U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CINCINNATI, OHIO 45226

# HEALTH HAZARD EVALUATION DETERMINATION
REPORT NO. 75-154-387

EMERY INDUSTRIES
CINCINNATI, OHIO

APRIL 1977

## I. TOXICITY DETERMINATION

Exposures of employees to airborne particulate, azelaic acid and carbon monoxide at bagging operations in Building #69 were not found to be toxic under conditions observed by the NIOSH Hazard Evaluation personnel during the survey dates of March 29, April 2, and May 25, 1976. This determination is based upon inspection of the work areas and materials used, medical evaluation of the exposed workers, measurements of worker exposures to airborne contaminants, and review of the current knowledge of the materials used.

Workers at this operation had reported irritation of skin areas, the eyes, nose (resulting in increased nasal secretions), and the upper respiratory tract. These irritant effects were reported by the workers to make the job generally unpleasant and to be more severe during hot weather periods. These irritant effects were reported to be of short duration and usually resolved after washing affected skin areas with soap and water and clearing the nose.

The NIOSH medical examination of affected workers included a brief physical examination, and blood and urine analysis. No permanent or serious health effects were detected. Slight irritation of the nasal mucosa was observed in one worker in the bagging operation.

Worker exposures to airborne particulate, azelaic acid, and carbon monoxide were determined by personal and area air sampling. Worker exposures to total airborne particulate were found to range from 0.2 to 6.2 $mg/M^3$. Worker exposures to azelaic acid were found to range from approximately 0.1 to 3.8 $mg/M^3$. Based on observations of work practices and conditions, it appears that worker exposures could be reduced by improved work practices, improved equipment design and maintenance, and proper use of personal protective equipment.

## II. DISTRIBUTION AND AVAILABILITY OF DETERMINATION REPORT

Copies of this Determination Report are currently available upon request from NIOSH, Division of Technical Services, Information 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:

a) The Requestor
b) Emery Industries, Incorporated, Cincinnati, Ohio
c) U.S. Department of Labor - Region V
d) NIOSH - Region V

For the purpose of informing the approximately eight "affected employees" the employer shall promptly "post" for a period of 30 calendar days the Determination Report in a prominent place(s) near where exposed employees work.

## III. INTRODUCTION

Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6), authorizes the Secretary of Health, Education, and Welfare, following a written request by an 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 National Institute for Occupational Safety and Health (NIOSH) received such a request from an authorized representative of employees regarding worker exposures to Emerox® 1110, Emerox® 1133, and Emerox® 1144 at operations in Building 69 at Emery Industries in Cincinnati, Ohio. Workers at this operation were alleged to have experienced skin reddening and burns, and "nose running" as a result of working at bagging operations.

## IV. HEALTH HAZARD EVALUATION

### A. Description of Process - Conditions of Use

Emery Industries is one of the largest oleo-chemical processors in the United States. The various oleo-chemicals (fatty acid products) produced by Emery are the result of the processing and purification of the tallow fractions.

Emerox® 1110, 1133, 1144 are trade name specifications for azelaic acid distributed by Emery Industries. Emery Industries is the only producer of azelaic acid in the United States. Azelaic acid is used as a component in the manufacture of plasticizers, a component of alkyd resins, lacquers and special lubricants (low temperature and extended life motor oils), and in various chemical synthesis processes.

The production of azelaic acid at Emery Industries involves the reaction of ozone with oleic acid, the separation of the azelaic acid and pelargonic acid fractions, pipe transport of the liquid azelaic acid to Building #69, and the flaking and bagging of the flaked azelaic acid (SIC Code 2818,

Industrial Organic Chemicals). Only the flaking, bagging, and storage of azelaic acid occurs in Building #69 (no other materials are processed or handled). The hot azelaic acid (melting point, 106°C) enters the second floor by pipeline on a controlled continuous basis and empties into one of two flakers. The flaker consists of a cold roll which uniformly congeals liquid azelaic acid. As the roll rotates, the thin film is removed by a stationary blade and falls into a hopper. The bagging is from the bottom of the hopper on the first floor. While the South flaker handles only Emerox® 1110, the North flaker will handle all of the azelaic acid products (Emerox® 1110, 1133, 1144). The bagging is not a continuous operation because the hoppers are large enough to allow the flaked azelaic acid to accumulate. This allows the operators to attend to other duties in the plant. Two employees (in the job classification of Utility Ozone Pumper) on each shift (a total of eight male employees with a mean age of 29) are required to bag for three 1-hour periods. The bagging process requires the operator to be present to operate the bagging equipment, seal the bag when filled, and stack. The filling of a bag begins with fitting the bag on the filling spout. The flaked azelaic acid falls by gravity from the hopper (the hopper has a mechanical vibrator to aid the gravity flow) onto a conveyor belt and screw-feed transport apparatus which empties into the bag. The bagging equipment is exhaust ventilated along the conveyor and screw-feed portions. The bags usually must be patted/slapped by the operator in order to get proper filling. The vibrator and screw feed are stopped when the bag has been filled with fifty pounds of the azelaic acid product. The operator must then lift the filled bag off of the fill-spout and tuck in the tongue of the bag. The bags are then placed on a pallet. A water-based glue is applied to the outside of the bags to better stabilize pallet loads. When 40 bags are stacked on a pallet, it is transported by a fork lift unit to storage racks in Building #69. The pallets are subsequently handled during the loading of trucks for shipment.

