



INTER-OFFICE CORRESPONDENCE

To: J. M. Davis
K. W. Richardson

Date: June 13, 1977

From: F. C. Dehn

Location: 10 West - G.O.

Subject: EDC Toxicity

Attached is the information portion of a report to MCA on the MCA--EDC studies being done in Italy. This is the first report I have seen. Thus far, EDC seems to be developing no statistically significant responses in the parameters measured.

Your medical doctor may be interested in how these blood results correspond in any way to employee blood tests.

A handwritten signature in cursive script, appearing to read 'F. C. Dehn'.

F. C. Dehn

/zak

Attachment

cc: Z. G. Bell
L. B. Grant, M.D.
I. C. Klimas
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The following is the description of the clinical chemistry data obtained after 6 months exposure of rats to inhalatory Ethylene Dichloride (ECD). As detailed in a previous report, animals (Sprague Dawley rats of both sexes) have been treated by Dr. Maltoni (Microbiological Institute, Bologna, Italy) according to his protocols of exposure and employing 4 levels of ECD exposure, i.e. : 250, 50, 10 and 5 ppm, whereas controls, caged in equal conditions, breathed only air. Blood samples were obtained by heart puncture of ether-anesthetized animals; urine samples were collected in the week preceding sacrifice by placing the animals in metabolic cages in the 'off' exposure hours. All samples were coded and analysed blindly, the code being broken after termination of all analyses.

Animal nos. 811-818 correspond to female controls (group C) and nos. 854-861 to male controls; rats nos. 9-16 correspond to females and nos. 54-61 to males exposed to 250 and later to 150 ppm (hereafter group 4) (cfr. Maltoni's protocol). Rats nos. 209-216 correspond to females and nos. 254-261 to males exposed to 50 ppm ECD (group 3); nos. 409-416 were females and nos. 454-462 to males exposed to 10 ppm ECD (group 2) whereas nos. 609-616 were female rats and nos. 654-651 were male rats exposed for 6 months to 5 ppm ECD (Group 1).

Details of the techniques employed for the various tests were presented in a former report to which we refer. Statistical significance at the $p < 0.05$ level of the data was assessed by means of Duncan's multiple range test.

Results obtained can be summarized as follows:

BUN - (Table 1 and 2). In female rats, a significant decrease in mean BUN levels in respect to controls was found in groups 1,2 and 3 , i.e. those exposed to the lower ECD levels, whereas in males a significant decrease was present only in group 1 although a tendency towards a decrease was present also in groups 2 and 3. No changes were found in groups 4 (i.e. 250 ppm later to 150 ppm) in either sex. The biological significance of this type of results is probably doubtful.

Serum Glucose - (Tables 3,4). No significant differences in respect to controls were found either in males or females exposed to ECD at any dosage level.

Serum bilirubin - (Tables 5,6) . No statistically significant differences were found in both sexes between control and exposed rats, although a tendency towards a dose-related increase was present , more evident in females.

Serum total proteins - (Tables 7,8). No statistically significant differences were found between control and exposed rats of either sex.

Serum albumin - (Tables 9 , 10). No statistically significant differences were found between control and ECD-exposed rats of either sex.

Serum GOT-levels - (Tables 11,12). No statistically significant differences were found between control and exposed rats of either sex.

Serum LDH - (Tables 13,14) . In female rats a tendency toward an increase in levels was present in all exposed groups, this increase showing however no dose relationship and reaching statistical significance only in group 3. Levels were slightly elevated in comparison to controls also in ECD-exposed males, again however no clear dose-response relationship was present and in no group the difference reached statistical significance.

Serum cholesterol - (Tables 15,16). In female exposed rats the values were superimposable to those of controls; in males a slight tendency towards an increase was seen in all groups, higher in groups 1 and 2 (i.e. ECD levels of 5 and 10 ppm respectively). However no statistical significance was reached in any group.

Uric acid serum levels - (Tables 17,18). In both males and female a tendency towards an increase in levels was observed which did not show a clear dose-relationship in males nor reached statistical significance in either sex or group.

Alkaline phosphatase - (Tables 19,20). In females a tendency towards a decrease showing a roughly inverse dose-relationship was present but the differences did not reach statistical significance in any group. In male rats, the values were very scattered with a profound decrease in group 1 (ECD 5 ppm) and lower decreases in groups 2 and 4; no differences with controls were seen in group 3.

Albumin percent levels - (Tables 21,22) . No statistically significant differences were found either in females or males.

Alpha-1 globulins - (Tables 23,24) . No statistically significant differences were found between controls and exposed rats.

Alpha-2 globulins - (Tables 25,27) . A tendency towards a dose-related increase was seen in females not reaching statistical significance. In males a not significant increase was seen only in groups 2 and 4.

Beta globulins - (Tables 27,28) No significant differences were seen.

Gamma globulins - (Tables 29,30) No differences in females; a slight , not significant, not dose-related tendency towards an increase in male rats.

