager  
(502) 586-3261

Fred Bolek, Plant Superintendent  
(502) 586-3261

David Siskind, Regulatory Attorney  
Boston Massachusetts  
(617) 423-2000

Dan Leonard, Industrial Hygienist  
Augusta, Georgia

**EMPLOYEE REPRESENTATIVES  
CONTACTED:**

No union.

**STANDARD INDUSTRIAL CLASSIFICATION  
OF PLANT (SIC):**

3842 - Orthopedic, Prosthetic and  
Surgical Appliances and Supplies



## ABSTRACT

On June 12-13, 1985, a walk-through survey was conducted at The Kendall Company, Franklin, Kentucky. Kendall has produced plastic adhesive bandages which are sterilized with ETO at this site since 1960. The purpose of this survey was to evaluate the industrial hygiene records, production processes, and personnel records to determine the suitability of including this facility in the mortality/industrial hygiene study of ETO being conducted by NIOSH researchers.

Industrial hygiene sampling data for ETO, which has been collected at this facility since 1981, are summarized in this report. Data collected in 1984 show that low levels of ETO were present throughout the facility. Personnel records are sufficient to document work in exposed areas.

This plant meets all eligibility requirements as defined by the protocol of the ETO mortality study and will, therefore, be included. These requirements are: 1) the plant must contribute at least 400 person years, 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.

At this time, there are no industrial hygiene surveys planned at this plant by NIOSH researchers.



## INTRODUCTION

Ethylene oxide (ETO) is one of the 25 chemicals of highest production volume in the United States.<sup>1</sup> 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.<sup>1</sup>

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.<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup> 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.<sup>5,6</sup> 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.<sup>5,6</sup>

This walk-through survey was conducted to determine the suitability of including The Kendall Company, Franklin, Kentucky, 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

The Kendall Company has two (2) plants located adjacent to each other in Franklin, Kentucky. The first plant, which was started in 1957, is called Polyken and produces two (2) main product lines: industrial tapes and pipe wrap tape. Ethylene Oxide (ETO) has never been used at this facility, therefore this facility will not be discussed in this walk-through report. The second facility, the Adhesive Plant, has three departments, one of which produce plastic adhesive bandages. All departments are located within the same single story building (see Figure 1). These departments are Plaster Finish, Solvent Spread, and Curad. The Adhesive Plant, which is about 290,000 ft<sup>2</sup>, started operations in 1960, with ETO sterilization of the Curad products beginning in 1962. The company estimates the total pounds of ETO used over the last several years has varied.

This facility has a cafeteria on-site, where the employees may eat and/or take their breaks.

## DESCRIPTION OF THE WORKFORCE

The age, race and sex composition of the workforce at this plant is diverse and is represented by both sexes, several racial groups, and people varying in age. Personnel records do include information on the age, sex, and race composition of the workforce as part of their equal employment opportunity program. There appears to be very low turnover of employees at this plant (see record review section).

## DESCRIPTION OF PROCESS

The Adhesive Plant, which was started in 1960, has three (3) departments. The first department is called Plaster Finish, and produces industrial, hospital, and sports tapes; spool adhesives; and cast film. The second department is called Solvent Spread, and produces industrial, hospital, and sports tapes all with a solvent base; pipeline primer; and coats an adhesive Curad vinyl film. The third department is called Curad, and produces Curad adhesive bandages, Telfa, foil pouch, and Polyskin. ETO gas mixture is used only in this department, therefore, this process description section will discuss only the production of Curad products.

Curads are composed of four parts: an adhesive coated substrate of either plastic or cloth, a polyethylene film, a griegge or non woven cotton or synthetic pad and a Mylar film, which covers the pad. The raw materials used in the Curad department are either manufactured on-site or are purchased and stored on-site (e.g. various chemicals for the adhesive). The various chemicals for the adhesive are loaded into reactors in the mixing room. The adhesive, an acrylic polymer base, is transferred to the spread line and applied to the plastic or cloth substrate. The coated substrate is rolled or "drummed", taken to the slitting room, and cut into various widths.

The polyethylene film, the second component of the Curad, is also made at this plant. The film is extruded in the calendar room and slit into the appropriate widths in the slitting room. The finished film is then

transferred to the Curad department. The Mylar film, which covers the pad, is the third component of the Curad. It is also slit and perforated before it is sent to the Curad department.