Emerox® 1110, 1133, and 1144 are products of the ozonation of commercial grade oleic acid. The use of azelaic acid as a component in the manufacture of plasticizers does not require an exceptionally pure azelaic acid. However, the use of azelaic acid for polymer production, such as polyesters, requires a low monocarboxylic acid content. Emery Industries provided NIOSH with the following typical component breakdown for Emerox® 1110 and Emerox® 1144:

| | Emerox® 1110 | Emerox® 1144 |
|---|---|---|
| Monocarboxylic Acids | 1% | 0.05% |
| Dicarboxylic Acids | | |
| C5 | 1% | |
| C6 | 2% | |
| C7 | 2% | |
| C8 | 4% | 1% |
| C9 (Azelaic Acid) | 80% | 90% |
| C10 | 2% | 2% |
| C11 | 6% | 6% |

B. Evaluation Design and Methods

The NIOSH evaluation of worker exposures and health effects from the azelaic acid bagging operation required several visits to the work site. NIOSH industrial hygienists first visited this operation on September 23, 1975. During the initial visit on September 23, 1975 a walk-through industrial hygiene survey was conducted and four of the eight employees at the bagging operation were administered non-directional medical questionnaires designed to elicit work related health problems. The four other employees at this operation were interviewed on September 25, October 15 and 17, 1975. On the basis of the results from these questionnaires and a lack of reported industrial experiences with azelaic acid, it was decided to conduct a concurrent medical/environmental evaluation.

A combined environmental/medical evaluation was performed by NIOSH industrial hygienists and medical officers during bagging operations on March 29 and April 2, 1976. The NIOSH medical officers questioned workers concerning work related health problems, obtained urine and blood samples for analysis, and performed brief physical examinations prior to and immediately after bagging operations. Blood analysis included complete blood counts, SGOT, lactic dehydrogenase, alkaline phosphatase, total bilirubin, serum albumin, total protein, cholesterol, uric acid, blood urea nitrogen, glucose, inorganic phosphate, and calcium. Worker inhalation exposures to azelaic acid were determined by personal and area air sampling. It was decided at this time to extend the medical evaluation into hot weather periods because skin irritation effects were reported to be more severe during hot weather.

Results of air sampling conducted on March 29 and April 2, 1976 indicated that the gravimetric weight gain method of analysis did not possess sufficient sensitivity due to the small volume of the air samples. Air sampling was performed on May 25, 1976 to test and compare alternative methods; filter gravimetric weight gain, and GCA Dust Monitor. It was on this date that "concurrent" air sampling was performed and the filter samples were retained for future analysis by a method specific for azelaic acid.

No hot-weather evaluation was performed during the summer of 1976 due to the inability to coordinate hot weather with the availability of NIOSH personnel, and Emery Industries operation shutdown/breakdown. On September 10, 1976 (a hoped for hot weather time) it became apparent that a hot weather evaluation would not be possible that year and it was decided by NIOSH, the Requestor and Company to conclude the study at that time.

Air Sampling and Analysis Methods

Airborne particulate was sampled for by drawing air through pre-weighed Gelman VM-1 filters (a vinyl metricel filter with a 5 micron mean flow pore size) in a closed face cassette.

Personal Samples - Breathing zone air samples were obtained by attaching the filter cassette to the worker's lapel. The air was drawn through the filter at 2.0 liters per minute by a MSA Model G pump attached to the worker's belt.

Area Samples - Area sampling was for both the total and respirable fraction of the airborne particulate. Respirable samples were obtained using two sampling units: A Gast pump drawing air at about 9 liters per minute through a one-half inch stainless steel cyclone (a size selective device) and filter; a MSA Model G pump drawing air at 1.7 liters per minute through a 10-mm nylon cyclone (a size selective device) and filter. The total airborne particulate was sampled by drawing air through a closed face cassette at about 9 liters per minute (with the Gast pump) or at 2 liters per minute (with the Model G pump).

All VM-1 filters were analyzed for gravimetric weight gain. The results from air sampling on March 29, 1976 and April 2, 1976 indicated that the precision and sensitivity of gravimetric weight gain analysis was not adequate for estimating airborne particulate levels. This sampling and analytic method was tested to determine its sensitivity and precision for the bagging operation in this evaluation. This was accomplished by attaching twelve sampling units to a ring stand. These samplers were presumably drawing air from the same point in space during the same time period. Ten of the samplers used MSA Model G pumps drawing air at 2.0 liters per minute. The other two samplers used a Gast Pump to draw air at about 9 liters per minute. These filter samples, as well as ten blank filters (filters which were identified to the laboratory as not having air drawn through them) and ten blind-blank filters (filters which did not have air drawn through them, but identified as being samples) were analyzed for gravimetric weight gain.

NIOSH laboratories developed an analytical method specific for azelaic acid.[1] The filter samples obtained on May 25, 1976 were analyzed by this method. An acid-base titrimetric method of analysis was initially attempted but did not prossess enough sensitivity to determine azelaic acid in the amount present on the sample filters. Analysis for the silyl $-Si(CH_3)_3$ ester derivative of azelaic acid was used to measure the azelaic acid collected on the filters. The analytic method was as follows:

> The analytical standards were prepared from Emerox® 1144 (this bulk material was collected on May 25, 1976) which was weighed on an electro balance. Each filter was placed in a screw cap vial with 5 ml ethanol and then in a 70°C water bath for twenty minutes. Each vial was shaken every five minutes. The filter was lifted with tweezers above the ethanol level in the vial and washed with ten 1-ml portions of ethanol. The vials were then placed in a vacuum-oven and ethanol evaporated to dryness.
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> One ml of pyridine was added to each vial to dissolve the acids, followed by 1 ml of Bis (Trimethyl Silyl) Trifluoroacetamide (BSTFA) containing one percent Trimethyl Chlorosilane (TMCS) as a catlyst. These vials were then placed in a 70°C hot water bath for 25 minutes and stirred every five minutes (95 percent of the esterification reaction was completed in the first five minutes). After cooling, each sample was analyzed by a Perkin and Elmer Gas Chromatograph Model 900 equipped with a flame ionization detector.

The chromatographic column consisted of ten feet of one-quarter inch O.D. glass packed with six percent SP2100 (Methyl Silicone) on 60/80 mesh supelcoport. The chromatograph oven was temperature programmed from 190°C to 250°C rising 6°/minute. The injector port was kept at 250°C and detector manifold at 250°C. The carrier gas was helium flowing through the column at 40 ml/minute. Sample size was 5 ul.

