U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
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NIOSH

Health Hazard Evaluation Report

HETA 85-257-1791
MERCY MEDICAL CENTER
DENVER, COLORADO

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

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NIOSH INVESTIGATOR:
Paul Pryor, MS, CIH

I. SUMMARY

In March of 1985, the National Institute for Occupational Safety and Health (NIOSH) was requested by the management of the Mercy Medical Center, Denver, Colorado to evaluate glutaraldehyde exposures among nurses who performed numerous disinfecting procedures on surgical equipment, bronchoscopes, x-ray table tops and other potentially contaminated surfaces. The requestor reported that employees who performed these procedures had experienced symptoms which included skin and respiratory irritation.

On April 30, and July 10, 1985, an environmental survey was performed in the Radiology, Respiratory Therapy, Surgery, and Emergency departments, where cleaning and disinfecting procedures are performed. Eight personal breathing zone and nine area air samples were collected to measure airborne concentrations of glutaraldehyde. Sampling times were approximately 15 to 45 minutes. A ventilation survey was also performed in each of the areas.

Personal breathing zone samples taken for glutaraldehyde ranged from nondetectable (ND) to 1.98 mg/M^3 and the area samples ranged from ND to 0.74 mg/M^3. Approximately 50 percent of the personal samples were above the American Conference of Governmental Industrial Hygienists (ACGIH) Ceiling-TLV of 0.7 mg/M^3. At present there is no NIOSH recommended exposure limit or OSHA Standard for glutaraldehyde. No laboratory hoods were used in any of the areas surveyed.

On the basis of the environmental results, it was concluded that a health hazard did exist from glutaraldehyde exposures at Mercy Medical Center to nurses who perform various cleaning/disinfecting procedures. Recommendations for reducing potential exposures to glutaraldehyde are included in section VIII this report.

KEYWORDS: SIC 8062 (General Medical and Surgical Hospitals), Glutaraldehyde, cleaning/disinfecting; eye, skin, and respiratory irritation.

II. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) received a request in March of 1985 from a representative of Mercy Medical Center, Denver, Colorado. The request was submitted after a previous NIOSH study (HETA 83-074) concluded that exposures to glutaraldehyde created an occupational health hazard under conditions similar to those existing at Mercy Medical Center. The current request specifically concerned the potential hazards to employees from the use of glutaraldehyde in departments that perform disinfection of contaminated surfaces and instruments. Air sampling was performed in the Radiology, Respiratory Therapy, Surgery, and Emergency departments.

The results of the evaluation were presented to the requestor and the employees as they became available. Recommendations to reduce potential exposures were given to management and employees during the survey period.

III. BACKGROUND

Mercy Medical Center, Denver, Colorado is one of the largest hospitals in Colorado. Mercy Medical Center's primary concern for making the HHE request was to determine if nurses who perform cleaning and disinfecting procedures on contaminated surfaces and equipment were being overexposed to glutaraldehyde. Health problems described by the employees were thought to be associated with glutaraldehyde vapors that are created during the disinfecting of various types of medical equipment (e.g., surgical instruments, bronchoscopes, x-ray tables, etc.) and especially when these activities are conducted in small rooms which lack proper ventilation. There are normally 1-2 employees who perform these activities on a daily basis. Glutaraldehyde is purchased and used in each of these departments as a 2% solution.

There are six departments at Mercy Medical Center that use the glutaraldehyde-based disinfecting solution; Family Practice, Radiology, Pathology, Respiratory Therapy, Surgery, and Emergency departments. After the initial survey, it was determined that the amount of glutaraldehyde used in Family Practice and Pathology was minor and only occasionally used throughout the year. We therefore omitted them from the survey. The following is a brief description of the use of glutaraldehyde in those departments evaluated and the personal protective clothing worn:

1. The radiology department uses glutaraldehyde primarily to disinfect x-ray tables and other contaminated surfaces. Typically, a gallon of solution is mixed, applied on a rag and the surfaces thought to be contaminated are wiped thoroughly. Once this process is complete, the employee disposes of any remaining solution in the toilet. The only personal protective clothing worn by the employee was a surgical gown and latex surgical gloves.

2. The respiratory therapy department uses a glutaraldehyde based solution for disinfecting bronchoscopes. This process is performed in a small room (10 X 12 FT) and there are 1-2 employees who perform this procedure. The process occurs three times each week and normally takes 30-45 minutes to perform. The employees wore smocks and surgical gloves during the procedure.