In the Curad department, the four parts are assembled and put into wrappers. The wrappers are cut, sealed, and palletized. Spore strips, which are used as Biological Indicators (BI), are placed in the pallets by the sterility expert and the pallets are preconditioned before they are placed in a sterilizer. The dwell time in the sterilizer is several hours. At the end of cycle, the chamber is evacuated and several air washes are done. The product is removed from the chambers, and the spore strips are removed by the vessel operator, material handler or the sterility expert. The product is then isolated in the sterile hold (quarantine) for many days. At the end of which time, the product is retrieved from the sterile hold area by the warehouse keepers and taken to the Curad department to be cut into individual strips and boxed. The boxes are wrapped, placed into shipping cases and sealed. The sealed cases are either shipped or placed in finished goods storage in the warehouse.

#### DESCRIPTION AND REVIEW OF PERSONNEL AND OTHER RECORD SYSTEMS

##### Personnel Records

Personnel records for all current and former employees are on file in the company's personnel department. Two separate record systems are maintained for current employees which are alphabetic and filed separately by wage categories (hourly, exempt and nonexempt). The most useful system for the study is a cardex record system which contains name, birthdate, social security number, and a complete occupational work history. The race of the worker is indicated on the cardex by highlighting the name with yellow marker. Personnel files are also maintained for current workers which contain application forms, payroll status change notices, attendance records, performance appraisals and various financial records. The personnel department also has separate computer systems for current hourly and salaried employees. These systems contain demographic information and only limited work history information. There are a total of 513 current workers who have records in these various systems of which 432 are hourly workers, and 81 are salaried workers.

Personnel records for former employees are essentially the same as for current employees. Cardex records for former employees are placed in the employees' personnel file. There are a total of 1947 files of former employees of which 1743 are from hourly employees and 204 are from salaried employees.

A number of workers from this facility have transferred to an adjacent Kendall facility (Polyken plant). The personnel records for these individuals have been transferred to the personnel department in this facility. Personnel records at this facility are identical to the records from the adhesives plant. There are 628 records of former employees and 345 records of active employees at this plant. It is not known how many of these workers have worked at the adhesives plant.

Payroll records are another potentially useful record system at this plant. These records list the names of individuals working in each department. However, payroll records only exist for the last 7 years.

#### Review of The Personnel Record System

Approximately 5 percent of the personnel records were randomly selected and reviewed. This review had several purposes including: to determine whether the department and job titles used in the personnel record could be used for identifying workers potentially exposed to ETO, to estimate the demographic (sex and age) composition of the potential study population, and to estimate the total number of workers who meet the study criteria and the number of person-years of observation that this group would contribute to the ETO mortality study. Personnel records from the neighboring Polyken plant were not included in this review, although some of the workers in this plant may have transferred from positions which were potentially exposed to ETO at the Adhesives plant. Thus the estimate developed for the number of workers exposed and the number of person-years that this cohort would contribute to the study should be regarded as conservative figures.

The results from the record review are summarized in Table 1. The department and job titles were sufficiently specific to identify workers who were potentially exposed to ETO. The majority of exposed workers were female (65%), and relatively young with a mean year of birth of 1939. Based on the sample it is estimated that approximately 996 workers meet the study criteria, and that this group would contribute approximately 26,113 person-years to the study.

#### DEFINITION OF EXPOSURE

Based on a review of available environmental data, the process and discussions with plant personnel a list of departments and jobs potentially exposed to ETO was developed. This list is presented in Appendix 1 along with a description of why these jobs are potentially exposed to ETO. Workers employed for more than 3 months in one or a combination of these jobs would be considered to be potentially exposed in the record review described in the following section, and in the mortality study.

#### DESCRIPTION OF PAST EXPOSURES

There have been many changes at this location since the first use of ETO in 1962, that would have effected employee exposure to ETO. These changes include product lines, sterilizers, product sterilization and process changes.

##### Product Lines

Curad and Telfa pads were introduction in 1962, and have been the largest product line sterilized with ETO since that time. In 1964, urological catheters, drainage bags, and dressings (wet dressings, dressing change kits, and Webcol) were added to the product line. Webcol product contained a solution of ETO and isopropanol. The wet dressings contained a solution

of ETO and distilled water. In 1969, the urological catheters, drainage bags and various dressings were transferred to the Kendall plant in Augusta, Georgia, and disposable baby bottles and Scrub and Dry pads were introduced. These were sterilized with ETO. In 1979, the disposable baby bottles and Scrub and Dry pads were dropped and Polyskin-3 was introduced. The Curad and Telfa pads were produced during the entire period from 1962 to the present.

### Sterilizers

In 1962, Kendall used a small sterilizer to sterilize product. In late 1962 or early 1963, an ETO gas mixture recycling system was added to the sterilizers. Two additional units were installed in 1964. All three (3) units were in operation until January, 1975. At which time, another unit was installed. The four (4) units were in operation until 1984 when another unit was installed, for a total of five (5) operating units. The stacks for the vessels go directly to the roof. There is one wall fan in the chamber area which exhausts air to the outside.