The azelaic acid silyl ester eluted 4.5 minutes after injection. The normal analysis time until all components higher than $C_9$ are eluted is ten minutes. The identification of the azelaic acid ester was accomplished using a gas chromatograph/mass spectrophotometry system (little emphasis was given to the identification of minor peaks). The minimum detectable amount of azelaic acid was found to be 0.5 nanograms per one microliter injection into the gas chromatograph. This corresponds to a concentration of 0.001 mg per filter sample. The analytical precision was determined from six gravimetric standards of 1, 2, 4, 6, 8, and 10 milligrams. The analytical Relative Standard Deviation was found to be two percent (calculated as the pooled coefficient of variation). Filters were spiked with 2, 4, 6, 8, and 10 milligrams of azelaic acid. The average percent recovery was found to be 94.8 percent.

GCA Model RDM 101 Respirable Dust Monitor was used in an effort to measure airborne particulate on May 25, 1976. This is a digital readout instrument which measures the mass of particulate collected on an impinging plate with a beta radiation source.

Carbon monoxide was measured using an Ecolyzer Model 2400. This direct reading instrument was connected to a strip chart recorder and operated during the periods of air sampling on March 29, 1976 and April 2, 1976.

C. Evaluation Criteria

1. Health Effects

Azelaic Acid

Very little information is available on the human health effects of exposure to azelaic acid. This section is an attempt to compile all of the pertinent information related to the human toxicity of azelaic acid.

Azelaic acid (nonanedioic acid, synonym) is not listed in the 1976 edition of the Registry of Toxic Effects of Chemical Substances.[2] A search of the commonly available industrial hygiene and toxicology references found only one mention of azelaic acid. Patty[3] makes reference to Enders[4] work which found azelaic, adipidic and sebacic acids to be slightly toxic. These animal studies included an evaluation of toxicity by the intravenous injection and oral routes, and urinary excretion.

The TOXLINE data system contained only one abstract concerning the effects and metabolism of azelaic acid by mammalian species. The abstract is as follows:

> "14C - Labeled azelaic acid, ingested by rats, did not undergo beta-oxidation, was not taken up by adipose tissue, and was not incorporated into triglycerides. Azelaic acid was incorporated essentially into globular lipids as phospholipids and diglycerides. Azelaic acid was, therefore, metabolized differently than monocarboxylic fatty acids.[5]"

Emery Industries made available to NIOSH a sheet which summarized the chemical properties of azelaic acid: "Chemical Properties of Azelaic Acid." The health hazard is stated as: "Slight - Very low. Skin or mucous membrane irritation may result from contact with dust or vapor." This same sheet recommends that contact and inhalation of the dust be avoided, and that work gloves, dust-type respirator, and goggles be worn, if necessary, when packaging or dumping.

Also made available to NIOSH were the results of acute animal toxicity studies[6] of Emerox® 1110 performed by Hill Top Research Institute, Inc. Emerox® 1110, 1133 and 1144 are azelaic acid products which differ in their purity. However, for the purposes of this discussion it is assumed that these products have similar toxicity. The results of these tests are as follows:

> Acute oral toxicity: Emerox® 1110 was administered by stomach tube to six groups of five male albino rats. The Emerox® 1110 was a 50 percent weight/volume suspension in water and dosage levels ranged from 0.215 to 10.0 grams/Kg of body weight. No mortalities occurred at any dosage level tested. Average body weight gains for each group were within normal limits. Gross autopsy showed no significant gross pathological findings among the rats in any dosage group.
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> Acute dermal toxicity: Emerox® 1110 was applied to the skin of four groups each with four albino rabbits. The dosage levels were 1.0, 2.2, 4.6, and 10.0 grams/Kg body weight. It was reported that with the exception of one rabbit, at the 4.6 gram/Kg dosage level, there were no mortalities at any dosage level. It was felt that this mortality was due to acute enteritis, a common syndrome in laboratory rabbits. Mild or moderate erythema was observed in a few animals for one to four days, otherwise, the exposed skin areas appeared grossly normal.
>
> Acute eye application: A three milligram sample of Emerox® 1110 was applied to an eye of three albino rabbits. Irritative effects in the eye were confined to mild erythema, edema, and discharge at one hour. This corresponded to a total eye irritation score (Draize method) ranging from four to six.

Biologic assay studies failed to detect mutagenic activity in either oleic acid or the products of ozonation.[7] This assay for mutagenic activity included the salmonella typhimurium (the "Ames" system) and saccharomyces cerevisiae systems (both types of assays were also performed following "metabolic activation" procedures). Mutagenic substances are those which act on genetic material and cause mutational changes potentially manifested as birth defects, fetal death, and cancer.

Azelaic acid is a primary irritant to the skin and mucous membranes due to its acidic quality. The extent of the primary irritant effect of a carboxylic acid is a result of the degree of acid dissociation, water solubility, and other factors influencing the penetration of skin and mucous membranes.[3]

In summary, a review of the literature and other pertinant information indicates that azelaic acid has a low toxicity. The health effects resulting from human exposures to azelaic acid would be expected to be primary irritation. Skin or mucous membrane irritation is likely to develop following contact and signs and symptoms as a result of contact could include: reddening of the skin and discomfort following skin contact; stinging and watering of the eyes, and eye tissue damage (in severe cases) following eye contact; and nasal and respiratory irritation manifested as coughing and sneezing. These effects, in most cases, would be of a minor and temporary nature.

Carbon Monoxide

Excessive carbon monoxide exposure can result in adverse health effects due to the blood's reduced ability to transport oxygen to the tissues. Hemoglobin, the blood's oxygen carrying protein, will preferentially bind carbon monoxide and reduce the oxygen binding capacity. Such an oxygen deficiency to the tissues is first observed as a headache, nausea and mental impairment. In extreme exposure conditions, unconsciousness and death can occur. Carbon monoxide in the blood can be reduced by removing the affected person to uncontaminated air or administering oxygen. Employees at this operation could potentially be exposed to carbon monoxide as a result of the operation of a faulty fork lift or space heater, and the smoking of cigarettes. Heavy cigarette smokers commonly have levels of carbon monoxide in their blood which are comparable to occupational over exposure.

