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# Occupational Safety and Health **Administration**

By Standard Number 1910.1052 App B - Medical Surveillance for Methylene Chloride

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**Part Number** 

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Number: <u>1910.1052 App B</u>

Title: Medical Surveillance for Methylene Chloride

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# Appendix B to Section 1910.1052 - Medical Surveillance for Methylene Chloride

# I. Primary Route of Entry

Inhalation

# II. Toxicology

Methylene Chloride (MC) is primarily an inhalation hazard. The principal acute hazardous effects are the depressant action on the central nervous system, possible cardiac toxicity and possible liver toxicity. The range of CNS effects are from decreased eye/hand coordination and decreased performance in vigilance tasks to narcosis and even death of individuals exposed at very high doses. Cardiac toxicity is due to the metabolism of MC to carbon monoxide, and the effects of carbon monoxide on heart tissue. Carbon monoxide displaces oxygen in the blood, decreases the oxygen available to heart tissue, increasing the risk of damage to the heart, which may result in heart attacks in susceptible individuals. Susceptible individuals include persons with heart disease and those with risk factors for heart disease.

Elevated liver enzymes and irritation to the respiratory passages and eyes have also been reported for both humans and experimental animals exposed to MC vapors.

MC is metabolized to carbon monoxide and carbon dioxide via two separate pathways. Through the first pathway, MC is metabolized to carbon monoxide as an end-product via the P-450 mixed function oxidase pathway located in the microsomal fraction of the cell. This biotransformation of MC to carbon monoxide occurs through the process of microsomal oxidative dechlorination which takes place primarily in the liver. The amount of conversion to carbon monoxide is significant as measured by the concentration of carboxyhemoglobin, up to 12% measured in the blood following occupational exposure of up to 610 ppm. Through the second pathway, MC is metabolized to carbon dioxide as an end product (with formaldehyde and formic acid as metabolic intermediates) via the glutathione dependent enzyme found in the cytosolic fraction of the liver cell. Metabolites along this pathway are believed to be associated with the carcinogenic activity of MC.

MC has been tested for carcinogenicity in several laboratory rodents. These rodent studies indicate that there is clear evidence that MC is carcinogenic to male and female mice and female rats. Based on epidemiologic studies, OSHA has concluded that there is suggestive evidence of increased cancer risk in MC-related worker populations. The epidemiological evidence is consistent with the finding of excess cancer in the experimental animal studies. NIOSH regards MC as a potential occupational carcinogen and the International Agency for Research Cancer (IARC) classifies MC as an animal carcinogen. OSHA considers MC as a suspected human carcinogen.

# III. Medical Signs and Symptoms of Acute Exposure

Skin exposure to liquid MC may cause irritation or skin burns. Liquid MC can also be irritating to the eyes. MC is also absorbed through the skin and may contribute to the MC exposure by inhalation.

At high concentrations in air, MC may cause nausea, vomiting, light-headedness, numbness of the extremities, changes in blood enzyme levels, and breathing problems, leading to bronchitis and pulmonary edema, unconsciousness and even death.

At lower concentrations in air, MC may cause irritation to the skin, eye, and respiratory tract and occasionally headache and nausea. Perhaps the greatest problem from exposure to low concentrations of MC is the CNS effects on coordination and alertness that may cause unsafe operations of machinery and equipment, leading to self-injury or accidents.

Low levels and short duration exposures do not seem to produce permanent disability, but chronic

exposures to MC have been demonstrated to produce liver toxicity in animals, and therefore, the evidence is suggestive for liver toxicity in humans after chronic exposure.

Chronic exposure to MC may also cause cancer.