Na⁺, K⁺, Ca⁺⁺, Cl⁻, inorganic P - (Tables 31-40) No statistically significant differences were observed.

Leukocyte numbers - (Tables 41 42) . A slight, not significant decrease was seen in group 4 animals both males and females; a higher decrease was however present in group 1 of male rats.

Hematocrit - (Tables 43,44) . No significant differences in either sex , the tendency towards an increase (not dose related, not significant) present in females being absent in males.

Hemoglobin content (Tables 45,46). No significant differences.

Erythrocytes numbers - (tables 47,48) . No significant differences.

Mean erythrocyte volume -(Tables 49,50). A tendency towards a decrease (not significant; not dose-related) was found in males.

Platelet number (Tables 51,52). No differences in females, a tendency (not statistically significant) towards a decrease in male rats exposed to 250-150 ppm ECD was on the other hand seen.

Basophilic and eosinophilic leukocytes - (Tables 53-56). No significant differences.

Segmented and non segmented neutrophilic leukocytes (Tables 57-60). Contrasting tendencies between males and females exposed to ECD, in any case no significant differences were detected. No differences for non-segmented neutrophils .

Lymphocytes (Tables 61, 62) . A slight, not dose-related, not significant decrease in females, the opposite in males again not significant.

Monocytes - (Tables 63,64). No significant differences.

Urinary erythrocytes and glucose - (Tables 65,66;69,70).

No significant differences.

Urinary albumin - (Tables 67,68). A tendency towards an increase in animals exposed to the higher ECD dose (250-150 ppm) was seen; the semi-quantitative assay does not permit statistical analysis.

Urinary ketones, bilirubin, casts (Tables 71,76). No differences between exposed and controls.

Urinary leukocytes, crystals, mucus, epithelial cells and microorganisms (Tables 77-86).

No obvious differences between exposed and ECD-exposed animals could be detected.

COMMENT:

On the basis of the data so far obtained, the ECD treatments employed would seem to be reasonably tolerated by the animals.

Although changes in some of the parameters investigated (LDH, SCOT, Cholesterol, Bilirubin, Uric acid levels) were seen, in no case these differences reached statistical significance nor was a dose-response relationship clearly evident; accordingly the biological significance of these results for a possible involvement of the liver and the kidneys, is at the moment very uncertain.

NIOSH Recommended Standard

for Occupational Exposure To

Ethylene Dichloride (1,2-Dichloroethane)

A complete criteria document for occupational exposure to ethylene dichloride (1,2-dichloroethane) has been prepared by the National Institute for Occupational Safety and Health (NIOSH). NIOSH recommends that occupational exposure to ethylene dichloride be controlled so that workers are not exposed in excess of 5 ppm (20 mg/cubic meter) determined as a time-weighted average for up to a 10-hour workday, 40-hour workweek. NIOSH also recommends that peak exposures not exceed 15 ppm (60 mg/cubic meter) as determined by a sampling period of 15 minutes. Furthermore, NIOSH recommends that nursing mothers not be exposed to ethylene dichloride since ethylene dichloride is readily absorbed into the mothers' milk. ||

Liquid ethylene dichloride is absorbed through the skin, and because spills are extremely hazardous, NIOSH recommends other preventative measures wherever ethylene dichloride is used. These measures include labeling of containers, informing employees of the hazards, use of protective clothing, and provision of showers and eyewash facilities. ||

About 75 percent of the approximately 8 billion pounds of ethylene dichloride produced in the United States is used to make vinyl chloride. Much of the remainder is used in anti-knock mixtures of leaded fuels, in fumigant-insecticides, in the formulation of some degreaser compounds, and in rubber cements. NIOSH estimated that 18,000 workers are potentially exposed to ethylene dichloride.

Little is known about the metabolism of ethylene dichloride, but the available animal data, as well as the signs and symptoms of acute human poisoning, indicate that ethylene dichloride is metabolized to more toxic substances. The metabolites may include 2-chloroethanol, chloroacetaldehyde, and monochloroacetic acid.

Fatalities have not been reported when the exposure concentrations were below 75 ppm. Signs and symptoms of acute poisoning include headache, dizziness, lassitude, nausea, vomiting, and abdominal pain. These signs and symptoms have not been reported when the exposure concentrations were below 25 ppm, but chronic cardiac, hepatic, and neurologic effects have been found.

Reports of occupational exposures that were without effect were not found in the literature, but evaluation of the available information suggests that adherence to the recommended airborne limits coupled with control of source exposure by adherence to recommended work practices should prevent the toxic effects that have been reported.

NIOSH recommends that workers exposed to ethylene dichloride at half or more of the recommended standard have comprehensive preplacement and annual medical examinations giving particular attention to cardiovascular, pulmonary, neurologic, liver, and kidney functions. Engineering controls should be used whenever feasible to maintain ethylene-dichloride concentrations below the prescribed limit, and respirators should only be used in certain nonroutine or emergency situations.

