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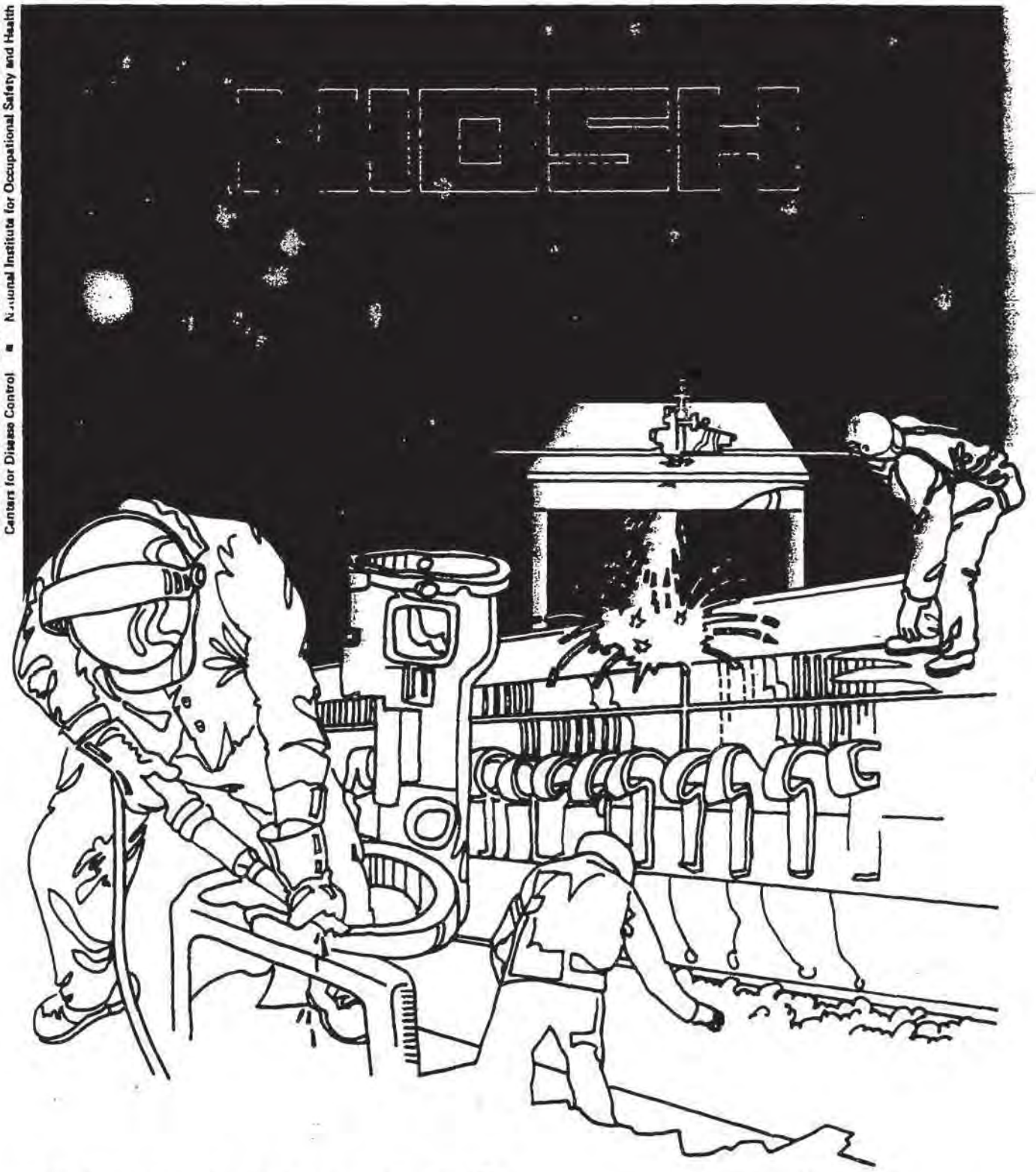

Health Hazard Evaluation Report

HETA 83-074-1525
NATIONAL JEWISH HOSPITAL
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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I. SUMMARY

In January 1983, the National Institute for Occupational Safety and Health (NIOSH) was requested to evaluate exposures to employees from glutaraldehyde used in small animal research projects, and in sterilizing and disinfecting of respiratory therapy equipment at National Jewish Hospital, Denver, Colorado.