#### IV. Surveillance and Preventive Considerations

As discussed in sections II and III of this appendix, MC is classified as a suspect or potential human carcinogen. It is a central nervous system (CNS) depressant and a skin, eye and respiratory tract irritant. At extremely high concentrations, MC has caused liver damage in animals. MC principally affects the CNS, where it acts as a narcotic. The observation of the symptoms characteristic of CNS depression, along with a physical examination, provides the best detection of early neurological disorders. Since exposure to MC also increases the carboxyhemoglobin level in the blood, ambient carbon monoxide levels would have an additive effect on that carboxyhemoglobin level. Based on such information, a periodic post-shift carboxyhemoglobin test as an index of the presence of carbon monoxide in the blood is recommended, but not required, for medical surveillance.

Based on the animal evidence and three epidemiologic studies previously mentioned, OSHA concludes that MC is a suspect human carcinogen. The medical surveillance program is designed to observe exposed workers on a regular basis. While the medical surveillance program cannot detect MC-induced cancer at a preneoplastic stage, OSHA anticipates that, as in the past, early detection and treatments of cancers leading to enhanced survival rates will continue to evolve.

#### A. Medical and Occupational History

The medical and occupational work history plays an important role in the initial evaluation of workers exposed to MC. It is therefore extremely important for the examining physician or other licensed health care professional to evaluate the MC-exposed worker carefully and completely and to focus the examination on MC's potentially associated health hazards. The medical evaluation must include an annual detailed work and medical history with special emphasis on cardiac history and neurological symptoms.

An important goal of the medical history is to elicit information from the worker regarding potential signs or symptoms associated with increased levels of carboxyhemoglobin due to the presence of carbon monoxide in the blood. Physicians or other licensed health care professionals should ensure that the smoking history of all MC exposed employees is known. Exposure to MC may cause a significant increase in carboxyhemoglobin level in all exposed persons. However, smokers as well as workers with anemia or heart disease and those concurrently exposed to carbon monoxide are at especially high risk of toxic effects because of an already reduced oxygen carrying capacity of the blood.

A comprehensive or interim medical and work history should also include occurrence of headache, dizziness, fatigue, chest pain, shortness of breath, pain in the limbs, and irritation of the skin and eyes.

In addition, it is important for the physician or other licensed health care professional to become familiar with the operating conditions in which exposure to MC is likely to occur. The physician or other licensed health care professional also must become familiar with the signs and symptoms that may indicate that a worker is receiving otherwise unrecognized and exceptionally high exposure levels of MC.

An example of a medical and work history that would satisfy the requirement for a comprehensive or interim work history is represented by the following:

The following is a list of recommended questions and issues for the self-administered questionnaire for methylene chloride exposure.

#### QUESTIONNAIRE FOR METHYLENE CHLORIDE EXPOSURE

### I. Demographic Information

1. Name	
2. Date	
3. Date of Birth	
4. Age	
5. Present occupation	
6. Sex	
7. Race (Check all that apply)	
a. White	d. Hispanic or Latino
b. Black or African American	e. American Indian or Alaska Native
c. Asian	f. Native Hawaiian or Other Pacific Islander

#### II. Occupational History

1. Have you ever worked with methylene chloride, dichloromethane, methylene dichloride, or CH<sub>2</sub>Cl<sub>2</sub> (all are different names for the same chemical)? Please list which on the occupational

history form if you have not already.

2. If you have worked in any of the following industries and have not listed them on the occupational history form, please do so.

Furniture stripping

Polyurethane foam manufacturing

Chemical manufacturing or formulation

Pharmaceutical manufacturing

Any industry in which you used solvents to clean and degrease equipment or parts

Construction, especially painting and refinishing

Aerosol manufacturing

Any industry in which you used aerosol adhesives

3. If you have not listed hobbies or household projects on the occupational history form, especially furniture refinishing, spray painting, or paint stripping, please do so.

#### III. Medical History

#### A. General

- 1. Do you consider yourself to be in good health? If no, state reason(s).
- 2. Do you or have you ever had:
  - a. Persistent thirst
  - b. Frequent urination (three times or more at night)
  - c. Dermatitis or irritated skin
  - d. Non-healing wounds
- 3. What prescription or non-prescription medications do you take, and for what reasons?
- 4. Are you allergic to any medications, and what type of reaction do you have?