The recommended standard is part of a continuing series of criteria documents developed by NIOSH in accordance with the Occupational Safety and Health Act of 1970. The document was transmitted to the U.S. Department of Labor on March 4, 1976, for review and consideration in the standard setting process. The criteria document was reviewed by six consultants, two professional societies, and Government agencies having interest and responsibility for occupational safety and health. In addition, consideration was given to two responses obtained from solicitation in the Federal Register. The proposed standard is considered appropriate and no additional information that would affect the recommended standard is available.

The following is the first chapter of the criteria document. It contains the NIOSH recommendations for controlling worker exposure to ethylene dichloride (1,2-dichloroethane).



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
National Institute for Occupational Safety and Health

Single copies of complete criteria document are available from:
Division of Technical Services
National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati Ohio 45226
Please include a self-addressed mailing label to assist in answering your request.

NIOSH Recommended Standard

I. RECOMMENDATIONS FOR AN ETHYLENE DICHLORIDE STANDARD

The National Institute for Occupational Safety and Health (NIOSH) recommends that worker exposure to ethylene dichloride (1,2-dichloroethane) in the workplace be controlled by adherence to the following sections. Based on present information available to NIOSH the standard is designed to protect the health and safety of workers for up to a 10-hour workday, 40-hour workweek over a working lifetime; compliance with the standard should therefore prevent adverse effects of ethylene dichloride on the health and safety of workers. The standard is measurable by techniques that are valid, reproducible, and available to industry and governmental agencies. Sufficient technology exists to permit compliance with the recommended standard. The standard will be subject to review and revision as necessary.

"Occupational exposure to ethylene dichloride" is defined as exposure above half the time-weighted average (TWA) environmental limit.

Occupational exposure to ethylene dichloride requires adherence to all the following sections. Exposure at lower environmental concentrations will not require adherence to Sections 1, 2, 7(b), (c), and (d), and 4(a) except 4(a)(4).

Section 1 — Environmental (Workplace Air)

(a) Concentration

Occupational exposure shall be controlled so that no worker will be exposed to ethylene dichloride in excess of 5 ppm (20 mg/cu m) determined as a TWA exposure for up to a 10-hour workday, 40-hour workweek, or to peak concentrations above 15 ppm (60 mg/cu m) as determined by a 15-minute sample. Unless future research shows it to be unnecessary, nursing mothers shall not work with ethylene dichloride.

(b) Sampling and Analysis

Procedures for sampling and analysis of workroom air for compliance with the standard shall be as provided in Appendices I and II or by any equivalent method.

Section 2 — Medical

(a) Comprehensive preplacement and annual medical examinations shall be made available to all workers exposed to ethylene dichloride unless a different frequency is indicated by professional medical judgment based on such factors as emergencies, variations in work periods, and preexisting health status of individual workers.

(b) These examinations shall include, but shall not be limited to:

(1) A comprehensive or interim medical and work history.

(2) A comprehensive medical examination giving

particular attention to cardiovascular, pulmonary, neurological, ~~liver~~, and kidney functions.

(3) An evaluation of the worker's physical ability to safely wear a respirator.

(c) Proper medical management shall be provided for workers exposed to ethylene dichloride.

(d) Medical records shall be maintained for all persons employed in work involving exposure to ethylene dichloride. All pertinent medical records with supporting documents shall be maintained for 20 years after the individual's employment is terminated. The designated medical representatives of the Secretary of Health, Education, and Welfare, of the Secretary of Labor, of the employer, and of the employee or former employee shall have access to these records.

Section 3 — Labeling (Posting)

The following warning sign shall be affixed in a readily visible location on processing or other equipment, on ethylene dichloride storage tanks or containers, and at or near entrances to areas in which there is occupational exposure to ethylene dichloride:

ETHYLENE DICHLORIDE

DANGER: FLAMMABLE

May generate toxic gases on contact with open flame, hot surfaces, or other heat-producing conditions.

BREATHING VAPOR MAY BE HAZARDOUS TO HEALTH.

Keep containers closed when not in use.

Use only with adequate ventilation.

Avoid breathing of vapor.

Avoid contact with skin.

This sign shall also be printed in the predominant language of non-English-speaking workers. All employees shall be trained and informed of the hazardous areas with special instructions given to illiterate workers.

Section 4 — Personal Protective Equipment and Clothing

(a) Respiratory Protection

(1) Engineering controls shall be used wherever necessary and feasible to maintain ethylene dichloride concentrations at or below the prescribed limit. Compliance with the permissible exposure limits may be achieved by the use of respirators only:

(A) During the time period necessary to install or test the required engineering controls.

(B) For nonroutine operations such as brief exposure to concentrations in excess of the environmental limit for maintenance or repair activities.

(C) During emergencies when air concentra-

tions of ethylene dichloride may exceed the permissible limit.

(2) When respirators are permitted by paragraph (1) of this section, a respirator program meeting the requirements of 29 CFR 1910.134 and 30 CFR 11.2-1 shall be established and enforced by the employer.