### Product Sterilization

From 1962 to 1966, an ETO gas mixture #1 was used to sterilize product. In 1966, another ETO gas mixture #2 was introduced to sterilize the urological drainage bags. The gas was returned to a holding tank so that it could be recycled. At the end of several loads, the gas was released into the atmosphere. The catheters were sterilized with a solution of ETO in water. Webcol alcohol pads were also injected with a solution of ETO in isopropanol. The wet dressings were sterilized with an ETO in distilled water solution. The use of all ETO solutions were discontinued in 1969, when the product lines that were sterilized this way were transferred to the Kendall plant in Augusta Georgia. The ETO solutions were poured into the drain when they were no longer needed.

Between 1970 and 1978, the ETO gas mixture #1 continued to be recycled before it was released into the atmosphere. The ETO gas mixture #2, however, was only used once and then released. Also during this time, the water from the sterilizers, which contained ETO was sent directly to the floor drains. The sterilizer operators indicated that the odor of ETO could be detected. This would indicate that the airborne levels of ETO could have been between 300 and 1500 ppm, the odor threshold range.<sup>3</sup>

In 1979, the use of ETO gas mixture #2 was discontinued, therefore, only the ETO gas mixture #1 was used after this time.

### Process Changes

Between 1962 and 1963, unknown quantities of ETO were lost during the sterilization procedure due to preparation of ETO solutions and the release of the ETO and water build up in the recycling tanks. The smell of ETO was frequently reported by the sterilizer operators. The various Curad products were loaded into cardboard totes (boxes) and sterilized. Following the release of the totes containing product from quarantine (after several days), the Curads were hand packed into cartons and/or tins.

In 1964, the use of Biological Spore Strips (BS) was instituted. The spores were placed in the totes containing Curads by the Quality Assurance (QA) technicians. Following sterilization, the operators or QA technicians removed the strips. The product was either used immediately or placed on storage racks for many days in the Curad department. A Webcol operation was located in a separate room, "the Hospital Room", in the southwest corner of the Curad Department. In this room, wet dressings (Webcol- two (2) machines) and urological catheters were produced. Each machine had a tank with a lid, which contained liquid ETO. The Webcol pads were produced by pumping ETO solution into the gauze pads, placing the pads into packages and then sealing. The ETO solution for the Webcol or the catheters was either mixed at the machine station or in the Q.A. Department. Liquid ETO was transported from the tank storage area to where it was mixed (machine station or QA) in open buckets during this time.

In July, 1969, hospital urological and dressing change products were transferred to the Kendall plant in Augusta, Georgia. In November of that same year, Webcol was also transferred to the Augusta plant.

In 1970, a quarantine room was established for sterilized product. At the end of the quarantine period, which was several days, the pallets containing the sterilized product were transferred to the warehouse for shipping or to the Curad department for further processing.

In late 1972 or early 1973, a heat exchanger was installed to heat the ETO so that more ETO would vaporize in the recycling tank prior to being returned to the sterilizer. This reduced the amount of ETO in the vessel exhaust water.

In 1976, the QA department began using 10 spore packages instead of 1 package per load. These packages were placed between the cases, and were removed by the QA technicians or the sterilizer operator. The number of times ETO was recycled in the sterilizer was reduced in April, however in August, this was changed back to the original number of recycles. It was also during August that a formal quarantine program began.

In 1980, preconditioning of the product was begun. Installation of various production machinery also allowed some product (Curad) to be packaged before it was sterilized. This reduced the amount of material that was hand packaged after it had been sterilized by about 20%. In 1983, installation of additional machinery allowed the quantity of hand packed material to be reduced by about an additional 30%.

In early 1984, a control room was built for the sterilizers. The controls for the process gas chromatograph, which had been installed in 1979, were also located in this room.

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DESCRIPTION OF MEDICAL, INDUSTRIAL  
HYGIENE AND SAFETY PROGRAMS

Medical Program

The plant does have a nurse available on the first shift. Some eye and physical examinations were conducted on sterilizer operators in 1981 and 1984. This is not an on-going program. There are no routine physical exams conducted on any employees.