In October 1983, NIOSH investigators performed an environmental investigation in the Pulmonary Animal Research and Physiology Laboratories (PARPL), outpatient clinic, and central services area of the hospital.

Eight personal breathing zone and thirteen area air samples were collected to measure airborne concentrations of glutaraldehyde. Sampling times ranged from 30 to 80 minutes. Informal interviews were conducted, and medical questionnaires were administered to the exposed employees.

Glutaraldehyde concentrations in the 8 personal breathing zone samples ranged from non-detectable (ND) to 1.5 mg/m^3. Six (75%) of these samples exceeded the American Conference of Government Industrial Hygienist Ceiling Threshold Limit Value of 0.7 mg/m^3. Concentrations in the 13 area air samples ranged from ND to 1.5 mg/m^3. Six (46%) of these samples exceeded the TLV. Evaluation of the ventilation systems revealed that in two of the three areas where glutaraldehyde was being used, the current ventilation systems were inadequate to remove glutaraldehyde vapors.

Medical questionnaires revealed that 9 (82%) of the 11 exposed workers reported irritative symptoms compatible with exposure to glutaraldehyde. Eye irritation (45%) and throat irritation were the most prevalent symptoms.

On the basis of the environmental sampling results, and medical questionnaire data, it was concluded that a health hazard existed from glutaraldehyde exposures at National Jewish Hospital. Recommendations for reducing exposures are included in this report.

KEYWORDS: SIC 8221 (Colleges, Universities, and Professional Schools) and SIC 8062 (General Medical and Surgical Hospitals), glutaraldehyde, 1,5-pentanedione, 1,5-pentanedial, glutaric dialdehyde, sterilization and disinfection; eye irritation, upper respiratory irritation, headaches

II. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) received a request in January 1983 from a representative of National Jewish Hospital, Denver, Colorado. The request was submitted after a previous NIOSH study (HHE 83-048)[1] was performed at the hospital on formaldehyde. It was determined at that time that glutaraldehyde as used at the hospital could also be a health hazard to the employees.

At the time of this request NIOSH did not have a sampling and analytical technique. NIOSH contracted with an outside laboratory to develop a method and a technique became available during October, 1983. NIOSH investigators began their environmental air sampling in December of 1983 and concluded in January, 1984. Sampling was performed in the small animal research laboratory and in areas where respiratory therapy equipment was being disinfected or sterilized. This included central services and the outpatient clinic at National Jewish hospital.

The results of each evaluation were presented to the requestor and employees when information became available. A letter with a complete copy of the results and recommendations regarding ways to reduce and/or eliminate the glutaraldehyde exposures also were presented to hospital management on April 30, 1984.

III. BACKGROUND

National Jewish Hospital and Asthma Center in Denver, Colorado, is a biomedical research hospital. The major areas of research performed at the hospital include immune diseases and inflammation and airway diseases of the lungs. Formaldehyde (formalin) and glutaraldehyde (Glutarex™) are used for tissue fixing for a portion of this research and both chemicals are used extensively in the Pulmonary Animal Research and Physiology Laboratories (PARPL). Glutaraldehyde is also used for disinfection and/or cold sterilization of respiratory therapy equipment and has been used for the past 15 years at the hospital.

Prior to NIOSH's environmental study, glutaraldehyde was used throughout the hospital by numerous employees. In 1983, however, the hospital reduced the number of employees and locations where glutaraldehyde was being used due to reports that glutaraldehyde produced similar symptoms, and in some cases more severe symptoms, as those experienced by the employees while working with formaldehyde. These included burning eyes; nose, throat and lung irritation; as well as cough and chest tightness. Other health complaints included headaches, staining of the hands (brownish/tan discoloration), skin sensitization and asthma like symptoms.

The following is a description of how glutaraldehyde was used in the past and how it is currently being used at the hospital; a discussion of the types of areas and personnel/jobs evaluated by NIOSH; and the work practices, engineering controls and personal protective clothing used by the employees who currently work with glutaraldehyde:

1. Past Exposures

Glutaraldehyde use was widespread in the hospital prior to 1983, including every nursing unit, the pulmonary physiology unit and many of the research laboratories. At the time nebulizers were being cleaned on each patient unit. In the patient care areas the 2% catalyzed solution was kept in 6-10 gallon plastic buckets with lids which had a perforated inner bucket to allow removal of equipment without wasting the solution. Glutaraldehyde was also used to clean ENT instruments, suction bottles and tubing, vitalograph tubing, medical sputum mouthpieces and corrugated tubing and medicine cups.