# B. Respiratory

- 1. Do you have or have you ever had any chest illnesses or diseases? Explain.
- 2. Do you have or have you ever had any of the following:
  - a. Asthma
  - b. Wheezing
  - c. Shortness of breath
- 3. Have you ever had an abnormal chest X-ray? If so, when, where, and what were the findings?

- 4. Have you ever had difficulty using a respirator or breathing apparatus? Explain.
- 5. Do any chest or lung diseases run in your family? Explain.
- 6. Have you ever smoked cigarettes, cigars, or a pipe? Age started:
- 7. Do you now smoke?
- 8. If you have stopped smoking completely, how old were you when you stopped?
- 9. On the average of the entire time you smoked, how many packs of cigarettes, cigars, or bowls of tobacco did you smoke per day?

#### C. Cardiovascular

- 1. Have you ever been diagnosed with any of the following: Which of the following apply to you now or did apply to you at some time in the past, even if the problem is controlled by medication? Please explain any yes answers (i.e., when problem was diagnosed, length of time on medication).
  - a. High cholesterol or triglyceride level
  - b. Hypertension (high blood pressure)
  - c. Diabetes
  - d. Family history of heart attack, stroke, or blocked arteries
- 2. Have you ever had chest pain? If so, answer the next five questions.
  - a. What was the quality of the pain (i.e., crushing, stabbing, squeezing)?
  - b. Did the pain go anywhere (i.e., into jaw, left arm)?
  - c. What brought the pain out?
  - d. How long did it last?
  - e. What made the pain go away?
- 3. Have you ever had heart disease, a heart attack, stroke, aneurysm, or blocked arteries anywhere in you body? Explain (when, treatment).
- 4. Have you ever had bypass surgery for blocked arteries in your heart or anywhere else? Explain.
- 5. Have you ever had any other procedures done to open up a blocked artery (balloon angioplasty, carotid endarterectomy, clot-dissolving drug)?

E. Central Nervous System

f. Lack of balance

e. Garbled speech

d. Loss of consciousness

a. Headacheb. Dizziness

c. Fainting

1. Do you or have you ever had (explain each):

- g. Mental/psychiatric illness
- h. Forgetfulness

#### F. Hematologic

- 1. Do you have, or have you ever had (explain each):
  - a. Anemia
  - b. Sickle cell disease or trait
  - c. Glucose-6-phosphate dehydrogenase deficiency
  - d. Bleeding tendency disorder
- 2. If not already mentioned previously, have you ever had a reaction to sulfa drugs or to drugs used to prevent or treat malaria? What was the drug? Describe the reaction.

## B. Physical Examination

The complete physical examination, when coupled with the medical and occupational history, assists the physician or other licensed health care professional in detecting pre-existing conditions that might place the employee at increased risk, and establishes a baseline for future health monitoring. These examinations should include:

- 1. Clinical impressions of the nervous system, cardiovascular function and pulmonary function, with additional tests conducted where indicated or determined by the examining physician or other licensed health care professional to be necessary.
- 2. An evaluation of the advisability of the worker using a respirator, because the use of certain respirators places an additional burden on the cardiopulmonary system. It is necessary for the attending physician or other licensed health care professional to evaluate the cardiopulmonary function of these workers, in order to inform the employer in a written medical opinion of the worker's ability or fitness to work in an area requiring the use of certain types of respiratory protective equipment. The presence of facial hair or scars that might interfere with the worker's ability to wear certain types of respirators should also be noted during the examination and in the written medical opinion.