2. Environmental Evaluation Criteria

No workplace exposure limit(s) for azelaic acid has been promulgated, recommended, or proposed by OSHA, NIOSH, ACGIH, or any other such group. The ACGIH has set a threshold limit for nuisance particulates:

> "A threshold limit of 10 mg/M$^3$, or 30 mppcf, of total dust <1 percent quartz is recommended for substances in these categories (nuisance particulates) and for which no specific threshold limits have been assigned. This limit, for a normal workday, does not apply to brief exposures at higher

concentrations. Neither does it apply to those substances which may cause physiologic impairment at lower concentrations but for which a threshold limit has not yet been adopted.[8]"

The following are some substances which are considered to be nuisance particulates:

Some Nuisance Particulates*
TLV, 30 mppcf or 10 mg/$M^3$ of Total Dust,
or 5 mg/$M^3$ Respirable Dust[8]

| | |
|---|---|
| Alundum ($Al_2O_3$) | Kaolin |
| Calcium carbonate | Limestone |
| Calcium silicate | Magnesite |
| Cellulose (paper fiber) | Marble |
| Portland Cement | Mineral Wool Fiber |
| Corundum ($Al_2O_3$) | Pentaerythritol |
| Emery | Plaster of Paris |
| Glass, fibrous**, or dust | Rouge |
| Glycerin Mist | Silicon |
| Graphite (synthetic) | Silicon Carbide |
| Gypsum | Starch |
| Vegetable oil mists (except castor, cheshew nut, or similar irritant oils) | Sucrose |
| | Tin Oxide |
| | Titanium Dioxide |
| | Zinc Stearate |
| | Zinc oxide dust* |

* When toxic impurities are not present, e.g. quartz <1%
** <7 um in diameter

The ACGIH has assigned these substances to the "nuisance" category because they have a long history of little adverse effect on lungs and do not produce significant organic disease or toxic effect when exposures are kept under reasonable control. The lung-tissue reaction caused by inhalation of nuisance dusts has the following characteristics:

1) The architecture of the air spaces remains intact.
2) Collagen (scar tissue) is not formed to a significant extent.
3) The tissue reaction is potentially reversible.

No evidence exists at the present time which indicates that azelaic acid is potentially more toxic than the above listed "nuisance" materials. However, based on the lack of long term exposure/effect studies, azelaic acid should not be included in the "nuisance" category.

NIOSH has recommended that occupational exposure to carbon monoxide be controlled so that no worker is exposed at a concentration greater than 35 ppm determined as a time-weighted average exposure for an 8-hour workday, and 200 ppm for any period of time.[9] OSHA enforces a carbon monoxide exposure limit of 50 ppm (time-weighted average concentration over an 8-hour workday).[10]

D. Results

1. Medical Evaluation

All of the eight examined workers reported that they had experienced, on at least one occasion in the past, reddening (erythema) of the skin related to azelaic acid exposure. Four of these workers complained of erythema around the wrists and four on the face including one description of erythema in a line around a respirator if the latter was worn in hot weather. The erythema usually resolved within one day of its onset. Five workers complained of increased nasal secretions including one of oddasional nosebleeds. An additional worker complained of sneezing and nasal burning. Four workers complained of burning of the eyes, which was reported in one case to occur only if the area fan was being used and to be relieved by flushing the eyes with water. Three workers complained of throat irritation. No workers described cough, shortness of breath or other symptoms. All symptoms were stated to be worse during hot periods in summer.

On examination one worker was observed to have slight nasal irritation. No skin or eye irritation was detected. Physical examination revealed no other occupationally related abnormality.

Complete blood counts were normal in each worker. Chem-12 examination (SGOT, lactic dehydrogenase, alkaline phosphatase, total bilirubin, serum albumin, total protein, cholesterol, uric acid, blood urea nitrogen, glucose, inorganic phosphate, calcium) was normal in all employees. Two employees had a slight abnormality detected initially (but a repeat examination failed to confirm these). In one worker urinalysis was abnormal with increased white cells and yeast in the urine. This did not appear to be occupationally related. In the other workers urinalysis was not abnormal.

Four men were examined before and after bagging operations conducted at from 50-70$^{o}$F. Three men had no complaints before or after the operation, one man described slight facial burning at the end of the operation but no objective skin changes were detected. Slight erythema of the nasal mucosa was noted in one asymptomatic worker after bagging 60 bags of Emerox® 1144, his nasal mucosa had been normal before the operation. Personal air sampling determined that this worker was exposed to about 1.5 mg/M$^{3}$ of azelaic acid (by the gravimetric method of analysis).

2. Air Sampling Results

Table I contains the results of personal and area air sampling on March 29, April 2 and 3, 1976 for airborne particulate at bagging operations. The personal air samples measured breathing zone concentrations ranging from 0.2 to 6.2 mg/$M^3$. These concentrations were calculated from weight gains which were not "blank-corrected." The reported mean weight gain of the filter samples was 0.21 mg (ranging from 0.01 to 0.59 mg). The reported weight gain for the blank and blind blank samples were as follows:

| Blank Sample Number | Weight Gain in mg |
|---|---|
| 1 | 0.00 |
| 2 | 0.00 |
| 3 | 0.00 |
| 4 | 0.03 |
| Mean: | 0.01 |

| Blind Blank Sample Number | |
|---|---|
| 1 | 0.00 |
| 2 | 0.01 |
| 3 | 0.21 |
| 4 | 0.02 |
| 5 | 0.00 |
| 6 | 0.22 |
| Mean: | 0.08 |

(Blank samples are those which were handled in an identical manner except without air drawn through them. Blind blank samples are blank samples which are identified to the laboratory as actual samples).

Table II contains the results of personal and area air sampling on May 25, 1976 for airborne particulate. The results of subsequent laboratory analysis for azelaic acid (by the gas chromatography method for the silyl ester of azelaic acid) are also included. Ten blank samples also were submitted and had a reported mean weight gain of 0.00 mg. Ten blind blank samples were also submitted and had a reported mean weight gain of 0.01 mg (the highest weight gain was 0.03 mg). The ten "concurrent" area air sample filters (those obtained with Model G pumps) had a mean weight gain of 0.16 mg (standard deviation of 0.04 mg) and a mean quantity of 0.099 mg of azelaic acid (standard deviation of 0.031 mg).

