HETA 87-043-1801
MAY 1987
ACMI COMPANY
NORWALK, OHIO

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I. SUMMARY

On November 6, 1986, the National Institute for Occupational Safety and Health (NIOSH) was requested by the ACMI Company, Norwalk, Ohio, to evaluate an outbreak of dermatitis. A NIOSH team conducted a site-visit on December 3, 1986. NIOSH investigators examined seven out of eight employees engaged in this process and analysed the working procedures.

From a review of company records, it was concluded that the dermatitis outbreak was restricted to the areas of light-carrier assembly, where 5 of 8 employees had reported a skin rash in 1986. The outbreak started after a change in production; fibermats were replaced by single optical fibers, and soon thereafter production was increased. Cases occurred both before and after the sealant, Loctite 640, was changed to Epo-Tec 377.

To assemble the light carriers, the fibers are wetted with isopropyl alcohol and the workpiece is made waterproof using a sealant. No protective measures were taken to prevent accidental skin contact to the sealant. Environmental and personal hygiene were insufficient. Consequently, the skin was continuously contaminated with the sealant (Loctite 640 or later Epo-Tec 377) to a minor or major degree.

At the time of the survey, two of the cases showed skin conditions typical for resolving dermatitis. Telephone interviews with the workers' physicians documented one case of sensitization to Loctite 640, and the other to Epo-Tec 377. All affected employees showed complete recovery when on sick leave or transferred to other areas of production.

Based on these results, the NIOSH investigators concluded that dermatitis was caused by exposure to isopropyl alcohol and sealants, either the acrylic resin, Loctite 640, or the epoxy resin, Epo-Tec 377.

Only if skin contact is reduced to a minimum, can development of further dermatitis be prevented when such irritant and allergenic resins are used. This makes it necessary to redesign the assembly procedures and to implement strict environmental controls and personal hygiene.

Key words: SIC 3841 (Manufacturing, Medical Equipment), acrylic resin, epoxy resin, isopropyl alcohol, dermatitis, optical fibers.

II. INTRODUCTION

On November 6, 1986, the National Institute for Occupational Safety and Health (NIOSH) received a request from the ACMI Company, Norwalk, Ohio, to investigate an outbreak of dermatitis among assemblers of cystoscopes. The request was initiated by the Industrial Commission of Ohio, Division of Safety and Hygiene. The requester asked NIOSH to identify the causes of dermatitis in light carrier assemblers.

On December 3, 1986, NIOSH visited the plant, evaluated the work process, and examined the skin of the assemblers.

III. BACKGROUND

The ACMI Company produces rigid and flexible cystoscopes and ureteroscopes that are used by physicians all over the world.
One hundred twenty production and maintenance workers are employed. The production is organized into five major shops of about 20 workers each. Most of the dermatitis cases reportedly occurred among light carrier assemblers (Electrical Assembly Department).

The process has been located in this area of the plant since the beginning of 1984. A cylindrical tube is first wrapped in fiberoptic glass fibers and then inserted into a wider one. The space between the two tubes is sealed to make it waterproof at both ends. Additionally, at the viewing end of the light carrier some parts are screwed on and tightened using the same resin. Prior to May 1986, the glass fibers were purchased in preformed sheets, with the fibers bonded together by an epoxy resin; these preformed sheets were wrapped around the inner cylindrical tube in the first stage of assembly.

Beginning in May 1986, a new technique was gradually introduced into the light carrier assembly operation. The company improved the light transmission by replacing the fiber mats with single, unbound fibers. These single fibers are temporarily bound together by wetting with isopropyl alcohol in the first stages of assembly. Greater dexterity is demanded. In July 1986, production increased. Consequently, overtime was frequent, and workers spent considerably more time each day assembling the light carriers. In September 1986, the anaerobic acrylic sealant (Loctite 640), which was used to seal both ends of the light carrier, was replaced by an epoxy resin (Epo-Tec 377). This change included economic and technical benefits and the company has no plans to return to the acrylic sealant.

Four women have worked in this department since the beginning of production in 1984. In April, July, September, and November 1986, four new women were trained in this operation. In the period between May and October 1986, two of the original four workers and three of the four new operators reported of blisters on the hands and discontinued this kind of assembly work.