3. In the surgery department glutaraldehyde based solutions are used for disinfecting instruments and scopes prior to surgery. During the normal surgical day there are 2-3 nurses involved in this process. The instruments are soaked for approximately 20 minutes in a long trough, removed and rinsed throughly with sterile water. This department has developed a rotation program whereby once each month the nurses rotate the responsibility for mixing new solutions and disposing of the used material. Each employee wears a surgical gown, gloves, and disposable surgical masks while working with the glutaraldehyde material.

4. The emergency department uses the glutaraldehyde solution for bronchoscope disinfection only. One nurse is responsible for assisting the physician during surgery, and disinfecting the scope after each procedure.

   There are normally 4 to 6 procedures performed each day and it takes approximately 15 to 30 minutes to disinfect a scope. The nurse wears a smock and surgical gloves during the disinfecting process. Until recently, this procedure was performed in a 10 X 15 foot room. It is now performed in a room of approximately 15 X 20 feet.

IV. SAMPLING DESIGN AND METHODS

Seventeen air samples, eight personal and nine general area, were collected by drawing air through sorbent tubes to trap the glutaraldehyde vapors. The sampling pumps drew air through the tubes at 0.2 liters per minute for approximately 30-45 minutes. The samples were analyzed using reverse phase High Pressure Liquid Chromotography (HPLC). NIOSH Method 2532 dated May 15, 1986 was used for analysis.

The ventilation system in each of the departments where glutaraldehyde is used was evaluated. Each employee using glutataldehyde was questioned regarding any adverse health effects experienced while working with the material.

V. EVALUATION CRITERIA

A. Environmental Evaluation

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects even if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and recommendations, 2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLV's), and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLV's are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLV's usually are based on more recent information than are the OSHA standards. The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH-recommended exposure limits, by contrast, are based primarily on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8 to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures. The following is the criterion used for this evaluation:

B. Glutaraldehyde Toxicology

Glutaraldehyde was originally developed as a quick-acting sporicidal agent without the undesirable health effects associated with formaldehyde. The use of this chemical has expanded over the last 20 years and is now and used primarily for disinfection and/or sterilization of a variety of medical, dental, and hospital equipment.

Glutaraldehyde has a pungent odor, an odor recognition threshold of 0.04 parts per million (ppm) by volume in air, and an irritation response level of 0.3 ppm (0.7 mg/M^3). In contrast to formaldehyde, which is a simple aldehyde, glutaraldehyde has two active carbonyl groups.

Glutaraldehyde is a relatively strong irritant to the nose and a severe irritant to the eye. It can produce staining and may be slightly irritating to the skin, however, it can also cause skin sensitization [allergic contact dermatitis]. Activated glutaraldehyde appears to retain the same skin sensitizing properties as pure glutaraldehyde. Furthermore, it appears that the irritant effect of pure glutaraldehyde on the eyes, nasal passages, upper respiratory track, and skin are slightly enhanced when the dialdehyde is activated. Recent information suggests that glutaraldehyde is teratogenic in animals producing central nervous system, musculoskeletal, and craniofacial, abnormalities

At present there is no OSHA standard or NIOSH recommended exposure limit for glutaraldehyde. The American Conference or Governmental Industrial Hygienists (ACGIH) TLV for glutaraldehyde is 0.2 (C) parts per million (ppm), which is equal to 0.7 mg/M^3. The designation (C) refers to a ceiling concentration that should not be exceeded even instantaneously.

VI. RESULTS AND DISCUSSION

A. Environmental

Air concentrations of glutaraldehyde in the personal samples ranged from ND to 1.98 mg/M^3 (Table 1). The area air samples concentration ranged from ND to 0.74 mg/M^3. Concentrations in all from personal samples (Table 1) in the Radiology and Emergency departments exceeded the ACGIH Ceiling value; in Surgery and the Respiratory Therapy departments all four personal sample concentrations were within the ACGIH Ceiling, the highest being 0.21 mg/M^3 (Table 1).

B. Ventilation

Each of the departments evaluated had general room ventilation where 90% of the air was recirculated and 10% fresh air added. This type of system would tend to increase the glutaraldehyde concentrations in the area studied over time and spread the chemical to other areas of the facility serviced by the system. The number of air changes ranged from 6 to 10 per hour for all rooms except the core area in the surgical department. This area had approximately 15 to 20 air changes per hour. It is apparent that if glutaraldehyde is to be used for disinfection purposes in the Radiology and Emergency departments, local exhaust ventilation should be installed. No local exhaust hoods currently exist in these areas. The use of general air ventilation is not recommended.