In research areas the glutaraldehyde was typically in a 2 percent solution and the majority of these mixtures were used for submerging tissues for extended periods. Once activated, the solution is effective for 28 days and can be used for disinfection or sterilization. The recommended soaking time to kill most bacteria is approximately 10 minutes; TB and other stronger bacteria and viruses take 10 hours.

During this period many of the employees who worked in the various areas described above, as well as patients, complained of side effects which could have been associated with exposures to the glutaraldehyde product. Persons developed skin rashes which required medical treatment. One employee's dermatological problems persisted even after she discontinued work with glutaraldehyde and the vapors appeared to be sufficient to sustain the problem.

Patients also complained that the presence of glutaraldehyde aggravated upper airway diseases, especially in asthma cases. A patient complained that there seemed to be residual glutaraldehyde on the nebulizer even after thorough rinsing. She declined breathing treatment at the hospital after the episode.

Other employees complained at various times of sneezing, watery burning eyes, and cough triggered by vapors from glutaraldehyde. One employee reported exacerbation of her asthma from exposure to the vapors.

2. Present Exposures

Concerns regarding the potential health hazards from glutaraldehyde prompted many changes at National Jewish Hospital. The first step taken was to remove the product from approximately seven nursing units. All nebulizers were taken to central service or the outpatient clinic for processing. Full-time technicians were required to handle the additional workload in central services. Other than in the research area, glutaraldehyde remained in use only in the Outpatient Clinic where processing of equipment now takes place.

Glutaraldehyde continues to be used in certain research areas as a tissue fixative (e.g., the electron microscopy laboratory and small animal research). In the electron microscopy laboratory (EML) glutaraldehyde vapors are potentially present during the preparation of new glutaraldehyde fixing solution and during tissue slicing operations.

In the PARPL area glutaraldehyde exposures are potentially present during placement or removal of lungs in the fixation tank and during maintenance operations (i.e., during cleaning, equipment repair or draining and replacement of fixing solution). The fixation tank has a 30 liter capacity and has been used in the new laboratory hood since NIOSH made its original recommendations in the previous formaldehyde evaluation.

Maintenance is performed on the fixing tank by one to two employees approximately once per month. This requires the tank to be drained, residual materials manually removed and then flushed with tap water repeatedly. Finally, the tank is refilled from a container of fresh glutaraldehyde solution. Normally, all maintenance tasks involving the glutaraldehyde tank are accomplished as rapidly as possible in order to minimize vapors released from the enclosure when the lab hood is raised and tank is open.

3. Work Process and Ventilation

The majority of work performed in the PARPL with glutaraldehyde is done in the tissue fixation tank which is located in a laboratory hood. The hood sash was normally positioned with approximately 4 to 6 inches left open at the bottom. In this position the flow rate averaged between 100 to 125 feet per minute (fpm) which is considered effective for exhausting the contaminant from the operators breathing zone. However, during placement and removal of lungs in the tank and during maintenance activities (e.g., changing solution, cleaning and repair) exposures were thought to occur. This is primarily due to the need for a greater work area to perform these operations which requires the sash/ window to be raised. Typically, the window is raised 2-3 feet from the bottom and the flow rate is then reduced to less than 50 fpm. The potential exposure is increased further by the need for the operator to move in closer to the tank in order to effectively perform the various tasks previously described.

There were no local exhaust ventilation systems in the outpatient clinic or in the central services area. In the outpatient clinic each of the glutaraldehyde operations were performed in a sink as well as on top of a counter in a small room (approximately 12X14). There was very little air exchange in the room and the employee typically spent 45 minutes to one hour cleaning nebulizers; preparing new glutaraldehyde solution and disposing of the old solution. During the cleaning process, all of the nebulizer equipment was submerged in glutaraldehyde solution for approximately twenty minutes. Each piece was then cleaned and rinsed separately. During these procedures the employee kept the door closed to prevent the odor from emanating into the hallway and other rooms.