Because of the importance of lung function to workers required to wear certain types of respirators to protect themselves from MC exposure, these workers must receive an assessment of pulmonary function before they begin to wear a negative pressure respirator and at least annually thereafter. The recommended pulmonary function tests include measurement of the employee's forced vital capacity (FVC), forced expiratory volume at one second (FEV <sub>1</sub>), as well as calculation of the ratios of FEV<sub>1</sub> to FVC, and the ratios of measured FVC and measured FEV <sub>1</sub> to expected respective values corrected for variation due to age, sex, race, and height. Pulmonary function

evaluation must be conducted by a physician or other licensed health care professional experienced in pulmonary function tests.

The following is a summary of the elements of a physical exam which would fulfill the requirements under the MC standard:

#### PHYSICAL EXAM

## I. Skin and appendages

- 1. Irritated or broken skin
- 2. Jaundice
- 3. Clubbing cyanosis, edema
- 4. Capillary refill time
- 5. Pallor

II. Head

- 1. Facial deformities
- 2. Scars
- 3. Hair growth

III. Eyes

- 1. Scleral icterus
- 2. Corneal arcus
- 3. Pupillary size and response
- 4. Fundoscopic exam

IV. Chest

1. Standard exam

V. Heart

- 1. Standard exam
- 2. Jugular vein distension
- 3. Peripheral pulses

VI. Abdomen

1. Liver span

VII. Nervous System

1. Complete standard neurologic exam

#### VIII. Laboratory

- 1. Hemoglobin and hematocrit
- 2. Alanine aminotransferase (ALT, SGPT)
- 3. Post-shift carboxyhemoglobin

#### IX. Studies

- 1. Pulmonary function testing
- 2. Electrocardiogram

An evaluation of the oxygen carrying capacity of the blood of employees (for example by measured red blood cell volume) is considered useful, especially for workers acutely exposed to MC.

It is also recommended, but not required, that end of shift carboxyhemoglobin levels be determined periodically, and any level above 3% for non-smokers and above 10% for smokers should prompt an investigation of the worker and his workplace. This test is recommended because MC is metabolized to CO, which combines strongly with hemoglobin, resulting in a reduced capacity of the blood to transport oxygen in the body. This is of particular concern for cigarette smokers because they already have a diminished hemoglobin capacity due to the presence of CO in cigarette smoke.

#### C. Additional Examinations and Referrals

## 1. Examination by a Specialist

When a worker examination reveals unexplained symptoms or signs (i.e. in the physical examination or in the laboratory tests), follow-up medical examinations are necessary to assure that MC exposure is not adversely affecting the worker's health. When the examining physician or other licensed health care professional finds it necessary, additional tests should be included to determine the nature of the medical problem and the underlying cause. Where relevant, the worker should be sent to a specialist for further testing and treatment as deemed necessary.

The final rule requires additional investigations to be covered and it also permits physicians or other licensed health care professionals to add appropriate or necessary tests to improve the diagnosis of disease should such tests become available in the future.

# 2. Emergencies

The examination of workers exposed to MC in an emergency should be directed at the organ systems most likely to be affected. If the worker has received a severe acute exposure, hospitalization may be required to assure proper medical intervention. It is not possible to

precisely define "severe," but the physician or other licensed health care professional's judgment should not merely rest on hospitalization. If the worker has suffered significant conjunctival, oral, or nasal irritation, respiratory distress, or discomfort, the physician or other licensed health care professional should instigate appropriate follow-up procedures. These include attention to the eyes, lungs and the neurological system. The frequency of follow-up examinations should be determined by the attending physician or other licensed health care professional. This testing permits the early identification essential to proper medical management of such workers.

#### D. Employer Obligations

The employer is required to provide the responsible physician or other licensed health care professional and any specialists involved in a diagnosis with the following information: a copy of the MC standard including relevant appendices, a description of the affected employee's duties as they relate to his or her exposure to MC; an estimate of the employee's exposure including duration (e.g., 15hr/wk, three 8-hour shifts/wk, full time); a description of any personal protective equipment used by the employee, including respirators; and the results of any previous medical determinations for the affected employee related to MC exposure to the extent that this information is within the employer's control.