Industrial Hygiene and Safety

The Kendall Adhesive plant does not have a formal written Industrial Hygiene program. Routine industrial hygiene sampling has been conducted, however, by the plant Analytical Lab Chemistry group, Kendall Research and Development, or the insurance carrier since 1981 to document employee exposure to ETO. This sampling, which consisted of charcoal tubes (Qazi Ketchem (QK)) is summarized in Table 2. The sterilizer operator appears in general, to have the highest 8-hour Time Weighted Average (TWA) exposure. Sampling was also conducted to compare 3M passive monitors with the QK tubes. These data, which are also summarized in Table 2, indicate that the average exposure to ETO for a given job, as determined by the 3M monitors was, in general, a little higher than the exposure for the same job as determined by the QK tubes. Kendall has conducted some short term sampling (about 20 minutes) to determine the ceiling level exposure for 2 job tasks which are exposed to the highest levels of ETO (open vessels, pull spores) (Table 3). The sterilizer operator is responsible for both tasks while pulling spores or BIs is also the responsibility of the sterile hold attendant and the sterility expert. The sterilizer operator also has the highest average exposure for these two tasks. It would appear that the exposure to ETO during removal of the BIs from the sterilized pallets should be similar for all 3 job categories. The sterilizer operator may be a little higher, however, because the operator pulls the pallets from the sterilizer before the BIs are removed.

Non-routine sampling was conducted by Kendall with a portable gas chromatograph (G.C.) or QK tubes to determine the extent of ETO exposure throughout the facility (see Tables 4 and 5). The July, 1984, survey used a portable GC, to evaluate ETO levels in areas where direct exposure to ETO did not occur as well as areas with known exposure to ETO. The data indicate that low levels of ETO did exist throughout the facility. There are several organic solvents which are used in the mill, solvent and spread line areas, some of which might have contributed to these levels. The probability, however, that any one of these organic solvents have the same elution time as ETO, thereby adding to the ETO levels observed, is very small. The data presented also indicate that the ambient levels of ETO appear to have decreased with time in this plant as a result of installation of various engineering controls. This observation is based on a rather limited subset of data, however, because there were only 6 areas sampled over time. Since 1984, continuous monitoring with a stationary G.C. has been conducted in ETO restricted access areas (sterilizer and quarantine).

MSA organic charcoal cannister respirators have been available from 1963 to 1983, for use in emergency situations. There were no emergencies noted, however. A formal respiratory protection program was put into place in June, 1984.

#### TOXICITY

Evidence from animal studies suggests that ETO may have carcinogenic properties.<sup>7,8</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9-11</sup> 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.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> 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.<sup>12,13</sup> ETO is also a positive mutagen in several in vitro systems such as Salmonella typhimurium, viruses, and Tradescantia poludosa.<sup>6</sup>

Chromosomal aberrations related to ETO exposure have been observed in a number of animal studies and epidemiologic investigations.<sup>8,13-20</sup> 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.<sup>14</sup> 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.<sup>8</sup> 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.<sup>15</sup> 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.<sup>16</sup>

American Hospital Supply initiated a cytogenetic survey of workers that were exposed to ETO in the sterilization of medical devices in 1978.<sup>17,18</sup> 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.<sup>19,20</sup> 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.<sup>21</sup> OSHA established a new PEL of 1 ppm as an 8-hour TWA on August 21, 1984.<sup>22</sup> 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).<sup>23</sup>

In 1977, NIOSH recommended a ceiling level of 75 ppm as determined during a 15 minute sampling period.<sup>6</sup> 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.<sup>24</sup> 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.<sup>24</sup> 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.

#### CONCLUSION

This plant meets all eligibility requirements as defined by the protocol of the ETO mortality study and will therefore be included. These requirements are: 1) the plant must contribute at least 400 person years, 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.

In addition, industrial hygiene data on 15 different jobs have been collected since 1981. The job with the highest exposure to ETO has been the sterilizer operator. The data collected do show that the ETO levels have decreased with time. Data collected in 1984 indicates that a low level of ETO did exist throughout the facility.

There are no industrial hygiene surveys by NIOSH researchers planned at this plant as part of the ETO study.