The ventilation system in the central services area again was minimal. The nebulizer cleaning process is performed in two steps. First, the employee submerges all the inhalation nebulizer equipment in a bucket of glutaraldehyde solution. This bucket is then placed in a small room (approximately 6X8) and left for approximately 30 minutes. The employee periodically stirs the equipment in the bucket to assure that the solution reaches all surfaces of the equipment. Once this phase of the process is complete the

operator then carries the bucket to an adjoining room and places it in a large sink to complete the cleaning process. This includes washing and rinsing each piece of equipment by hand, placing the individual pieces on a clean surface and finally disposing of the waste glutaraldehyde into the sink.

4. Personal Protective Clothing

During each of the operations described above, the employees normally wear some personal protection. This included either lab coats, aprons, gloves, goggles and/or respirators. Three different types of protective gloves were available including latex, rubber, and polyvinyl. Two different types of respirators were available to the employees, surgical or disposal organic vapor type respirators. No operator routinely wore all of the protective clothing while glutaraldehyde was being used.

IV. ENVIRONMENTAL DESIGN AND METHODS

A. Envronmental

Twenty-one air samples, eight (8) personal and thirteen (13) general area type samples were collected by drawing air through sorbent tubes to trap the glutaraldehyde vapors present. The sampling pumps drew air through the tubes at 0.2 liters per minute for 30, 45 and 80 minute periods. The samples were analyzed using reverse phase High Pressure Liquid Chromotography (HPLC). The samples were collected in the PARPL, outpatient clinic and central services on each of the employees working with glutaraldehyde.

B. Medical

Employees, including physicians and nurses, who had been exposed to the glutaraldehyde solution in the past were interviewed. Also, each of the employees currently working with the chemical were interviewed and a medical questionnaire was completed by each of the workers.

V. EVALUATION CRITERIA

A. Environmental

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 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 standards, by contrast, are based solely 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 only 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. At present neither OSHA or NIOSH have a standard or criteria for glutaraldehyde. The following is the criteria that has been established by the American Conference of Governmental Industrial Hygienist (ACGIH) for glutaraldehyde:

> The ACGIH has established an environmental exposure criteria of (C) 0.2 parts per million (ppm) which is equal to (C) 0.7 mg/M^3. The designation C refers to a Ceiling concentration that should not be exceeded even instantaneously.

B. Chemistry/Toxicology

The use of glutaraldehyde has expanded over the last twenty years and is now used in a variety of different fields. It was originally developed as a quick acting sporicidal agent without the undesirable properties of formaldehyde. Today, glutaraldehyde is used primarily for disinfection or sterilization of medical, dental and hospital equipment.

In a recent NIOSH-National Occupational Exposure Survey (NOES 1981-82) it was determined that glutaraldehyde is being used not only in a variety of areas in the medical industry (e.g., inhalation therapy, dental, urology, gastrointestinal, ambulatory services, electron microscopy and cytochemistry) but also in photography, shoe repair, dyes and tanning operations. The survey estimated that approximately 14,000 workers are presently exposed to glutaraldehyde in the industries described.

Since 1982, glutaraldehyde has been marketed as a replacement for formaldehyde in dialysis reuse processes and it was estimated at that time that approximately 1 percent of hemodialysis operations in the United States have now begun to use glutaraldehyde for this procedure. The following information is an accumulation of studies and articles written on the chemistry and toxicology of glutaraldehyde.

1. Chemistry [2,3,4,5]

Products containing glutaraldehyde are most frequently available as 2%, 10%, 25% and 50% aqueous solutions, which have no flash points and are non flammable. In general, glutaraldehyde is a saturated dialdehyde with the following formula: $CHO-CH_2-CH_2-CH_2-CHO$. Its molecular weight is 100.12. In contrast to formaldehyde, which is a simple aldehyde, glutaraldehyde has two active carbonyl groups. Under proper conditions these two groups, either singly or together, undergo most of the typical aldehyde reactions to form acetals, cyanohydrins, oximes, and hydrazones. Through the crosslinking reaction, the carbonyl groups react with protein.