(3) Only appropriate respirators as described in Table I-1 shall be used pursuant to the following requirements:

(A) For the purpose of determining the class of respirator to be used, the employer shall measure, when possible, the atmospheric concentration of ethylene dichloride in the workplace initially and thereafter whenever process, worksite, climate, or control changes occur which are likely to increase the ethylene dichloride concentration. This requirement shall not apply when only supplied-air, positive pressure respirators are used.

(B) The employer shall ensure that no worker is being exposed to ethylene dichloride in excess of the exposure limit because of improper respirator selection, fit, use, or maintenance.

(C) The employer shall provide respirators in accordance with Table I-1 and shall ensure that the employee uses the respirator provided.

(D) Respiratory protective devices described in Table I-1 shall be those approved under provisions of 30 CFR 11.

(E) Respirators specified for use in higher concentrations of ethylene dichloride are permitted in atmospheres of lower concentrations.

(F) Because of the poor warning properties of ethylene dichloride at the environmental limit, chemical cartridges and canisters shall not be used with ethylene dichloride except for evacuation or escape.

(G) The employer shall ensure that respirators are adequately cleaned, maintained, and stored, and that employees are instructed on the use of respirators and on testing for leakage.

(4) Where an emergency may develop that could result in employee injury from overexposure to ethylene dichloride, the employer shall provide respiratory protection as listed in Table I-1.

(b) Protective Clothing

In any operation where the worker may come into direct contact with liquid ethylene dichloride, protective clothing shall be worn. The clothing shall be both impervious and resistant to ethylene dichloride. Gloves, boots, overshoes, and bib-type aprons that cover boot tops shall be provided when necessary. Impervious supplied-air hoods or suits shall be worn when entering confined spaces such as pits or tanks unless known to be safe. In situations where heat stress is likely to occur, air-supplied suits shall be used. All protective clothing shall be well-aired and inspected for defects prior to reuse.

TABLE I-1
RESPIRATOR SELECTION GUIDE FOR PROTECTION
AGAINST ETHYLENE DICHLORIDE

Concentrations of Ethylene Dichloride	Respirator Type
50 ppm or less	(1) Any supplied-air respirator. (2) Any self-contained breathing apparatus.
250 ppm or less	(1) Any supplied-air respirator with a full facepiece, helmet or hood. (2) Any self-contained breathing apparatus with a full facepiece.
>250 ppm or entry and escape from unknown concentrations	(1) Self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive pressure mode. (2) A combination respirator which includes a Type C supplied-air respirator with a full facepiece operated in pressure-demand or other positive pressure or continuous-flow mode and an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive pressure mode.
Firefighting	Self-contained breathing apparatus with a full facepiece operated in pressure-demand or other positive pressure mode.
Escape	(1) Any gas mask providing protection against organic vapors. (2) Any escape self-contained breathing apparatus.

(c) Eye Protection

Eye protection shall be provided for, and worn by, any employee engaged in an operation where ethylene

dichloride liquid or spray may enter the eye. Chemical-type goggles, safety glasses with splash shields, or plastic face shields made completely of ethylene

dichloride-resistant materials shall be used. Suitable eye protection shall be in accordance with 29 CFR 1910.133.

Section 5 — Informing Employees of Hazards from Ethylene Dichloride

All new and present employees in any ethylene dichloride area shall be kept informed of the hazards, relevant symptoms, effects of overexposure, and proper conditions and precautions concerning safe use and handling of ethylene dichloride.

A continuing educational program shall be instituted to ensure that all workers have current knowledge of job hazards, proper maintenance procedures, and cleanup methods, and that they know how to correctly use respiratory protective equipment and protective clothing.

The information explaining the hazards of working with ethylene dichloride shall be kept on file and readily accessible to the worker at all places of employment where ethylene dichloride is manufactured, used, transported, or stored.

Information as required shall be recorded on US Department of Labor Form OSHA-20, "Material Safety Data Sheet," or similar form approved by the Occupational Safety and Health Administration, US Department of Labor.

Section 6 — Work Practices

(a) Handling and Storage

(1) Storage containers, piping, and valves shall be periodically inspected for leakage.

(2) Storage facilities shall be designed to contain spills and prevent contamination of workroom air.

(3) Processes and storage facilities shall not be located near open flames or high-temperature operations, unless precautions are taken to prevent fire and explosion hazards and exposure to pyrolysis products.

(4) Where ethylene dichloride is transferred from one metal container to another, the 2 vessels shall be grounded or electrically interconnected by bonding. The use of mechanical equipment likely to give off sparks should be avoided.

(5) Where ethylene dichloride is used as a fumigant, strict adherence to label requirements for application and personal protection shall be followed. In addition, standards for pesticide use by agricultural workers can be found in 40 CFR 170.

(b) Contaminant Controls

(1) Suitable engineering controls designed to limit exposure to ethylene dichloride to that prescribed in subsection (a) of Section 1 shall be utilized. Ventilation systems shall be designed to prevent the accumulation or recirculation of ethylene dichloride in the workroom and to effectively remove ethylene dichloride from the breathing zones of workers. Ventilation systems shall be subjected to regular preventive maintenance and cleaning to ensure maximum effectiveness, which shall be verified by periodic airflow measurements.