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FIGURE 1  
THE KENDALL COMPANY  
FRANKLIN, KENTUCKY

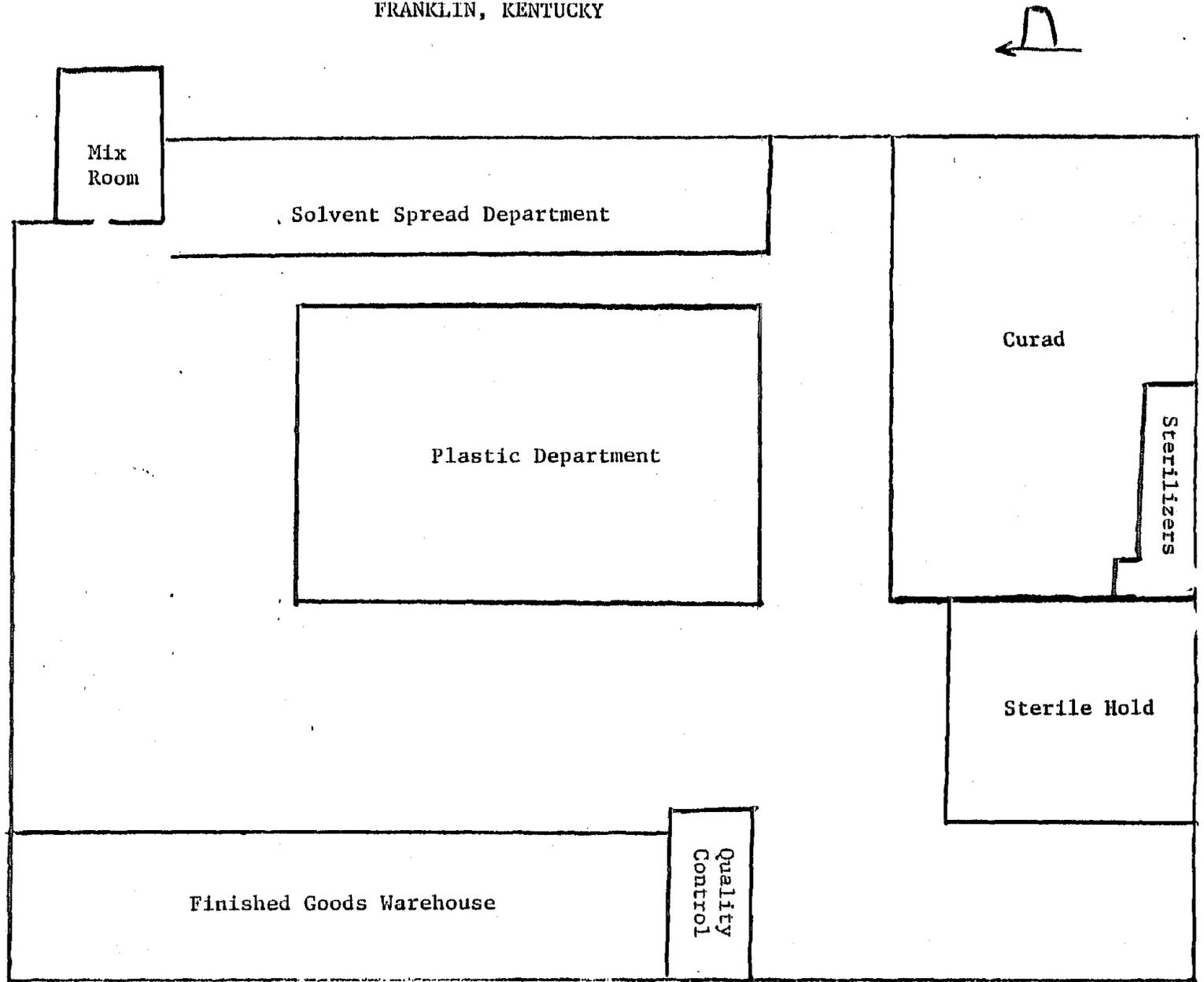


TABLE 1

RESULTS FROM REVIEW OF A 5% SAMPLE OF THE PERSONNEL RECORDS<sup>a,b,c</sup>

STATUS	TOTAL # RECORDS (# SAMPLED)	%EXP MALE	EST %EXP	EST #EXP	AVERAGE			SAMPLE PYRS	TOTAL PYRS <sup>d</sup>
					YR BIRTH	YR 1ST EXP	YR LAST EXP		
ACTIVE	513(27)	29%	63%	323	1941	1968	1982	263	4997
INACTIVE	1947(97)	78%	72%	643	1939	1968	1974	1052	21,116
OVERALL	2460(124)	35%	39%	966	1939	1968	1975	1315	26,113

- a. Only personnel records from the Adhesives plant were included in this review.
- b. Workers considered exposed in this review must have been employed in an exposed job for at least 3 months prior to 1978.
- c. The following abbreviations are used in this table: exp for exposed, yr for year, and pyrs for person-years.
- d. The total number of person-years was estimated by multiplying the number of person-years in the sample times the inverse of the fraction of records sampled.