As a raw material, glutaraldehyde is synthesized and commercially available as an acidic aqueous solution. Aqueous solutions of glutaraldehyde are mildly acid in reaction and at an acid pH of approximately 3-4, glutaraldehyde solutions are stable for a period of many months. In this acid state they are not sporicidal. When rendered alkaline, however, the glutaraldehyde gradually undergoes polymerization. Above a pH of 9, the polymerization proceeds comparatively rapidly and eventually loses activity. In the pH range of 7.5 to 8.5 the polymerization reaction is slowed down considerably, so that full antimicrobial activity (i.e., sporocidal, bactericidal, viricidal, and fungicidal) is maintained for at least two weeks (14 days).

Most glutaraldehyde used in hospitals is a 2.0% concentration which has a two-component system that must be mixed together, or activated, prior to use for disinfection or sterilization. The activated solution that contains 2.0% glutaraldehyde is buffered to an alkaline pH of 7.5-8.5 as described above. To buffer this concentration of glutaraldehyde to the required alkaline range, the addition of 0.3 percent of sodium bicarbonate is necessary. Although other alkalinating agents may be employed, the alkali metal bicarbonates, such as sodium bicarbonate, have given best results.

To provide greater utility to the activated or buffered glutaraldehyde solution, it has been convenient to add, in addition to the alkaline buffer, surfactants to promote the wetting and rinsing of surfaces, sodium nitrite as a corrosion inhibitor, a peppermint oil odorant, and a yellow and blue FD and C dyes, indicating that activation through mixing the two components has been completed. Before the addition of the buffer-dye combination, the unactivated glutaraldehyde solution is colorless; after the addition, the solution turns a characteristic fluorescent green. It should be noted that there are approximately eight different brands of this type of material on the market today and each of these may have slightly different chemical ingredients as well as percent concentrations.

The majority of the 2% water solution available is used primarily as a cold disinfectant and sterilizer for hospital-medical and dental work. In addition to the 2% solutions the most frequently used are the 25 and 90% solutions which are used as intermediates and fixatives for tissues, and for crosslinking polyhydroxy materials and proteins.

2. Toxicology 2,3,5,6-14

The majority of research articles available on glutaraldehyde today concern its ability to disinfect and/or sterilize against spores, bacteria, virus and fungus. There have been no epidemiological research studies reported in the literature to date and there have been only a limited number of human toxicological findings which have been reported recently on glutaraldehyde. The following is an accumulation of the more important information on animal, as well as the human toxicity studies currently available:

A. Dermatologic Effects

The Environmental Protection Agency in 1969, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) established that glutaraldehyde was considered to be a moderate skin irritant based on information collected on animal studies at that time.

In one study, aqueous solutions of 2 percent activated glutaraldehyde produced faint yellow staining of the skin and hair on rabbits after the first application and became more intense and turned to a golden brown over the six week period of application. Discoloration persisted up to 35 days after application ceased. A mild "rash" appeared during the early stages but disappeared despite continued application of the solution. In the same study a 25 percent solution of glutaraldehyde produced a severe erythematous reaction with edema after one to two daily applications with necrosis and eschar formation in seven to ten days.

In two recent occupational studies it was shown that activated glutaraldehyde retains the skin sensitizing properties of pure glutaraldehyde. In one study it was reported that allergic contact dermatitis was found in radiologist and x-ray technicians from handling x-rays solutions containing glutaraldehyde. The authors concluded that all persons with hand dermatitis who handle x-ray films should have a patch test with one percent aqueous solution of glutaraldehyde.

B. Respiratory Tract Effects

Glutaraldehyde has a pungent odor, an odor recognition threshold of 0.04 ppm by volume in air and an irritation response level of 0.3 ppm.

In one study, activated glutaraldehyde versus pure glutaraldehyde increased the irritant effects to the upper respiratory tract of workers. Another study indicated that the vapors from pure glutaraldehyde were noticeable and considered irritating by some persons. The authors, therefore, concluded that glutaraldehyde should be kept covered whenever possible and used in a well-ventilated area in such a manner so as to prevent prolonged breathing of the fumes.

C. Eye Effects

Studies on the effects of glutaraldehyde on the eyes of rabbits produced severe corneal opacity and irritation of the irises and conjunctiva. These reactions were not reversed during a seven-day observation period. In rinsed eyes, there was similar irritation of the conjunctiva which remained during the seven-day observation period. The corneas and irises showed less irritation, which was partially reduced during the seven-day observation period.