IV. EVALUATION DESIGN AND METHODS

Methods and Materials

Three NIOSH physicians, one of whom is a dermatologist, conducted a survey at the plant on December 3, 1986. Information was obtained concerning plant processes and materials used. The working conditions, cutaneous exposures, and production methods in the light assembly area were directly observed. OSHA logs for the last 5 years and health records from the company nurse for 1986 were reviewed, for cases of dermatitis.

All light carrier assemblers and other employees with skin problems on the fingers or hands were interviewed, and their hands were examined. The interview consisted of questions concerning work history, symptoms, onset of symptoms, and medical treatment.

V. EVALUATION CRITERIA

A. Contact dermatitis

In general terms toxic chemicals can cause dermatitis by two different mechanisms: 1) irritation, and 2) allergic sensitization.

1) Irritation of the skin can be the consequence of mechanical trauma, abrasion, or toxic chemical alterations of the various layers of the skin surface. For example, contact with solvents degreases the skin, causing it to becomes dry and cracked. Lye softens the skin, and acids may cause reactions similar to burns. All these alterations reduce the natural protective capabilities of the skin and may facilitate the penetration of any toxic substances. The longer and/or the more the skin is exposed to irritating conditions the greater is the likelihood for the development of dermatitis. Limiting contact with toxic substances prevents further development of irritant dermatitis, although it may take a long period of time until it completely resolves.

2) Sensitization of the skin can be caused by a great variety of substances. The ability to induce allergy varies from substance to substance (e.g. it is high for poison ivy or epoxy resin and low for alcohols). The mechanism involved is an immunological response, not an irritant effect. In most circumstances, one has to repeatedly come into contact with a substance to become allergic. Exposures at higher concentrations may increase the risk of developing contact allergies.

   The susceptibility to develop allergy varies from person to person. A person, not suffering from allergic contact dermatitis even after a longlasting continuous exposure may still become allergic at some later time. There is no sure method to predict who will become sensitized.

   Once a person has become sensitized to a certain substance, exposures to even minimal amounts may cause severe allergic reactions. Very often a decrease in exposure does not prevent repeated attacks. The allergenic substances have to be eliminated from the environment or the allergic individual has to be transferred to another environment.

   Often, irritant chemicals destroy the protective shield of the outer skin layers and makes them more permeable to allergenic substances. Contact allergy may become superimposed on an irritant skin disorder.(2,5)

   In the following, the dermal toxicity of the most important used chemicals are discussed:

B. Specific substances

1. Isopropyl alcohol

Isopropyl alcohol is a frequently used solvent. It moderately irritates and dries the skin. Allergic sensitivity is very rare. Similar to ethyl alcohol that is contained in alcoholic beverages, it can affect the central nervous system.(1,2) In the air its permissible exposure limit is 400ppm (98)mg/m^3.

2. Loctite 640

Anaerobic acrylic sealants are liquid adhesives that harden between metal parts in the absence of air. The fully polymerized product is not toxic but the original compounds may have irritant and allergenic potential.(2,4,5) In some circumstances, during processing on machines, swarf of the hardened resin is produced and may also cause both allergic or irritant skin reactions.(6) Only incomplete information is available on possible toxicological effects of the chemicals specified on the Material Safety Data Sheet (MSDS) for Loctite 640. Similar compounds of methacrylates or dimethacrylates have been described to cause allergic dermatitis.(2,5) They are mild irritants to eye and skin. Acrylic acids are irritating.

Severe corneal burns have been reported after acute exposure to methacrylic acid. Acrylic acid has also proved to be embryotoxic and teratogenic in rats.(6)

3. Epoxy resins

Epoxy Technology Incorporated, the manufacturer of EPO-Tec 377, considers the composition of it this product as a trade secret. A general description will be given of the toxicological properties of epoxy resins.