C. Medical Concerns

Symptoms such as eye, nose, throat irritation and chest tightness were described by the employees as having occurred during past exposures to glutaraldehyde. These symptoms have been reduced by increasing the area where the work is performed, leaving the doors open during the procedure, and by limiting the amount of time and personal contact with the solution.

VII. CONCLUSIONS

NIOSH documented overexposures to glutaraldehyde among employees in the Radiology and Emergency departments.

VIII. RECOMMENDATIONS

A. Environmental

1. Engineering controls are the preferred method for resolving chemical hazards. Therefore, local exhaust hood ventilation should be installed in these areas which have high glutaraldehyde exposure.

2. The use of personal protective clothing should be mandatory when using glutaraldehyde; therefore, a written procedure detailing type and proper use of protective clothing should be provided to employees involved in placement/removal of surgical or bronchial instruments and other maintenance operations (e.g., wiping instruments, tables, wall, etc). Two gloves should be worn on each hand during these procedures to further minimize the potential for skin absorption. ACGIH recommends a variety of different materials that can be used when working with aldehydes. These include butyl rubber (described as excellent); polyurethane, polyethylene, styrene, butadiene rubber (described as good to fair), and polyvinyl alcohol and Viton (described as only acceptable).

3. An organic vapor/formaldehyde cartridge respirator is appropriate for protection against glutaraldehyde. This type of respirator is specifically designed for organic vapors and formaldehyde but also suitable for glutaraldehyde. Surgical masks provide no protection against these or any other vapors. If respirators are to be used a written program describing proper use must be developed along with a fit testing program.

4. Work practices in all areas where glutaraldehyde is used should be reviewed periodically in order to prevent overexposures. Emphasis on the avoidance of exposures in confined spaces should be a primary concern.

5. The training and education of new and current employees regarding safe work practices is essential in reducing and/or eliminating chemical exposures. All new or current employees should be instructed on the potential hazards associated with glutaraldehyde, proper use of protective clothing, safe work practices, avoidance of confined space exposures, and personal hygiene concerns. This would include education regarding signs and symptoms associated with overexposure to glutaraldehyde.

6. Air monitoring should be performed periodically and records kept of the results. This is especially important if there is any modification in the operation; that is, if location or process changes are made or there is an increase in the use of glutaraldehyde.

B. Medical

1. Eye contact with glutaraldehyde should (after prompt irrigation with water for at least fifteen minutes) be reported to a physician. Skin contact should be avoided and the skin should be promptly washed if contact is made.

2. Medical evaluations should be provided when adverse effects to workers from past or current exposures exist. If overexposures are suspected of causing skin sensitization or asthma-like symptoms, the employee should not be required to work with the solution. It should be understood, as described earlier, that engineering controls should be the first consideration if an overexposure does exist in the work area.

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X. AUTHORSHIP AND ACKNOWLEDGMENTS

Report Prepared By:

Paul Pryor, MS, CIH
Industrial Hygienist
NIOSH, Region VIII
Denver, Colorado

Originating Office:

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

Report Typed By:

Patricia Griffith
Clerk Typist
NIOSH, Region V
Cincinnati, Ohio

XI. DISTRIBUTION AND AVAILABILITY

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Copies of this report have been sent to:

1. Mercy Medical Center
2. U.S. Department of Labor/OSHA - Region VIII
3. NIOSH Denver Region
4. Colorado Department of Health

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

TABLE 1

BREATHING ZONE AND AREA AIR CONCENTRATIONS
FOR GLUTARALDEHYDE
Mercy Medical Center
Denver, Colorado
June, 1986

AREA/JOB DESCRIPTION	SAMPLING TIME (MINUTES)	mg/M^3 GLUTARALDEHYDE
Radiology		
Personal	15	1.42*
Personal	15	1.98*
Area	30	0.54
Area	30	ND
Area	30	ND
Emergency		
Personal	45	1.88*
Personal	45	1.02*
Area	45	0.74*
Surgery		
Personal	20	0.17
Personal	20	0.21
Area	30	0.18
Area	30	0.14
Respiratory Therapy		
Personal	45	0.03
Personal	45	0.04
Area	45	0.04
Area	45	0.03
Area	45	0.04

EVALUATION CRITERION: (ACGIH) 0.7

LABORATORY LIMIT OF DETECTION: 3.0 ug/sample

Note: Levels which exceeded the ACGIH criteria.

ND = Non Detectable (no glutaraldehyde was detected on these samples).
mg/M^3 = milligrams of substance per cubic meter of air.

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