(2) Portable exhaust ventilation or suitable general ventilation shall be provided for operations that require the spray application of ethylene dichloride such as in fumigation operations.

(3) Buildings in which ethylene dichloride is used where it could form an explosive air mixture shall be explosion-proof. Explosion vents are available and effective on windows, roof and wall panels, and skylights as a safeguard against destruction of buildings and equipment in which flammable vapors may accumulate. Stair enclosures shall also be fire-resistant and shall have self-closing fire doors.

(4) Forced draft ventilation systems shall be equipped with remote manual controls and designed to turn off automatically in the event of a fire in the building.

(c) Equipment Maintenance and Emergency Procedures

(1) Ethylene dichloride hazard areas

A hazard area that workers may enter shall be considered as any space with physical characteristics and sources of ethylene dichloride that could result in concentrations of ethylene dichloride in excess of the environmental limit. Exits shall be plainly marked. Emergency exit doors shall be conveniently located and shall open into areas which will remain free of contamination in an emergency. At least 2 separate means of exit shall be provided from each room or building in which ethylene dichloride is stored or handled in quantities that could create a hazard.

(2) Confined spaces

(A) Entry into confined spaces or into other areas where there may be limited egress shall be controlled by a permit system. Permits shall be signed by an authorized representative of the employer certifying that preparation of the confined space, precautionary measures, personal protective equipment, and procedures to be used are all adequate.

(B) Tanks, pits, tank cars, process vessels, tunnels, sewers, grain storage bins, or other confined spaces which have contained ethylene dichloride shall be thoroughly ventilated to assure an adequate supply of oxygen, tested for ethylene dichloride and other contaminants and inspected prior to each entry. Ventilation shall be maintained while workers are in the space.

(C) Inadvertent infiltration of ethylene dichloride into the confined space while work is in progress inside shall be prevented by disconnecting and blanking off ethylene dichloride supply lines.

(D) Personnel entering confined spaces shall be furnished with appropriate personal protective equipment and protected by a lifeline tended by

another worker outside the space, who shall also be equipped for entry with approved respiratory, eye, and skin protection, lifeline, and have contact with a third party.

(E) Written operating instructions and emergency medical procedures shall be formulated and posted in conspicuous locations where accidental exposure to concentrations of ethylene dichloride which exceed the environmental limit may occur. These instructions and procedures shall be printed both in English and in the predominant language of non-English-speaking workers, if any. Special instructions shall be given to illiterate workers.

(d) Showers and Eye Wash Fountains

Showers and eye wash facilities shall be provided and so located as to be readily accessible to workers in all areas where skin or eye splash with ethylene dichloride is likely. If ethylene dichloride is splashed on the skin, contaminated clothing shall be promptly removed and the skin washed with soap and water. If liquid ethylene dichloride contacts the eyes, they shall be thoroughly irrigated with clean water, following which medical assistance shall be promptly provided. Such incidents shall be reported to the immediate supervisor by the affected employee or by a fellow worker.

Section 7 — Monitoring and Recordkeeping

(a) Where it has been determined that the environmental concentrations do not result in TWA workday exposures above one-half the TWA environmental limit, environmental monitoring shall not be required. However, records which form the basis for concluding that the exposures are at or below one-half the limit shall be maintained and exposure surveys shall be made when any process change indicates the need for reevaluation or at the discretion of the compliance officer.

(b) Where exposure concentrations have not been determined, they shall be determined within 6 months of the promulgation of a standard incorporating these recommendations.

(c) Where it has been determined that environmental concentrations result in TWA workday exposures above one-half the limit, employers shall maintain records of environmental exposures to ethylene dichloride based upon the following sampling and recording schedules:

(1) Samples shall be collected at least quarterly in accordance with Appendix I for the evaluation of the work environment with respect to the recommended limit.

(2) Environmental samples shall be taken when a new process is installed or when process changes are made which may cause an increase in environmental concentrations. Increased production, relocation of existing operations, or other functions which can increase concentrations shall require resampling.

(3) In all monitoring, samples shall be collected which are representative of breathing-zone exposures characteristic of each job or specific operation in each work area. Sufficient numbers of samples shall be collected to express the variability of exposure for the work situation and to estimate TWA workday exposure for the work situation and to estimate TWA workday exposures for every employee.

(4) The minimum number of representative TWA exposure determinations for an operation or process shall be based on variation in exposures and production schedules considering the number of workers exposed as suggested in Table I-2, or as otherwise indicated by a professional industrial hygienist.

TABLE I-2
SAMPLING SCHEDULE

Number of Employees Exposed	Number of TWA Determinations
1-20	50% of the number of workers
21-100	10 plus 25% of the excess over 20 workers
More than 100	30 plus 5% of the excess over 100 workers

(d) When exposure levels are found to be greater than those prescribed in Section 1(a), environmental concentrations shall be reduced by suitable engineering controls. Exposures shall be monitored at least weekly until the effectiveness of the controls is established.