Epoxy resin systems, including EPO-Tec 377, consist of two parts - a resin and a hardener - which must be mixed immediately prior to application, if cure occurs at room temperature. The epoxy resin is characterized by a chemically reactive configuration of an oxygen atom and two carbon atoms, the so called epoxy group. Over 90% of the epoxy resins are made by the reaction between epichlorohydrin and bisphenol A. By controlling the ratio of epichlorohydrin to bisphenol A, manufactures can obtain resins with various molecular weights. The viscosity of these resins increases with the increase in molecular weight. Many resins of this type are soluble in each other, and a variety of combinations can be obtained.(2) Many other chemicals having an epoxide group are produced and used as epoxy resins.(2,5,6,7) Polymerization and the creation of a tight cross-linked polymer network are achieved by adding curing agents and catalysts.(2) Curing agents include aliphatic amines, amine adducts, polyamides, tertiary amines, aromatic amines, cyclophatic amines, acid anhydrides, and others. Modifiers or additives are incorporated to change flexibility, viscosity, strength, color, and heat and ultraviolet resistance. The most important modifiers concerning the skin are reactive dilutents or solvents, such as glycidyl ethers.

Epoxy compounds may adversely affect the skin, mucous membranes, lungs, central nervous system, and liver. The low-molecular-weight monoepoxides are weakly anesthetic and are strong irritants. Inhalation can cause pulmonary edema and secondary pulmonary infection. Skin irritation in varying degrees up to necrosis can result from prolonged contact, typically due to saturated clothing. In addition to pulmonary effects, including sensitization from volatile hardeners, vapors may also cause eye irritation. Tumors have been produced in experimental animals following both cutaneous and subcutaneous administration of several epoxy compounds.(6)

Dermatitis from contact with the epoxy resins or their curing agents may be due to either irritation or allergic sensitization. Epoxy resins have been shown to be strong sensitizers to humans. The most highly sensitizing is the resin with a molecular weight of 340. Oligomers with molecular weights of more than 900 were found to be practically nonsensitizing. High-molecular weight resin formulations, however, may also contain resins of lower molecular weight.

The aliphatic amine hardeners are strong irritants, particularly because of their highly alkaline nature, but may also occasionally cause allergic sensitization.

Epoxy dermatitis usually appears first on the hands, particularly between the fingers, in the finger webs, on the back of the hands, and on the wrists. It may vary in severity from mild erythema to a marked bullous eruption resembling a burn. Sensitization is usually associated with a highly pruritic eruption consisting of fine vesicles on the fingers and hands. The eruption may spread rapidly to other regions of the body.(2,5,7)

VI. RESULTS

A. Evaluation of work practices

The manipulations performed by light carrier assemblers have involved direct skin contact with isopropyl alcohol, anaerobic acrylic sealant (Loctite 640 prior to September 1986), and epoxy resin (Epo-Tec 377 since September 1986).

The resin and the hardener compounds are manually poured into an open container, accidental spills may occur.

For assembly, the optical fibers are wetted by pouring isopropyl alcohol over the fibers and coating them by sliding the fingers over the length of the wetted fibers. Although gloves were provided, this procedure was not always done using gloves, because they decrease manual dexterity. Since the optical fibers are not contaminated by pieces of small glass fibers and do not easily break, they are not likely to pose any hazard to the skin.

The rest of the assembly is mostly done without gloves. For sealing, the resin is applied by cotton sticks. It easily flows along the metal surfaces and gets into contact with the skin of the hand holding the work piece. At the viewing end of the light carrier, where additional small pieces are attached, the optical fibers are coated with resin in the same fashion as with isopropyl alcohol. The resin may also drop onto the table surface, so that finally the whole workplace may be contaminated.

Thus, the fingers and hands are in minor or major contact with the resin most of the work day.

B. Medical Data

On a company listing of accidents or illnesses eight cases of skin rash were reported for 1986. No skin rashes were recorded in prior years. Based on the case definition - reported skin rash during 1986 - we calculated relative risk of dermatitis for the different departments of the company, each in comparison to the rest of the company workforce (Table 1). The prevalence of dermatitis was highest (63%) in the El-Med department. All 5 cases were in the light carry assembly group (relative risk compared to the rest of the workforce: 22, 95% confidence interval 9-58). The skin examination was offered to the light carrier assemblers; all were examined except for one person on leave. One person in Quality Control, who reported a skin rash on the hand was also examined. Five of the seven light carrier assemblers examined described their skin rashes as itching and blisters, that occurred predominantly on their fingers. The person from Quality Control reported only redness and itching.