D. Mutagenic and Teratogenic Effects

In the most recent publication of the Registry Of Toxic Effects Of Chemical Substances (RTEC), 1981-82 two studies were sited in which glutaraldehyde was evaluated for possible mutagenic and teratogenic effects in animals. The study on mutagenic research on chickens showed that glutaraldehyde at 8 parts per hundred (pph) did not produce DNA damage.

The second study referenced stated that glutaraldehyde did not produce teratogenic effects. The study did illustrate, however, that glutaraldehyde administered to mice at 50 gm/Kg produced central nervous system, musculoskeletal and craniofacial damage (including nose and tongue). It was also determined in this study that glutaraldehyde at 8 gm/kg produced fetotoxicity (i.e., stunted fetus).

E. Other Research

The results of two studies demonstrated an increased irritation from glutaraldehyde when the dialdehyde is activated. In one study mice were exposed at 8 and 33 ppm (33 and 133 mg/m^3) of alkalinized glutaraldehyde for 24 hours. The animals reacted with distinctly nervous behavior, panting and washing of the face and limbs, with symptoms disappearing after a few hours. Half of each group were sacrificed immediately postexposure, and the rest one day later. Lungs and kidneys showed no histopathologic damage, but the livers of the mice exposed at 33 ppm showed definite signs of toxic hepatitis, possibly still reversible, since it was present to a somewhat lesser degree in the animals autopsied one day postexposure.

In a second study, simulating a complete cold-sterilizing procedure lasting twelve minutes, the integrated sample of activated, 2% aqueous solution resulted in 0.38 ppm of glutaraldehyde measured at the operator's breathing zone. Although some irritation had been felt throughout this procedure, it was not until the end of the operation, when the equipment being sterilized was air-hose dried, that severe eye, plus nose and throat irritation were felt by the operator and the investigators, who also experienced sudden headache.

In summary, the current literature illustrates that 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 cause skin sensitization (allergic contact dermatitis) from occasional or incidental occupational exposures. Thus, activated glutaraldehyde appears to retain the skin sensitizing properties as those described for pure glutaraldehyde. Furthermore, it

appears that the relatively strong irritant effect of pure glutaraldehyde on the eyes, nasal passages, upper respiratory track and skin are slightly enhanced when the dialdehyde is activated. Finally, recent information suggests that glutaraldehyde should not be considered mutagenic or teratogenic, but can produce central nervous system, musculoskeletal, craniofacial and fetotoxicity to animals.

VI. RESULTS AND DISCUSSION

Three different groups of employees exposed to glutaraldehyde were evaluated. These included activities in central services, the outpatient clinic and the PARPL areas. NIOSH's evaluation included air monitoring, medical evaluations (interviews and questionnaires), evaluation of the ventilation systems and the personal protective clothing used by the employees while working with glutaraldehyde. The following are the results of NIOSH's study:

A. Environmental

Twenty one samples were taken at National Jewish Hospital, eight personal and thirteen area samples and the sampling times ranged from 30 to 80 minutes. The results for the personal samples ranged from non-detectable (ND) to 1.32 mg/M^3. Seventy-five percent of these samples exceeded the ACGIH Ceiling TLV of 0.7 mg/M^3. The area air samples ranged from ND to 1.32 mg/M^3 and forty-six percent of these samples exceeded the TLV (refer to Table 1).

Specifically, the results received in the Outpatient nebulizer cleaning process were both 1.07 mg/M^3 and the area samples ranged from 0.18 to 1.32 mg/M^3. The personal sampling results found during the nebulizer cleaning process in Central Services ranged from 0.86 to 1.28 mg/M^3 and the area samples were all ND.

The personal sampling results for the Tissue Fixing operation, during normal operations were both ND and the area samples ranged from 0.10 to 0.18 mg/M^3. However, the results for the Tissue Fixing operation evaluated during maintenance procedures ranged from 0.75 to 1.5 mg/M^3 for the personal samples and 0.75 to 1.5 mg/M^3 for the area samples.

B. Medical

Eleven employees were interviewed and requested to fill out a medical questionnaire. The medical evaluation showed that 9% (827.) of 11 workers surveyed had symptoms which may be attributable to glutaraldehyde exposures. This included eye irritation (45%), nose irritation (36%), throat and lung irritation (45%), cough and/or chest tightness (27%), headache (27%), skin irritation (18%), and asthma-like symtoms (18%).