(e) All records of sampling and of pertinent medical examinations shall be maintained for at least 20 years after the individual's employment is terminated. Records shall indicate the type of personal protective devices, if any, in use at the time of sampling. Each employee shall have access to information on his own environmental exposure.

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NIOSH

The 1969 ANSI Z-37 standard, adopted as the federal standard, 29 CFR 1910.1000, Table G2, is a TWA of 50 ppm for an 8-hour day, a ceiling concentration of 100 ppm, and a maximum peak above the ceiling of 200 ppm for no more than 5 minutes in any 3 hours.

1.4.1. The Recommended Environmental Standard

The recommended standard is based on occupational exposure experiences, mostly from Europe where ethylene dichloride has been used extensively, and is intended to protect workers from the adverse health effects that have been reported.

Ethylene dichloride has a wide array of effects and it is difficult to identify primary target organs or systems. The information on the metabolism or mechanism of action of ethylene dichloride suggests that it is metabolized to more toxic substances such as chloroacetaldehyde, 2-chloroethanol and chloroacetic acid which inhibit glucose metabolism.

Exposure to ethylene dichloride has adversely affected the circulatory, respiratory and nervous systems, and the liver, kidneys, skin, and mucous membranes. [4,64,74-77,80,88,97,98,100] Acute exposure has often been fatal. The progression of signs and symptoms prior to death usually included headache, dizziness, nausea, vomiting, anorexia, tenderness or pain in the epigastrium, rapid and weak pulse, cyanosis, unconsciousness, then respiratory, circulatory, or kidney failure. Death was usually ascribed to circulatory failure and the most outstanding autopsy observations were pulmonary edema, hyperemia, congestion of the visceral organs, and hemorrhaging into most of the organs. [46,47,49,50,54,56,64,75,76,81] Fatalities from occupational exposure have

resulted from acute exposures in which narcosis or anesthesia did not occur from inhalation of ethylene dichloride vapor. [77,80,81,86]

Many of the signs and symptoms associated with fatalities followed exposure even when death was not the final outcome. However, Rosenbaum [88] reported that when some workers experienced these symptoms 2 or more times in 2 or 3 weeks, fatalities resulted.

Rosenbaum was reporting on 10 years experience with ethylene dichloride in Russian industries where the atmospheric concentrations causing the symptomatic responses were reported to be between 75 and 125 ppm. Although this report lacked detail, it is consistent with other literature.

Byers [93] reported that many persons exposed to ethylene dichloride experienced the worst symptoms in the evening after the conclusion of a day's work. The symptoms varied from lassitude and malaise, to nausea, vomiting, and abdominal pain. The workers were exposed at daily concentrations of approximately 100 ppm, and even when the addition of ventilation reduced the atmospheric concentration to 70 ppm, not all of the symptoms were alleviated.

Environmental concentrations ranging from 10 to 200 ppm were found in an oil refinery in Poland. [9,104] Of 42 exposed workers, 6 complained of a sweetish aftertaste, dizziness, nausea, vomiting, and lack of appetite. Two of them had pain in the epigastrium and 3 had enlarged livers which were tender to pressure.

Further examination of a limited number of persons revealed that 6 of 10 workers exposed at 62-200 ppm had dryness of the mouth, an unpleasant sweetish aftertaste, dizziness (as from being drunk), lassitude,

sleepiness, nausea, vomiting, constipation, and poor appetite leading to weight loss. All 10 of these workers complained of a burning sensation of the eyes and lacrimation, and 3 workers complained of pain in the epigastrium.

One of 6 workers exposed at 10-37 ppm complained of the previously mentioned symptoms. Physical examinations further showed emaciation in all workers, and augmented reflexes and autonomic neurosis in 3 of 16 workers. Eight of 16 workers had an abnormal percentile distribution of white blood cells. All signs and symptoms of disease disappeared when the workers were removed from the workplace but returned when the workers were again exposed to the ethylene dichloride-containing atmosphere.

Intermittent exposure to ethylene dichloride for a total of about 1.5 hours/day resulted in sensory and neurological problems after 6-9 months of exposure. [97] The exposure conditions were well described in this report by Guerdjikoff, [97] but the information on exposure concentrations was not complete. During one of the operations which was repeated several times daily, the workers wore an air-supplied gas mask and were only exposed to ethylene dichloride occasionally due to improper fit. These operations accounted for about 30 minutes of the total time. During another operation which required 10 minutes and was repeated 3-4 times/day, the workers were exposed at about 120 ppm of ethylene dichloride. During a final operation which occurred once daily, the workers were exposed for about 15 minutes at a higher, but unknown, concentration. [97]

The 2 workers studied by Guerdjikoff [97] experienced anorexia, epigastric pains, fatigue, irritability and nervousness after about 3 weeks of exposure and eventually experienced tremors in hands, hyperhidrosis, and difficulty in walking.