## E. Physicians' or Other Licensed Health Care Professionals' Obligations

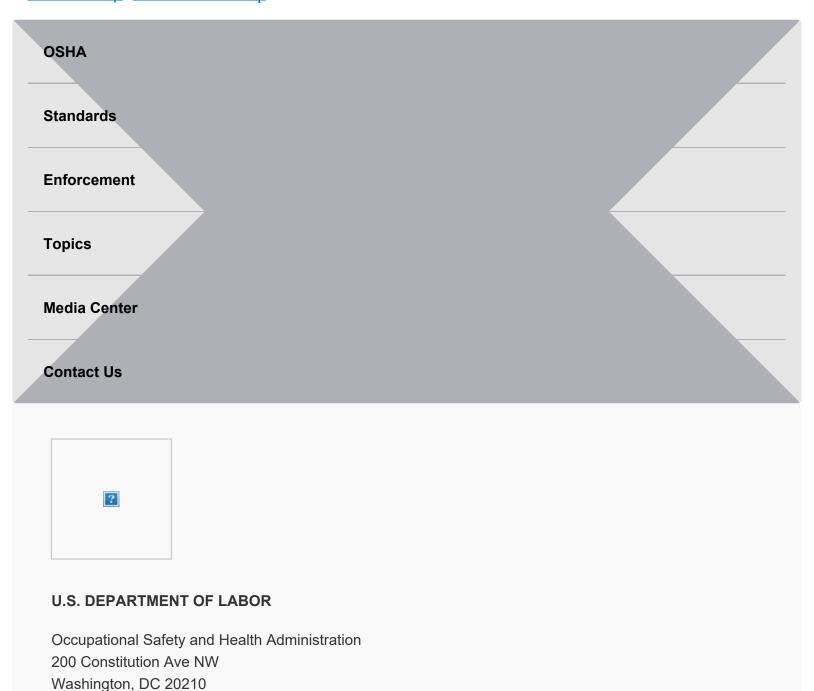
The standard in this section requires the employer to ensure that the physician or other licensed health care professional provides a written statement to the employee and the employer. This statement should contain the physician's or licensed health care professional's opinion as to whether the employee has any medical condition placing him or her at increased risk of impaired health from exposure to MC or use of respirators, as appropriate. The physician or other licensed health care professional should also state his or her opinion regarding any restrictions that should be placed on the employee's exposure to MC or upon the use of protective clothing or equipment such as respirators. If the employee wears a respirator as a result of his or her exposure to MC, the physician or other licensed health care professional's opinion should also contain a statement regarding the suitability of the employee to wear the type of respirator assigned. Furthermore, the employee should be informed by the physician or other licensed health care professional about the cancer risk of MC and about risk factors for heart disease, and the potential for exacerbation of underlying heart disease by exposure to MC through its metabolism to carbon monoxide. Finally, the physician or other licensed health care professional should inform the employer that the employee has been told the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion must not contain any information on specific findings or diagnosis unrelated to employee's occupational exposures.

The purpose in requiring the examining physician or other licensed health care professional to

supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in assuring that their health is not being impaired by exposure to MC, and to assess the employee's ability to use any required protective equipment.

[62 FR 1601, Jan. 10, 1997, as amended at 62 FR 42667, Aug. 8, 1997; 62 FR 54383, Oct. 20, 1997; 62 FR 66277, Dec. 18, 1997; 63 FR 1295, Jan. 8, 1998; 63 FR 20099, Apr. 23, 1998; 63 FR 50729, Sept. 22, 1998; 71 FR 16674, Apr. 3, 2006; 71 FR 50190, Aug. 24, 2006; 73 FR 75587, Dec. 12, 2008; 77 FR 17785, Mar. 26, 2012; 78 FR 9313, Feb. 8, 2013; 84 FR 21544, May 14, 2019]

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