Table 2  
 The Kendall Company, Franklin, KY  
 Personal Breathing Zone Samples, 8-Hour TWA\*  
 Qazi Ketchem Tubes vs 3M Passive Monitors

Job	Date	Qazi Ketchem Tubes					3M Passive Monitors				
		N	AVG	STD	MIN	MAX	N	AVG	STD	MIN	MAX
Auto Cartoner	Sep-84	7.00	0.03	0.03	0.03	0.03	7.00	0.40	0.41	0.41	0.41
Curad Operator	Aug-82	2.00	0.10	0.00	0.10	0.10					
Curad Operator	Mar-83	4.00	0.18	0.13	0.10	0.40	4.00	0.31	0.27	0.05	0.63
Curad Operator	Jun-84	2.00	0.08	0.01	0.06	0.09					
High Speed	Sep-84	15.00	0.05	0.09	0.00	0.37	15.00	0.26	0.27	0.10	1.17
Inspector Auto Cartoner	Sep-84	9.00	0.04	0.05	0.00	0.14					
Line Inspector	Mar-84	1.00	0.17								
Material Handler	Aug-82	2.00	0.65	0.05	0.60	0.70					
Material Handler	Mar-83	4.00	0.73	0.68	0.20	1.90	3.00	1.39	0.95	0.40	2.67
Material Handler	Mar-84	2.00	2.51	0.00	2.50	2.51					
Material Handler	Jun-84	2.00	1.01	0.01	1.00	1.02					
Material Handler	Sep-84	5.00	0.13	0.12	0.02	0.31					
Pack Line	Mar-83	4.00	0.20	0.10	0.10	0.30					
Paper Print	Aug-82	1.00	0.60								
Paper Print	Mar-83	1.00	2.00								
Shrink Wrap	Aug-82	2.00	0.10	0.00	0.10	0.10					
Spore Operator	Mar-84	1.00	0.24								
Sterility Expert	Aug-82	2.00	1.05	0.15	0.90	1.20					
Sterility Expert	Mar-83	2.00	0.45	0.25	0.20	0.70					
Sterility Expert	Mar-84	2.00	0.45	0.25	0.20	0.70					
Sterile Hold Attendant	Sep-84	10.00	0.11	0.09	0.00	0.27	10.00	0.18	0.12	0.05	0.44
Sterilizer Operator	Jan-81	5.00	2.20	1.35	0.40	4.00					
Sterilizer Operator	Apr-81	1.00	5.70								
Sterilizer Operator	Aug-82	2.00	2.00	0.30	1.70	2.30					
Sterilizer Operator	Mar-83	2.00	4.10	2.60	1.50	6.70	2.00	4.58	3.21	1.37	7.78
Sterilizer Operator	Mar-84	6.00	1.58	1.86	0.19	4.20					
Sterilizer Operator	Jun-84	3.00	2.57	0.31	2.13	2.80					
Sterilizer Operator	Sep-84	15.00	0.52	0.23	0.10	0.84	15.00	0.50	0.19	0.15	1.05
Sterilizer Operator	Apr-85	15.00	0.42	0.33	0.00	1.18					
Sterilizer Operator Asst.	Mar-84	2.00	0.24	0.04	0.19	0.28					
Sterilizer Technician	Jun-84	2.00	0.46	0.09	0.36	0.55					

\*Data collected by company.

Table 3  
 Comparison of Ceiling Levels to 8-Hour TWA\*  
 The Kendall Company  
 Franklin, Kentucky

Open Vessel							
<u>Job</u>	<u>Date</u>	<u>PPM</u>	<u>N</u>	<u>AVG</u>	<u>STD</u>	<u>MIN</u>	<u>MAX</u>
Sterilizer Operator	Aug-82	16.00	4.00	10.65	6.41	1.40	17.20
Sterilizer Operator		1.40					
Sterilizer Operator		8.00					
Sterilizer Operator		17.20					
8 hr TWA X	Aug-82		2.00	2.00	0.30	1.70	2.30
Pull Spores							
<u>Job</u>	<u>Date</u>	<u>PPM</u>	<u>N</u>	<u>AVG</u>	<u>STD</u>	<u>MIN</u>	<u>MAX</u>
Sterile Hold Attendant	Aug-82	1.30	1.00	1.30			
Sterility Expert		4.30	2.00	5.30	1.00	4.30	6.30
Sterility Expert		6.30					
Sterilizer Operator		5.90	2.00	7.05	1.15	5.90	8.20
Sterilizer Operator	Aug-82	8.20					
X			5.00	5.20	2.31	1.30	8.20
8 hr TWA							
Sterile Hold Attendant			2.00	0.65	0.05	0.60	0.70
Sterility Expert			2.00	1.05	0.15	0.90	1.20
Sterilizer Operator	Aug-82		2.00	2.00	0.30	1.70	2.30
X			6.00	1.23	0.60	0.60	2.30

\*Data collected by company, ceiling level represents 15 minutes.