The skin examination revealed dryness of fingers in all eight persons, but examinations among unexposed workers and secretarial staff showed similar findings. In two cases the skin condition was indicative of resolving dermatitis.

The first cases occurred shortly after the change from fiber mats to single fibers (Figure 1). Furthermore, an increase in production, involving longer periods of uninterrupted pure assembly, preceded most of the cases.

At the time of our investigation, we reviewed results of contact allergy patch tests (including Loctite 640 and Epo-Tec 377), which had been done on three light carrier assembly employees, by private physicians. These tests documented an allergy to Loctite 640 in one person and allergy to a routine test-mix, Para-phenylene diamine, in a second. The relevance of the allergy to PPD, which is often found in black rubber, is not clear, since no clear source of exposure could be identified. The third person reacted strongly to Loctite 640, as well as Epo-Tec 377 but contact allergy could not be confirmed since the test concentrations (50%) were well above the usual test range, and may have been false positive reactions. (The two other cases among light carrier assemblers have not been tested.)

Following our investigation in January 1987, the company informed us that a sixth person developed a skin rash and that allergy to Epo-Tec 377 was confirmed by patch testing.

VII. DISCUSSION

To date, six of eight light carrier assemblers have experienced onset of skin rashes within the past year. In two, cases allergy testing suggests or confirms an allergy to Loctite 640 or Epo-Tec 377. There have been few reported skin problems within other departments of the plant. Since May 1986, assembly has been done in a way that has caused intense and prolonged skin contact with sealants. The change from fibermats to single fibers, and increased production, coincide with the outbreak of dermatitis. Both events have led to a relative increase in exposure to Loctite 640 (now replaced by Epo-Tec 377) and isopropyl alcohol. On the basis of the sequence of events and the changes in the production process, it is very likely that the skin problems were caused by contact with resins.

Both acrylic and epoxy resins are potent sensitizers and have irritant properties as well. "In the first decade after their introduction to the United States, the epoxy resins were responsible for a great many cases of dermatitis. Some factories reported a dermatitis rate as high as 50 percent of the exposed workers, with sensitization in approximately 10 percent. As the hazards of these substances and safe methods of handling them have become better known, the incidence has decreased, despite the fact that they are used by more people in a greater variety of ways than ever before."(2) The quotation relates to epoxy resins, but acrylic resins pose similar problems.

VIII. RECOMMENDATIONS

1. The work process should be re-designed so that no unnecessary contact with the resin occurs.

2. Protective clothing, such as synthetic rubber gloves, should be worn whenever there is any chance for skin contact. Gloves made of polyvinylchloride (PVC) are preferable, since latex rubber and many plastic gloves are penetrated by the resins and catalysts. However, even PVC can be destroyed by certain epoxy compounds. Information on the protective properties of gloves may be available from the supplier.

3. Gloves should not be worn when not necessary, but they must be worn during actual contacts with the resin. They must be correctly removed. Repeated use of the contaminated gloves may lead to continuous contact with the toxic compounds inside the gloves, so they should be changed frequently.

4. Tabletops should be covered with heavy paper, which should be changed frequently.

5. An uninterrupted supply of disposable paper towels must be provided, to clean-up any accidental spill.

6. Accidental spills on the skin should be removed immediately, using a waterless skin cleaner. Then the skin should be washed with soap and water.

7. A preventive skin care program should be implemented. Before the work shift and every time after cleaning the skin, the skin should be moisterized. A moisterizer should be provided by the company and placed in the hand wash area.

IX. REFERENCES

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XI. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. 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. AMCI COMPANY, NORWALK, OHIO