Agricultural workers in Poland were exposed to ethylene dichloride by skin absorption and by inhalation when applying it in the field as an insecticide. [104] An environmental field sample showed 4 ppm ethylene dichloride but because of practical difficulties of collecting the sample, field conditions were simulated in the laboratory to better estimate the concentrations to which workers could have been exposed. This determination found about 15 ppm of ethylene dichloride. During the pouring operation, which was considered to produce the highest concentrations at which a worker would be exposed, the environmental concentration was found to be 60 ppm. Among 118 of these agricultural workers, 90 had clinical findings including conjunctival congestion in 72%, weakness in 45%, reddening of the pharynx in 42%, bronchial symptoms in 36%, metallic taste in the mouth in 34%, dermatographism in 31%, nausea in 26%, cough in 26%, liver pain in 25%, irritation of the conjunctiva in 20%, rapid pulse in 18%, and dyspnea after effort in 18%. [104] This report justifies the recommended use of protective clothing.

In 100 factory workers exposed from 6 months to 5 years at not more than 25 ppm ethylene dichloride, no changes were found in the blood or internal organs, but heightened lability of the autonomic nervous system, diffuse red dermatographism, muscular torus, bradycardia, increased hidrosis, and frequent complaints of fatigability, irritability, and sleepiness were found. [88] The TWA concentrations at which these workers were exposed were not reported.

A study where data were presented in sufficient detail to estimate a TWA exposure of 10-15 ppm for 5 years was reported by Kozik. [105] The maximum concentration reported was about 50 ppm and concentrations in

excess of 20 ppm occurred about 15% of the time. The concentrations above 20 ppm were reported to have occurred when an ethylene dichloride-based glue was applied to large rubber sheets and to have been maintained for 5-6 minutes at a time several times a day. The exposed workers experienced increased morbidity, particularly from gastrointestinal, liver and bile-duct diseases, that Kozik [105] concluded were due to ethylene dichloride exposure. In addition, neurotic and asthenic conditions, autonomic distonia, and struma and hyperthyreosis were found in a group of 83 workers studied. A study of nervous system function at the beginning and the end of 14 workdays in 17 of the workers indicated impairment at the beginning of the workdays as well as at the end, compared to 10 control workers who showed no impairment at the beginning of the workday.

Reports of occupational exposures that were without effect have not been found in the literature. The report of adverse cardiac and nervous system effects in 100 factory workers exposed at not more than 25 ppm of ethylene dichloride suggests that peak exposures need to be kept below this level. This is strongly supported by the additional effects on the liver and bile ducts reported by Kozik [105] in workers when peak exposures exceeded 20 ppm about 15% of the time. Definitive studies that delineate safe peak exposures do not exist but evaluation of available data and professional judgment suggest that ethylene dichloride exposures should not exceed a ceiling of 15 ppm.

The report by Kozik [105] of adverse nervous system and liver effects in workers exposed at TWA concentrations of 10-15 ppm also suggests a much lower TWA exposure. Considering the magnitude of the effects reported and

the systems involved (nervous, respiratory, cardiac, and hepatic), NIOSH recommends a time-weighted average exposure concentration of 5 ppm.

Adherence to this limit, with prevention of other sources of absorption by appropriate work practices, should prevent effects of ethylene dichloride on the respiratory tract, nervous system, liver and kidneys, and on the blood and blood clotting. However, in the complete absence of information on the susceptibility of babies to ethylene dichloride, and information [99,118] that the compound appeared in the milk of nursing mothers, it is recommended that nursing mothers not work with ethylene dichloride.

There has been a wide range of susceptibility to ethylene dichloride exposure. [76,82,88] Where groups of workers have been exposed, some have escaped serious injury, while others have died. The nature of the susceptibility was not obvious from the reports. Ethylene dichloride has been shown to be metabolized to more toxic compounds. [126,128-132] The variations in susceptibility could be due to individual variations in rate of metabolism of ethylene dichloride or to diet, previous exposure, or many other uncontrolled factors. [106,88] The recommended environmental standard should protect the more sensitive workers.

It is recognized that many workers handle small amounts of ethylene dichloride or work in situations where, regardless of the amounts used, there is only negligible contact with the substance. Under these conditions, it should not be necessary to comply with all of the provisions of this recommended standard. However, concern for worker health requires that protective measures be instituted below the enforceable limit to ensure that exposures stay below that limit. Therefore, environmental

monitoring and recordkeeping is recommended for those work situations which involve exposure above one-half the recommended limit, to delineate work areas that do not require the expenditure of health resources for control of inhalation hazards. One-half the environmental limit has been chosen on the basis of professional judgement rather than on quantitative data that delineate nonhazardous areas from areas in which a hazard definitely exists.

VI. WORK PRACTICES

The principal method for manufacturing ethylene dichloride is by reacting chlorine with ethylene. [1] Other chlorinated ethanes may be co-products of ethylene dichloride manufacture and caution must be taken to avoid exposure to these substances as well.