Table 4  
 Area Evaluation of Plant for ETO\*2  
 The Kendall Company  
 Franklin, Kentucky

<u>DATE</u>	<u>AREA</u>	<u>PPM</u>	<u>N</u>	<u>AVG</u>	<u>STD</u>	<u>MIN</u>	<u>MAX</u>	<u>INSTRUMENT</u>	<u>COMMENTS</u>
Aug-82	Packing	2.50	3.00	1.73	0.54	1.30	2.50	Q.K. Tubes <sup>4</sup>	
Aug-82	Packing	1.40						Q.K. Tubes	
Aug-82	Packing	1.30						Q.K. Tubes	
Aug-82	Quarantine	1.70	3.00	1.33	0.39	0.80	1.70	Q.K. Tubes	
Aug-82	Quarantine	1.50						Q.K. Tubes	
Aug-82	Quarantine	0.80						Q.K. Tubes	
Mar-83	Curad	0.10	4.00	0.10	0.00	0.10	0.10	Century GC	
Mar-83	Curad	0.10						Century GC	
Mar-83	Curad	0.10						Century GC	
Mar-83	Curad	0.10						Century GC	
Mar-83	Packing	0.10	6.00	0.10	0.00	0.10	0.10	Century GC	
Mar-83	Packing	0.10						Century GC	
Mar-83	Packing	0.10						Century GC	
Mar-83	Packing	0.10						Century GC	
Mar-83	Packing	0.10						Century GC	
Mar-83	Packing	0.10						Century GC	
Mar-83	Packing	0.10						Century GC	
Mar-83	Quarantine	2.00	8.00	1.19	0.81	0.30	2.00	Century GC	2 Day Old Product
Mar-83	Quarantine	2.00						Century GC	2 Day Old Product
Mar-83	Quarantine	0.40						Century GC	2 Day Old Product
Mar-83	Quarantine	0.30						Century GC	2 Day Old Product
Mar-83	Quarantine	0.40						Century GC	2 Day Old Product
Mar-83	Quarantine	2.00						Century GC	2 Day Old Product
Mar-83	Quarantine	2.00						Century GC	2 Day Old Product
Mar-83	Quarantine	0.40						Century GC	2 Day Old Product
Mar-83	Ster Area	1.00	8.00	4.71	6.91	0.70	22.00	Century GC	
Mar-83	Ster Area	1.00						Century GC	
Mar-83	Ster Area	8.00						Century GC	
Mar-83	Ster Area	1.00						Century GC	
Mar-83	Ster Area	2.00						Century GC	
Mar-83	Ster Area	2.00						Century GC	
Mar-83	Ster Area	22.00						Century GC	Fresh Product
Mar-83	Ster Area	0.70						Century GC	
Mar-83	Storage	0.50						Century GC	Directly North of Quarantine
Mar-83	Storage	0.20	2.00	0.35	0.15	0.20	0.50	Century GC	Directly North of Quarantine
Jul-84	Auto Cart	0.10						Photovac GC	Before Wall
Jul-84	Bartelt	0.10						Photovac GC	Before Wall
Jul-84	Cast Form Line	0.12						Photovac GC	Before Wall
Jul-84	Curad	0.11						Photovac GC	Before Wall
Jul-84	Engineering	0.48	2.00	0.36	0.13	0.23	0.48	Photovac GC	Before Wall
Jul-84	Engineering	0.23						Q.K. Tube	Before Wall
Jul-84	High Speed	0.08						Photovac GC	Before Wall
Jul-84	Lavermatic	0.05						Photovac GC	Before Wall
Jul-84	Maintenance	0.35						Photovac GC	Before Wall
Jul-84	Mill	0.18	4.00	0.33	0.09	0.18	0.38	Q.K. Tube	Before Wall
Jul-84	Mill	0.41						Photovac GC	Before Wall

Table 4 (continued)  
 Area Evaluation of Plant for ETO  
 The Kendall Company  
 Franklin, Kentucky

<u>DATE</u>	<u>AREA</u>	<u>PPM</u>	<u>N</u>	<u>AVG</u>	<u>STD</u>	<u>MIN</u>	<u>MAX</u>	<u>INSTRUMENT</u>	<u>COMMENTS</u>
Jul-84	Mill, Calander	0.38						Photovac GC	Before Wall
Jul-84	Mill, Slit Area	0.35						Photovac GC	Before Wall
Jul-84	Mix Room	0.02						Photovac GC	Before Wall
Jul-84	Office	0.50						Photovac GC	Before Wall
Jul-84	Packing	0.14						Photovac GC	Before Wall
Jul-84	QA	0.44						Photovac GC	Before Wall
Jul-84	Quarantine	0.31	2.00	0.46	0.14	0.31	0.60	Q.K. Tube	Before Wall
Jul-84	Quarantine	0.60						Photovac GC	Before Wall
Jul-84	Solvent, Slit Are	0.01						Photovac GC	Before Wall
Jul-84	Spread Line	0.01						Photovac GC	Before Wall
Jul-84	Warehouse	0.38						Photovac GC	Before Wall
Jul-84	Warehouse Office	0.07						Photovac GC	After Wall <sup>3</sup>
Sep-84	Engineering	0.02						Photovac GC	After Wall
Sep-84	Mill	0.11						Photovac GC	After Wall
Sep-84	Quarantine	0.03						Photovac GC	After Wall
Sep-84	Warehouse	0.03						Photovac GC	After Wall

\*Data collected by company.