Measurements of airborne particulate on May 25, 1976 using the GCA Dust Monitor failed to detect levels above outside ambient levels.

Measurements for carbon monoxide are summarized in Table III. The maximum concentration of carbon monoxide measured at any time was about 70 ppm.

E. Discussion of Results

The number of bags filled during a work period was observed to vary widely. This variation at the bagging operation appeared to be due to such factors as equipment failure and decreased user demand. Because of the numerous on-site visits, it is likely that the range of working conditions were observed. However, evaluation of exposure and effects was not observed during a hot weather period (the outdoor ambient temperatures did not exceed about 75°F). Workers had complained of the most severe skin irritation during hot weather.

This evaluation was conducted during bagging operations at the North flaker/bagger only. It appears that the performance and integrity of this equipment effected worker exposures. Workers reported that more dust is generated, resulting in nasal irritation, when the flaker apparatus required maintenance. Also, skin contact with the azelaic acid occurred when workers had to free the flow of flake from the hopper to the screw feed apparatus: the flow of flake periodically stops because of compaction, requiring the operator to pull back a rubber-plate cover and reach into the hopper to free the blockage. Besides the resulting skin contact with the azelaic acid, the rubber cover had been removed by operators (in order to facilitate the reaching into the hopper) resulting in a disruption of the equipment ventilation. Also, because of the poor packing characteristics of the azelaic acid, the bags usually required hand slapping by the operator to achieve proper filling of the bags. This results in the generation of a visible dust cloud. The exhaust ventilation of the conveyor/screw feed portions of the bagging equipment were observed (by the smoke tube method) to adequately control dust generation. However, no ventilation was provided for the filling spout area.

Worker exposures could be reduced by observance of proper work practices and the proper use of personal protective equipment. Hard hats and safety glasses (side shields were available) were observed to be in use at all or most times. While gloves and barrier creams were available, their use was observed to be not frequent. Long sleeved shirts were usually worn. This clothing appeared to provide adequate protection against skin contact even though clothing appeared to be contaminated at times. An airborne dust was generated by the practice of slapping the bags as they filled and by broom sweeping of the area. Arm skin areas periodically came in contact with azelaic acid when the operator reached up into the neck of the hopper to free/loosen the plugged flow of azelaic acid.

The single use disposable type respirator which is provided to the workers was generally not used during this evaluation. This was apparently because of improper fit of the respirators which allowed for channeling of air (between the edge of the respirator and the face) and a resulting

impaction of dust on the skin. The respirator "in use" was inappropriate because of the inability to perform fit testing on the user and the lack of an exhalation valve (allowing moisture to accumulate inside and at the edge of the respirator).

Nasal irritation was experienced by the industrial hygienist following exposure to air which had a visible quantity of airborne azalaic acid dust (and was probably at a comparable level to the bagger's exposure). Moderate stinging, occasional sneezing, and increased nasal secretions were experienced during these intermittant exposures which occurred during the conduct of this evaluation. These irritant symptoms were reduced upon removal from the contaminated areas and the nose was cleared (residual irritant effects were not experienced for longer than several minutes).

The medical evaluation of workers failed to detect severe or permanent health effects as a result of exposure to azelaic acid. The long term or chronic effects of azelaic acid exposures, however, can not be conclusively determined from this study because of the relatively short exposure time of these employees (the mean period of azelaic acid exposure was about one year and one month at the time of the medical evaluation). The nasal, throat, and eye irritation which has been experienced appears to have been caused by airborne azelaic acid dust. The worker who developed slight nasal erythema had bagged 60 bags of Emerox® 1144 and was exposed to about 1.5 $mg/M^3$ of azelaic acid (as determined by the gravimetric method of analysis). It appears (in most cases) that nasal irritation is instantaneously detected with exposure to high airborne levels of the dust but is reduced when exposure is stopped and the nose cleared.

Personal air sampling during azelaic acid bagging operations determined that worker exposures to airborne particulate ranged from about 0.2 to 6.2 $mg/M^3$. Results of air sampling on March 29, April 2 and 3, 1976 (Table I) are questionable due to the lack of sensitivity, and high variability of blank filters by the gravimetric method of analysis. (The sensitivity of the gravimetric method of analysis may be adequate with similar air concentrations and longer duration sampling periods). The high weight gains of several of the blind blank filters, although higher than expected, were probably due to weighing error. Although there is no reason to believe that similar weighing errors did not occur for the sample filters, it was decided not to blank-correct the sample weight gains. It is assumed that the particulate collected was azelaic acid or another carboxylic acid of comparable toxicity.

The respirable fraction (that which would reach the lung) of airborne particulate was estimated by high volume air samples near the bagging operation. Concentrations of the respirable fraction (of samples taken during the same time period as the personal samples) ranged from 0.3 to 0.7 $mg/M^3$. The respirable dust concentrations were 29 percent (mean percentage) of the concurrent total dust concentrations. These area samples (bench area) were 42 percent (mean values) of the personal exposure concentrations. The actual worker exposures to respirable dust during bagging operations may be lower than 29 percent (of the total fraction) because of the more rapid sedimentation of the larger dust particles resulting in an over representation of the smaller dust particles.

Concurrent air sampling was conducted on May 25, 1976 for the purpose of determining the sensitivity and variation of gravimetric analysis (Table II). The coefficient of variation (the standard deviation divided by the mean value) for these samples was 25 percent by the gravimetric method of analysis. This amount of variation is not unusual since the filter sample values approached the analytic lower limit of detection. The subsequent analysis of the filter samples found mean azelaic acid quantities to be 62 percent of the mean reported weight gain. The coefficient of variation of the concurrent samples, when analyzed for azelaic acid, was 31 percent. However, calculation of the correlation coefficient showed a poor correlation between weight gain and azelaic acid ($r = .48$). (Personal exposures to azelaic acid on March 29 and April 2-3, 1976, if extrapolated from the 62 percent azelaic acid: weight gain figure, could range from 0.1 to 3.8 $mg/M^3$). This poor correlation could be due to several factors:

i) weighing error
ii) loss of material during the transfer of filters and weighing
iii) incomplete and inconsistent extraction of azelaic acid from the filters (although laboratory tests showed a 95 percent recovery of azelaic acid from the filters).