C. Ventilation

No local exhaust ventilation systems were available to remove the vapors from the operator's breathing zone while working with glutaraldehyde in either the central services or outpatient clinic. The small animal lab operation evaluated did use a laboratory hood during the majority of the tissue fixing processes and the

exhaust flow rate measured during this period was approximately 100 to 125 fpm. During lung placement and removal, as well as during general maintenance operations, the flow rate would drop off to 25 to 50 fpm. This was primarily because it was necessary for the operator to move the lab hood window sash up two to three feet above the bottom shelf in order to perform these activities. This situation would then potentially expose operators to higher levels of glutaraldehyde.

D. Confined Spaces

Confined space refers to a space which by design has limited openings for entry and exit; unfavorable natural ventilation which could contain or produce dangerous air contaminants, and which is not intended for continuous employee activities. The operations surveyed in this study do not meet the classical definition of confined space. However, considering the current ACGIH Ceiling-TLV two of the three areas surveyed were considered as meeting this criteria.

These types of conditions were observed in central services and the outpatient clinic during the sampling period. In the outpatient clinic the operator performed the cleaning process in a very small room which had no ventilation and with the door closed . In the central services area the operator was required to spend a portion of the cleaning process in a closet which also lacked ventilation. It is our opinion that these conditions, especially in light of the current criteria value given glutaraldehyde, increases the overall glutaraldehyde level, and therefore, places the employee at greater risk to glutaraldehyde exposures while working in such confined spaces.

E. Personal Protective Clothing

A variety of personal protective clothing was available to the employees while working with glutaraldehyde including lab coats, protective goggles, aprons, respirators (surgical and organic vapor disposable types) and gloves (either latex, rubber or polyvinyl types). There did not appear to be any uniform description on what the employees should wear when working with glutaraldehyde. That is, the employee in central services wore only a lab coat, hair net and protective gloves during the cleaning process. The operator in the outpatient clinic wore only a lab coat and gloves and the operator who worked in the small animal lab wore the majority of personal protective clothing during glutaraldehyde use. This included a lab coat, gloves and disposable organic respirators.

VII. CONCLUSIONS

In conclusion, due to the current criteria given glutaraldehyde; the toxicological effects of glutaraldehyde as well as the environmental air sampling and medical results obtained by NIOSH, a potential health hazard did exist to the employees who work in central services, the outpatient clinic and in the PARPL at National Jewish Hospital.

Therefore, based on these findings it is recommended that when glutaraldehyde is being used by the employees at the hospital that ingestion should be avoided and that glutaraldehyde not be allowed to come in contact with the skin or mucous membranes of the eyes. Finally, based on glutaraldehydes current Ceiling-TLV this material should not be breathed for even a short period of time.

VIII. RECOMMENDATIONS

In view of the findings of NIOSH's evaluation, as well as personal communications with individuals who have performed activities with glutaraldehyde in the past and currently, the following recommendations are made to ameliorate potential health hazards and to provide a better work environment for the employees covered by this report.

A. Environmental

1. Local exhaust ventilation should be installed in areas where glutaraldehyde is being used at the hospital. A capture velocity of at least 100 fpm is required in order to exhaust the glutaraldehyde vapor at the source of the contaminate and away from the operators breathing zone. This exhaust system will also require appropriate make-up air in order to make the system work sufficiently.

2. Once the exhaust systems have been installed, an environmental air monitoring survey should be performed again in these areas to determine the effectiveness of the ventilation systems.

3. If possible, substitution, of materials which are less hazardous is an excellent way to avoid exposures to the employees and should be investigated for the operations evaluated in this study.