<sup>2</sup> These samples are short term or grab samples and do not necessarily represent 8 hr TWA exposure to employees in these areas.

<sup>3</sup> Wall built to isolate sterile hold area

<sup>4</sup> Qazi Ketchem Tubes

Table 5  
ETO Area Data  
The Kendall Company  
Franklin, Kentucky

<u>Area</u>	<u>Aug-82</u>	<u>Mar-83</u>	PPM*	<u>Jul-84+</u>	<u>Sep-84</u>
Auto Cartoner				0.10	
Bartelt				0.10	
Cast Form Line				0.12	
Curad		0.10		0.11	
Engineering				0.36	0.02
High Speed				0.08	
Lavermatic				0.05	
Maintenance				0.35	
Mill				0.33	0.11
Mix Room				0.02	
Office				0.50	
Packing	1.73	0.10		0.14	
QA				0.44	
Quarantine	1.33	1.19		0.46	0.03
Solvent, Slit Area				0.01	
Spread Line				0.01	
Sterilizer Area		4.71			
Storage		0.35			
Warehouse				0.38	0.03
Warehouse Office				0.07	

+ Note data collected in July, 1984 was in anticipation of isolation of the sterile hold area. data collected in September 1984 was after completion of the sterile hold area isolation.

\* PPM values are averages of data presented in Table 4.



APPENDIX 1  
 LIST AND DESCRIPTION OF DEPARTMENTS AND JOBS  
 CONSIDERED TO BE POTENTIALLY EXPOSED TO ETO

<u>DEPARTMENT</u>	<u>JOB</u>	<u>DESCRIPTION OF ETO RELATED ACTIVITIES</u>
Curad (44)	Sterilizer Operator	Operated the ETO sterilizer
"	Sterility Attendant	"
"	Assistant Operator Auto Cartoner	Worked in Curad area in which sterilized products are packed and offgas ETO.
"	Automatic Cartoner Operator	"
"	Bartelt Machine Operator	"
"	Boxmaker	"
"	Carton Packer - Box Making Machine	"
"	Clerk	"
"	Curad Machine Operator	"
"	Elms Machine Operator	"
"	Foreman	"
"	Fork Truck Operator	"
"	Hand Packer	"
"	High Speed Curad Machine Operator	"
"	Inspector Auto Cartoner	"
"	Issue and Delivery Clerk	"
"	Jones Machine Operator	"
"	Machine Adjuster	"
"	Mixing Machine Operator	"
"	Packer	"
"	Paper Printer Operator	"
"	Perforation Operator	"
"	Polyskin Converting and Packaging Operator	"
"	Porousing & Strip Machine Operator	"
"	Printer	"
"	Scheduling Clerk	"
"	Shrink Wrap Operator	"
"	Sterility Hold Distributor	"
"	Stockkeeper	"
"	Storekeeper	"
"	Supervisor	"
"	Time Clerk	"
"	Telfa Machine Operator	"
"	Utility Operator	"
"	Webcol Operator	"

Shipping &  
Receiving  
(81&89)

Rotating Count & Inventory Leader

This job was located in a warehouse in which ETO sterilized goods are stored and offgas ETO. In late 1984 exposures were reduced in this area due to the isolation of the sterile hold area and the increase in the number of air washes used in the sterilization process.

" Expeditor-Receiving  
" Expeditor-Shipping  
" Lead Shipper  
" Checker Finished Goods  
" Checker Raw Materials  
" Assistant Expeditor  
" Issue Worker  
" Stock Picker  
" Fork Truck Operator  
" Material Handler Raw & Fin Goods  
" Redresser

"  
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"

Quality  
Assurance  
(87)

Sterility Specialist

Monitored the sterility of products. Entered the sterilization area and worked with biologic indicators.

Sterility Technician  
Curad Inspector  
Sterility Expert

"  
"  
"

Buildings &  
Grounds (47) Janitor

Cleaned in the curad department and was thereby incidentally exposed to ETO.

Cleaner

"

Maintenance All Jobs Within This Dept.  
(47)

Since detectable levels of ETO have been observed in this department all jobs in this department are potentially exposed. In addition, pipefitters and electricians would occasionally work on the ETO sterilizers.



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