Based on the precent of azelaic acid in Emerox® 1144, it would be expected that 90 percent of the collected particulate would be azelaic acid. Further testing would be required to identify the cause of the discrepancy between the gravimetric and azelaic acid analysis. The determination of exposure to irritant substances at such an operation (e.g., bagging of Emerox® 1144) should include the determination of the other carboxylic acids which produce similar effects.

Laboratory tests determined that the analytic sensitivity (0.001 mg per sample), analytic precision (a Relative Standard Deviation of 2 percent), and recovery rate of azelaic acid from filters (95 percent) was good. The sampling sensitivity should be comparable to the analytic sensitivity, although it was not actually determined. The analytical precision of 2 percent was determined from gravimetric standards ranging from 1 to 10 mg and was not determined at lower levels. However, the analytical precision at lower levels should be comparable because of the linear precision throughout the 1 to 10 mg range. It is expected that the recovery rate of the collected azelaic acid was comparable to 95 percent figure although this was not determined.

F. Conclusions

Worker exposures to azelaic acid at bagging operations in Building #69, Emery Industries, were determined by conducting air sampling and observation of work practices. The immediate and long term health effects from these exposures was medically evaluated.

There were consistent worker complaints of increased nasal secretions, and skin, nasal, throat, and eye irritation as a result of exposures to azelaic acid at bagging operations. The irritation of the skin was reported to be more frequent and severe during hot weather. Medical evaluation of this irritant effect (conducted during moderate temperatures) failed to detect objective signs of skin damage although slight nasal erythema was observed to develop in one worker during bagging operations. The use of respirators during hot weather was reported to cause a reddening on the face where the respirator contacts the face. Any erythema was reported to have usually resolved within one day of its onset. While these irritant effects are relatively moderate and of a temporary nature, work at this operation was described as unpleasant, at times, because of the irritation caused by inhalation and direct contact with the azalaic acid.

Blood and urine analysis results were within normal limits for all workers and signs of systemic disease were not detected. Review of the pertinent toxicology literature does not suggest that health effects other than irritation of the skin and mucous membranes will occur as a result of exposure to azelaic acid.

Inhalation exposures to azelaic acid were determined by personal sampling. Air sampling was initially performed using a gravimetric weight gain method of analysis. The precision of these sampling results may be poor because the samples had weight gains approaching the analytic lower limit of detection. In order to improve the sensitivity of measurements, and in anticipation of future air sampling in environments with another airborne particulate (with azelaic acid), a gas chromatographic method of analysis was developed for the silyl ester derivative of azelaic acid. Worker exposures to azelaic acid ranged from approximately 0.1 to 3.8 $mg/M^3$ (these values are based on an extrapolation). While the accuracy of the combined sampling and analytical method has not been determined, it is believed to be reliable and the best available at the present time.

It was not possible to determine the airborne concentration at which azelaic acid causes irritation. The concentration at which irritation is experienced will probably depend on individual factors but would be expected to increase with increasing concentration of the airborne dust. Furthermore, it is not possible or appropriate to recommend an acceptable exposure limit at this time. However, due to the irritant properties, unknown long range health effects of exposure to azelaic acid, and engineering feasibility, worker exposures should be reduced. Recommendations for reducing worker exposures to azelaic acid follow.

## V. RECOMMENDATIONS

Good industrial hygiene practices dictate that worker exposures to chemicals be minimized to the greatest extent possible. While serious or permanent health effects have not resulted from exposures to azelaic acid, worker exposures to azelaic acid have produced irritant effects. Worker exposures could be reduced by a combination of engineering controls, good work practices, administrative controls, and personal protective devices.

1. Engineering controls - Bagging equipment should be designed to minimize the generation of airborne dust and the likelihood of worker exposures. Portions of the bagging equipment which have the potential for the release of dust into the air should be enclosed or ventilated. Engineering control measures for bagging operations are discussed in several publications available from NIOSH. In most cases, a capture velocity of 500 fpm at the point of dust release will effectively control the release of dust into the work environment. Duct velocities should be a minimum of 3,500 fpm to prevent accumulation of dust in the ductwork. These figures should be used as guidelines in designing equipment which must meet production needs as well as prevent excessive or unnecessary work exposures.

2. Work practices - Bagging and other operations which generate a dust, or result in skin contact with azelaic acid should be avoided. Practices such as patting/slapping oF bags should be minimized.

3. Protective clothing - When there exists the possibility of skin contact with azelaic acid, gloves and clothing (long sleeved shirts) should be worn which effectively prevents skin contact. In most cases, any type of clothing which covers potentially exposed skin areas will provide adequate protection.

4. Washing facilities - At least a wash basin and soap and water should be available in Building #69. If skin contact occurs, washing with soap and water should be performed. Workers should avoid such practices as rubbing their eyes before thoroughly washing azelaic acid from their hands. The use of showers at the end of a shift with a change of clothes should be encouraged.