2. Industrial Commission of Ohio, Division of Safety and Hygiene

3. Evelyn Ewing, President, Local 718 AIW

4. NIOSH, Region V

5. OSHA, Region V

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

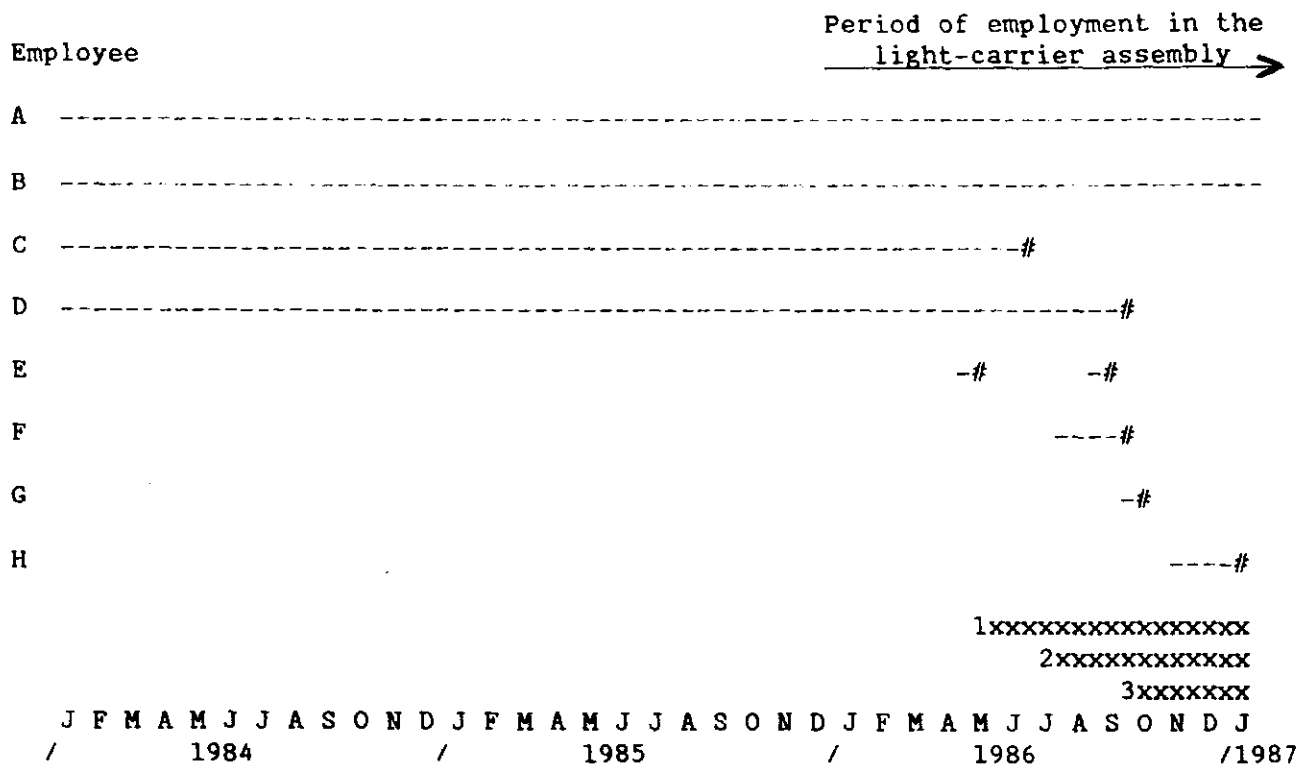
Table 1.
Prevalence and Relative Risk for Hand/Finger Dermatitis in
Different Departments during 1986
ACMI COMPANY
NORWALK, OHIO
HETA 86-043
June 6, 1986

Department	No. of Employees'	No. of Cases with Dermatitis	Prevalence (%)	Relative Risk[2]	95% Confidence Interval	Fishers Exact Test
Flexible Assembly	26	1	4			
Machine Shop	25	1	4			
Urology	17	0	0			
Polish Plating	15	0	0			
El-Med	17	5[A]	29	10	3 - 30	p=0.002
Light Carrier Assembly[B)]	8	5[A]	63	22	9 - 58	p=0.00002
Quality Control	5	1	20	3	0.5 - 22	p=0.3
Others (Stock, Tooling, Maintenance)	10	0	0			
Total	115	8	7			

1. Employed as of 12-15-86 and before ll-1-86.
2. Compared to all other departments.

A. A sixth case has been reported subsequent to our investigation.
B. Light carrier assembly is a special part within El-Med.

Figure 1: Duration of Employment, Changes in Production, and Onset of Skin rash in Eight Light-Carrier Assemblers since Start of Production, January 1984.



Legend:
-- employed in light carrier assembly
\# onset of skin rash
1 change from fiber mats to single fibers
2 increased production
3 change from Loctite 640 to Epo-Tec 377