Further information concerning specific work practices for ethylene dichloride can be found in the Manufacturing Chemists Association's Safety Data Sheet SD-18. [7]

(a) Transport, Handling, and Use

The addition of small amounts (0.1% by weight) of alkylamines acts to stabilize ethylene dichloride, and in this form, ethylene dichloride can be transported in unlined tank cars and stored in steel drums or cans for indefinite periods of time. Without the addition of alkylamines, containers for storage and transportation should be of plain, galvanized, or lead lined, mild steel because ethylene dichloride may be corrosive to iron and other metals, especially if in contact with moisture at elevated temperatures. [7] Rubber is not resistant to ethylene dichloride.

Ethylene dichloride decomposes slowly, becoming acidic and darkening in color. In the presence of strong ultraviolet light, air, and moisture, or in contact with open flame or hot surfaces, ethylene dichloride decomposes rapidly and toxic quantities of phosgene, hydrogen chloride, carbon monoxide, carbon dioxide, acetylene, and vinyl chloride may be formed. [1,6] Because of this possibility, ethylene dichloride should be stored in cool, dry, well-ventilated areas, away from direct sunlight.

Damaged drums or other storage or transporting containers may not be welded until thoroughly purged with steam, flushed with water and air-dried. [7]

All piping and valves at the loading or unloading station should be of ethylene dichloride resistant material and should be carefully inspected prior to connection to the transport vehicle and periodically during the operation. Personal protective clothing must be provided during both inspection and connection. Eye wash and safety shower installations should be readily available in the immediate area. Signs indicating the location of safety showers and eye wash facilities should be prominently displayed throughout the work area. Unloading areas must be posted "Danger: loading or unloading ethylene dichloride".

Due to the toxicity of ethylene dichloride, processes in which it is used in large quantities should be carried out in closed systems. Well-designed hoods and ventilation systems should be used to maintain exposures at or below concentrations specified by this standard. Further protective measures include the use of personal protective equipment and clothing and purging of equipment prior to and during servicing and maintenance.

Ethylene dichloride is a component in many insecticidal fumigants and conventional work practice guidelines are inappropriate to protect agricultural workers from the hazards of exposure. For these uses, fumigants containing ethylene dichloride must be used in a manner consistent with their labeling requirements. These usually specify allowable time limits before a fumigated field may be reentered, and safe practices for the application of the particular pesticide. Consideration must be given to the wearing of personal protective equipment including long-sleeved shirt, long-legged pants (or suitable coveralls), a hat,

shoes, socks, and gloves. Specific requirements of worker protection standards for agricultural pesticides may be found in 40 CFR 170.

Where a fumigant is applied to a crop in confined storage, hazardous concentrations may be encountered and entry to such areas must not be made without proper personal protective equipment including self-contained breathing apparatus.

Safety showers and eye wash facilities are necessary in areas where ethylene dichloride is handled. In locations where such facilities are not available, a container of water for emergency use must be kept with the first aid supplies.

(b) Equipment Maintenance

All equipment used for handling ethylene dichloride must be emptied and purged prior to entry or disassembly. Steaming followed by washing with water is recommended for purging tanks and other containers which have held ethylene dichloride. [7] Pipe lines should be disconnected and capped. Under conditions where it is necessary to enter or otherwise work with ethylene dichloride contaminated equipment, maintenance personnel must use either a self-contained breathing apparatus of the pressure-demand mode, with an impervious protective suit, or a combination supplied-air suit with auxiliary self-contained air supply. Ventilation should still be continued during this time by blowing or drawing fresh air through the system. Safety precautions for emergency rescue require that all maintenance personnel be informed of the toxic properties of ethylene dichloride, and be instructed on the necessity of wearing personal protective equipment. [7] Constant observation of anyone entering a tank should be maintained in case rescue work is necessary.

(c) Emergencies

Spills must be anticipated. Storage tanks should be diked to contain the contents of the tank. Drum storage areas must also be diked to contain the volume of ethylene dichloride present in the drums, so as to prevent release to other areas. Areas where major spills are likely to occur should be constructed so that they may be closed until properly protected personnel can ventilate, enter, and clear the area. Warning signs shall be posted so that no unauthorized personnel will enter the area. Normal work should not be continued until the concentration of ethylene dichloride has been reduced to that prescribed by this standard. Any combustion operations must be stopped until the spill is cleared. Disposal of ethylene dichloride should be done in compliance with local, state, and federal waste disposal regulations. Consideration should be given to pumping the diked spill to another tank. In addition, it is advisable to have facilities for transfer of the contents of a leaking tank to another suitable tank.

Areas in which small spills have occurred shall be evacuated and well-ventilated. Small portable sparkproof fans may be used in confined areas where local exhaust ventilation is not feasible. Workers should not return to any work area if the odor of ethylene dichloride is still perceptible.

Ethylene dichloride is flammable, and products of combustion include extremely noxious gases such as phosgene, hydrogen chloride, acetylene, and vinyl chloride. Firefighters should be equipped with self-contained breathing apparatus of the pressure-demand mode and an impervious suit, or a combination supplied-air suit with auxiliary self-contained air supply.