5. Respiratory protection - Respirators should be provided for individuals who feel that they may experience discomfort or inconvenience from inhaling azelaic acid. The use of respirators should be considered as an interim measure until engineering controls can be instituted, however. Medical evaluation of an individual's ability to wear a respirator should be determined before issue is made (persons with existing lung or heart problems should not, in most cases, use respirators). A quarter or half face piece air purifying respirator for protection against dusts should be used. The face piece should have an exhalation valve to prevent moisture accumulation. (Disposable respirators do not usually provide a good fit on the face). The most comfortable and acceptable respirator (which still provides the desired protection) should be selected for each individual. Respirators should be close fitting in order to avoid the impaction of azelaic acid dust at the perimeter of the mask which may lead to skin irritation in these areas. The fit of the respirator should be determined for each individual. The field respirator fit-test using irritant smoke around the seal of the respirator (see Appendix A) should be performed although inspection of face areas for dust impaction may be adequate. A regular respirator maintenance and cleaning program should be established. Regular soap and water washing of the respirators will prevent the accumulation of azelaic acid on the respirators and reduce the probability of facial irritation. NIOSH publications are available which discuss respiratory protection[13] and certified equipment.[14]

6. Vacuuming - Areas where azelaic acid is spilled should be vacuumed rather than swept with a broom.

7. Maintenance - Periodic maintenance of bagging and ventilation equipment should be performed to prevent malfunction. Maintenance personnel should be appropriately protected to prevent exposure to azelaic acid.

8. Evaluation of control measures and worker exposures - A regular performance evaluation of ventilation and other exposure control equipment should be made (every three months may be frequent enough). Workers should be encouraged to report any equipment malfunctions to supervisors for repair. Worker exposures should be evaluated on an annual basis to insure that work practices and other exposure control measures are effective. Analysis of air samples should be by the chromatographic method described in this report (gravimetric analysis will usually lack the sensitivity). Air sampling for the duration of a bagging period (15 minutes to one hour) would be appropriate for determining the irritant potential of an exposure. Worker exposures to azelaic acid over the normal work shift period should also be determined.

As there is little or no information in the literature concerning the human health effects of azelaic acid exposure, medical surveillance of exposed workers should be performed. The frequency and types of tests will be dictated by professional medical judgment.

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APPENDIX A

1. STANDARD OPERATING PROCEDURE

RESPIRATOR FIT TESTING[15]

1. All users or potential users of respiratory protection devices shall be fit tested to insure proper facepiece to face seal of the respirator.

2. The fit test shall be accomplished by use of one of the tests aerosols listed below by application of the most desirable method feasible.

3. Users will be tested with a selection of brands of masks and allowed to choose the most comfortable from those that fit satisfactorily.

4. Complete records shall be made of all fit tests and a file of these records maintained at the central fitting and training facility.

| TEST AEROSOL | METHODS OF TESTING |
|---|---|
| a. Iso amyl-acetate | 1. Field Test - Swab or brush<br>4. Field Test - Plastic bag enclosure or Harvard Hood<br>5. Harvard Hood<br>6. Full Test Chamber |
| b. Irritant Smoke (Ventilation Smoke Tube) | 2. Field Test - Around Seal<br>3. Field Test - Plastic Bag enclosure or Harvard Hood |
| c. Di-octyl Phthalate (DOP) | 7. Harvard Hood<br>8. Full Test Chamber |

The footnote numbers by methods of testing denote the desirability of method in ascending order.

5. Any individual with facial hair (sideburns, beard, moustache) which protrudes into the sealing surface of the masks will be refused fitting. Fitting and issue will be based on clean shaven faces only.

6. To expedite quantitative (DOP) testing, qualitative (amylacetate) testing will be done on a selection of masks and the quantative test done on the proferred masks only.

7. All individuals fitted will be issued a laminated card, to be affixed to security badge clip, containing information pertinent to the fitting.

8. The medical status of all users will be determined prior to fitting.

9. The user will be required to wear each mask at least five (5) minutes.

## 2. STANDARD OPERATING PROCEDURE

## RESPIRATOR FIT TESTING USING IRRITANT SMOKE

## FIELD TEST - PLASTIC BAG ENCLOSURE OR HARVARD HOOD

1. Respirators equipped with high-efficiency filters will be used for this test.

2. Both ends are broken on an MSA ventilation smoke tube. One end is inserted into the tube connected to the positive pressure end of a two-way respirator bulb and the other end covered by a 1-2" length of tygon, surgical or rubber tubing. The test aerosol is generated by squeezing the aspirator bulb.

3. The test subject will don the respirator and a visual inspection of the facepiece to face seal made by the tester. An obvious leak in the facepiece to face seal shall be reason to abort the test and record that mask as unsatisfactory. Expression of discomfort created by the mask shall also be reason to abort the test.

4. The smoke will be generated into the input of the harvard hood or a hole punched in the top of the plastic bag enclosure until a concentration can be detected throughout the bag or hood visually.

5. The test subject shall be instructed to enter the bag or hood and breathe shallowly during a short (30-60 seconds) sedentary period. If a half-mask is being tested, the subject shall be instructed to close his eyes prior to entry and keep them closed until he exits. If no leakage is detected during the sedentary period, the subject shall be instructed to perform various exercises, simulating, as near as possible, work conditions (i.e., talking, running in place, head movements, bending over, etc.) while breathing normally. Leakage at any time shall be cause to terminate the test.

6. Any indication of detection of the smoke by the test subject, during fitting, indicates a failure of that respirator. If leakage is detected, the subject shall be removed from the test atmosphere and the facepiece to face seal visually inspected for obvious leakage. If any doubt about the condition of the respirator or the filter exists, another like respirator shall be tested to assure the leakage was due to facepiece to face seal.

3. STANDARD OPERATING PROCEDURE

RESPIRATOR FIT TESTING USING IRRITANT SMOKE

FIELD TEST - AROUND SEAL

1. Respirators equipped with high effeciency filters will be used for this test.

2. The test shall be performed in an area where no noticeable air movement is observed.

3. Both ends are broken on an MSA ventilation smoke tube. One end is inserted into the tube connected to the positive pressure end of a two-way respirator bulb and the other end covered by a 1-2" length of tygon, surgical or rubber tubing. The test aerosol is generated by squeezing the aspirator bulb.

4. The test subject will don the respirator and a visual inspection of the facepiece to face seal made by the tester. An obvious leak in the facepiece to face seal shall be reason to abort the test and record that mask as unsatisfactory. Expression of discomfort created by the mask shall also be reason to abort the test.