4. Personal protective clothing should be mandatory when handling glutaraldehyde and a written program on proper use and correct clothing is recommended. This should include the following:

   a. Respirators are necessary when the exposures to a chemical exceed known standards and/or criteria. However, respirators should not be considered a primary control and should only be used in lue of more permanent controls (e.g., engineering controls, substitution, etc.). Respirators can be used in a useful manner for such activities as non routine maintenance or repair activities and emergencies. In the case of glutaraldehyde a NIOSH/MSHA approved organic vapor cartridge with a high efficiency pre-filter should be used. However, if respirators are to be used, a complete training program on selection, maintenance and fit testing is required for adequate protection.

   b. Each employee who works with glutaraldehyde should wear protective gloves for the extent of the work process. The ACGIH recommends that a variety of different materials be used when working with aldehydes. This includes butyl rubber (described as excellent); polyurethane, polyethylene, PVC and styrene butadiene rubber (as good to fair) and polyvinyl alcohol and Viton (as only exceptable).

c. Other personal protective equipment should include lab coats, protective goggles and impervious aprons. The material described above should also be considered when selecting the appropriate aprons.

B. Medical

1. Eye contact with glutaraldehyde should, after prompt irrigation with water, be reported to a physician. Skin contact should be avoided and promptly washed if contact is made.

2. Preplacement or initial medical questionnaires and examinations for employees who will be expected to work with glutaraldehyde should include questions on skin sensitization, eye and respiratory irritations.

3. If adverse effects to workers from past or current exposures to glutaraldehyde are suspected these employees should be evaluated medically. If confirmed (e.g., skin sensitization, asthma like symptoms or other related health problems) the employee should not be required to work with the solution or they should be adequately protected from future exposures to glutaraldehyde as described above.

C. Other

1. Work practices in each of those areas where glutaraldehyde is used should be reviewed periodically in order to assure that potential overexposures are not occurring. Emphasis on the avoidance of exposures in confined spaces as described earlier in this report should be of primary concern.

2. The training and education of employees regarding safe work practices is essential to reducing and/or eliminating chemical exposures. Therefore, each employee should be instructed on the potential hazards associated with glutaraldehyde, proper use of personal protective clothing, work practices, avoidance of confined space exposures and health and sanitation concerns. This would include signs and symptoms associated with glutaraldehyde as well as the avoidance of eating, drinking or smoking while this chemical is being used.

3. An educational program to instruct new employees on the hazards of glutaraldehyde should be implemented, as well as an annual review of glutaraldehyde for all concerned employees should be implemented if it has not been already.

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

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NIOSH is thankful to the employees at National Jewish Hospital for their cooperation and assistance with this Health Hazard Evaluation. The information gathered from this study will not only assist in maintaining the health and safety of those persons working here, but also other facilities that perform similar operations.

XI. DISTRIBUTION AND AVAILABILITY

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Information Resources and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from NIOSH, Publications Office, at the Cincinnati address.

Copies of this report have been sent to:

1. National Jewish Hospital
2. U.S. Department of Labor/OSHA - Region VIII.
3. NIOSH - Region VIII.
4. Colorado Department of Health.
5. State Designated Agency.

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

TABLE 1

BREATHING ZONE AND AREA AIR CONCENTRATIONS
FOR GLUTARALDEHYDE

National Jewish Hospital
Denver, Colorado
March 1984

JOB/AREA DESCRITPION	SAMPLING TIME (MINUTES)	Mg/M^3 GLUTARALDEHYDE
NEB Cleaning-Outpatient+		
Operator	30	1.07*
Operator	30	1.07*
Sink - Left side	30	0.71*
Sink - Center side	30	1.13*
Sink - Right side	30	1.32*
Center of Room	30	0.18
NEB Cleaning - Central Services		
Operator	30	1.28*
Operator	30	0.86*
Sink - Left side	80	ND
Sink - Right side	80	ND
Sink - Center	80	ND
Tissue Fixing		
Operator	30	ND
Operator	30	ND
Lab Hood - Left side	45	0.10
Lab Hood - Central	45	0.18
Lab Hood - Right side	45	0.14
Tissue Fixing and "Maintenance"**		
Operator	30	1.5*
Operator	30	0.75*
Lab Hood - Left side	45	1.5*
Lab Hood - Center	45	0.8*
Lab Hood - Right side	45	0.75*

EVALUATION CRITERIA: (ACGIH) 0.7 mg/M^3

LABORATORY LIMIT OF DETECTION: 3.0 ug/sample

mg/M^3 = milligrams of substance per cubic meter of air
ug/sample = micrograms per sample
+ = NEBULIZER for inhalation therapy/mouthpieces
* = exceeded the current threshold limit value (C-TLV)
** = sampled with lab hood opened during tank cleaning process

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