5. The smoke will be generated and directed around the entire sealing surface of the mask. The tube will be held no closer than 3" nor farther than 6" from the sealing surface. The test subject will be instructed to breathe shallowly during initial test around surface and normally thereafter if no leakage is detected. If a half-mask is being tested, the subject shall be instructed to close his eyes for the duration of the test. The test shall be performed first with the test subject sedentary, then with the subject performing head and face movements (i.e., talking, moving side to side and up and down). Leakage at any time shall be cause to terminate the test.

6. Any indication of detection of the smoke by the test subject, during fitting, indicates a failure of that respirator. If leakage is detected, the subject shall be removed from the test atmosphere and the facepiece to face seal visually inspected for obvious leakage. If any doubt about the condition of the respirator or the filter exists, another like respirator shall be tested to assure the leakage was due to facepiece to face seal.

TABLE I

Results of Sampling for Airborne Particulate During Emerox® 1144 Bagging Operations at Emery Industries on March 29, April 2 & 3, 1976

| Person/Location Sampled | Sample Type | Comments | Sample Period | Concentration of Airborne Particulate mg/M$^3$ |
|---|---|---|---|---|
| | | | 3/29/76 | |
| Ozone Pumper #1 | Personal/Total | 96 bags of Emerox® 1144 bagged | 1541 - 1647 | 2.4 |
| Ozone Pumper #2 | Personal/Total | Operating Fork Lift | 1543 - 1616 | 1.4 |
| Bench area near the bagging operation | Area/Total<br>Area/Respirable | High volume sample | 1544 - 1648 | 0.6<br>0.3 |
| Azelaic Acid Storage Rack | Area/Total<br>Area/Respirable | | 1549 - 1648 | 2.5<br>5.1 |
| Azelaic Acid Storage Rack | Area/Total<br>Area/Respirable | | 1506 - 2050 | 0.0<br>0.1 |
| Ozone Pumper #1 | Personal/Total | Emerox® 1144 was bagged, followed by broom sweeping of the work area | 1958 - 2050 | 2.3 |
| Area above Hopper | Area/Total | | 2005 - 2050 | 1.8 |
| Bench area near the bagging operation | Area/Total<br>Area/Respirable | High volume sample | 2002 - 2050 | 1.1<br>0.3 |
| | | | 4/2-3/76 | |
| Ozone Pumper #3 | Personal/Total | 18 bags of Emerox® 1144 bagged, followed by broom sweeping of Area | 2222 - 2239 | 6.2 |
| Bench Area near the bagging operation | Area/Total<br>Area/Respirable | High volume sample | 2222 - 2239 | 3.9<br>0.7 |
| Area above Hopper | Area/Total | | 2224 - 2236 | 10.0 |
| Ozone Pumper #4 | Personal/Total | 60 bags of Emerox® 1144 bagged | 2330 - 0009 | 1.5 |
| Bench Area near the bagging operation | Area/Total<br>Area/Respirable | High volume sample | 2330 - 0047 | 0.5<br>0.1 |
| Area above Hopper | Area/Total | | 2330 - 0047 | 0.5 |
| Ozone Pumper #5 | Personal/Total | 60 bags of Emerox® 1144 bagged | 0013 - 0047 | 0.2 |

*mg/M$^3$ - milligrams of perticulate per cubic meter of air

TABLE II

Results of Sampling for Airborne Particulate and Azelaic Acid During Emerox® 1144 Bagging Operations at Emery Industries on May 25, 1976

| Person/Location Sampled | Sample Type | Comments | Sample Period | Concentration of Particulate mg/M$^3$ | Concentration of Azelaic Ac mg/M$^3$ |
|---|---|---|---|---|---|
| Ozone Pumper #6 | Personal | All samples collected the total particulate. 55 bags of Emerox® 1144 were bagged during this sampling period. | 1230 - 1314 (All samples were taken during the same period). | 0.57 | 0.25 |
| Bench Area near the bagging operation | | | | | |
| #1 | | High Volume Sample | | 0.38 | 0.10 |
| #2 | | High Volume Sample | | 1.26 | 0.72 |
| #3 | | | | 1.36 | 0.84 |
| #4 | | | | 1.70 | 0.73 |
| #5 | | | | 1.25 | 0.82 |
| #6 | | | | 1.59 | 1.14 |
| #7 | | | | 1.82 | 1.20 |
| #8 | | | | 1.82 | 1.00 |
| #9 | | | | 1.48 | 1.20 |
| #10 | | | | 2.16 | 1.98 |
| #11 | | | | 2.16 | 1.07 |
| #12 | | | | 2.73 | 1.23 |

*mg/M$^3$ - milligrams of contaminant per cubic meter of air

TABLE III

Summary of Air Sampling for Carbon Monoxide*
at Emery Industries on
March 29 and April 2-3, 1976

| Time | Concentration of Carbon Monoxide ppm** |
|---|---|
| 3/29/76 | |
| 1600 | 18 |
| 1605 | 17 |
| 1610 | 25 |
| 1615 | 27 |
| 1620 | 23 |
| 1625 | 19 |
| 1630 | 17 |
| 1635 | 12 |
| 1640 | 11 |
| Time weighted average concentration - | 19 ppm |
| 2015 | 2 |
| 2020 | 2 |
| 2025 | 8 |
| 2030 | 5 |
| 2035 | 3 |
| 2045 | 2 |
| 2050 | 10 |
| 2055 | 10 |
| Time weighted average concentration - | 6 ppm |
| 4/2/76 | |
| 2152 | 3 |
| 2201 | 2 |
| 2210 | 2 |
| 2219 | 2 |
| 2228 | 26 |
| 2237 | 10 |
| 2246 | 6 |
| 2255 | 5 |
| 2304 | 2 |
| 2313 | 2 |
| 2322 | 2 |
| 2331 | 3 |
| 2340 | 5 |
| 2349 | 9 |
| 2358 | 39 |
| 4/3/76 | |
| 0007 | 13 |
| 0016 | 10 |
| 0025 | 8 |
| 0034 | 7 |
| 0043 | 7 |
| 0052 | 5 |
| Time weighted average concentration - | 8 ppm |

*OSHA Standard - 50 ppm

**ppm - parts of contaminant per million parts of contaminated air by volume.