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<p>18. Abstract (Limit: 200 words) This testimony addressed the concerns of NIOSH regarding the advance notice of proposed rulemaking (ANPR) dealing with occupational exposure to methylene-chloride (75092) (MC). Specifically the testimony addressed the studies that OSHA should consider in its assessment of the potential health risks, especially the carcinogenic, chronic neurological, encephalopathic, teratogenic, and mutagenic effects of MC; the dermal absorption studies available and the extent of the potential adverse health effects resulting from dermal exposure; studies or evidence indicating the combined effects of inhalation and dermal exposures; how OSHA should estimate the significance of risk at the current exposure limits; what the permissible exposure levels should be; production and control systems; substitution availability; protective equipment and clothing; worker exposure and monitoring; worker training; and medical surveillance.</p>				
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Comments to DOL

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH COMMENTS ON THE
OCCUPATIONAL SAFETY AND HEALTH ADVANCE NOTICE OF PROPOSED RULEMAKING:
OCCUPATIONAL EXPOSURE TO METHYLENE CHLORIDE

29 CFR Part 1910
Docket No. H-71

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

February 25, 1987

The National Institute for Occupational Safety and Health (NIOSH) is pleased to provide the Occupational Safety and Health Administration (OSHA) with comments on the advance notice of proposed rulemaking (ANPR), Occupational Exposure to Methylene Chloride. NIOSH has previously expressed concern about the adverse health effects among workers exposed to methylene chloride in a variety of occupational settings. In 1976, NIOSH published the document, "Criteria for a Recommended Standard...Occupational Exposure to Methylene Chloride." In that document, NIOSH recommended that occupational exposure to methylene chloride be controlled to 75 ppm as a 10-hour time weighted average (TWA), and if the concentration of carbon monoxide in the same workplace exceeded 9 ppm as a 10-hour TWA, then exposure to methylene chloride should be reduced accordingly. This recommendation was based on the fact that the toxicities of carbon monoxide and methylene chloride are additive. At the time of this initial recommendation there was no evidence of methylene chloride's carcinogenicity.

In April 1986, NIOSH published Current Intelligence Bulletin 46: Methylene Chloride. In that current intelligence bulletin (CIB), NIOSH examined several studies of the carcinogenicity of methylene chloride, including those conducted by the Halogenated Solvents Industry Alliance (HSIA) and the National Toxicology Program (NTP). NIOSH also evaluated the existing epidemiologic studies. Based on our evaluation, we concluded:

"...NIOSH believes that the collective carcinogenicity data provide sufficient evidence to warrant concern about the potential consequences of occupational exposure to methylene chloride."

We recommended that methylene chloride be considered a potential human carcinogen in the workplace. This recommendation is consistent with the provisions of the OSHA cancer policy (Identification, Classification, and Regulation of Potential Occupational Carcinogens), 29 CFR 1990. NIOSH further recommended that:

"As prudent public health policy, employers should, voluntarily assess the conditions under which workers are exposed to methylene chloride and take all reasonable precautions to reduce exposures to the lowest feasible limit."

At this time, based on OSHA method no. 59, the lowest quantifiable (feasible) limit that has adequate data demonstrating storage stability, precision, and accuracy appears to be 1.0 ppm as determined in a 10-liter air sample. A concentration of 1.0 ppm is well within the range of concentrations over which the OSHA method has been evaluated.

RESPONSES TO SPECIFIC ISSUES IN THE ANPR

A. Health Effects

- (1) What studies, including their strengths and weaknesses (if any) should OSHA consider in its assessment of potential health risks, especially the carcinogenic, chronic neurological effects, encephalopathy, teratogenic and mutagenic effects of DCM?

NIOSH believes that the results of the NTP bioassay provide sufficient support for lowering the PEL. In addition to the NTP study, NIOSH is aware of two studies that are examining the reproductive effects of methylene chloride. One study is being conducted by the Greater Cincinnati Occupational Health Clinic and the other is being conducted by NIOSH. As soon as these studies are completed, we will transmit them to OSHA.

- (2) What dermal absorption studies are available and what is the extent of potential adverse health effects resulting from dermal exposure?

and

- (3) Are there studies or evidence indicating the combined effects of inhalation and dermal exposures?

NIOSH has conducted a literature search to identify information on dermal absorption. In addition to those studies already recounted by OSHA in the ANPR and those studies described in the NIOSH criteria document, OSHA may want to consider the attached report by McDougal et al. (1986). In that study, the investigators demonstrated that methylene chloride can be absorbed through the skin of animals as a result of vapor exposure. Although the amount of methylene chloride absorbed was small in relation to the concentration at which the animals were exposed, the amount of methylene chloride found in the blood was proportional to the vapor concentration. This finding demonstrates the need to eliminate skin contact.

- (4) How should OSHA estimate the significance of risk at the current exposure limits, including risks at the 1000 ppm STEL and 2000 ppm peak? Specifically:
 - (a) What methods are most appropriate to quantify the risk of cancer and other adverse health effects from exposure to DCM?
 - (b) Which studies of DCM should be used for a quantitative risk assessment?
 - (c) Which tumor incidences, in which animal species, by which route(s) of administration and dose level(s) should be selected for use?
 - (d) How should dose levels in experimental studies be converted to equivalent dose for occupationally exposed persons and how should the dose levels be expressed?

- (e) Should corrections be made for species-to-species extrapolation and for combined routes of exposure (i.e. dermal and inhalation)? How?
- (f) Which mathematical models should be used for describing the dose response relationship between DCM occupational exposures and the risk of cancer or other health effects?
- (g) Are there data available to indicate a "dose-rate" effect for DCM exposure? (i.e., are any health effects of DCM dependent on the time period over which exposure occurs rather than solely on the total dose received?)

The results of the NTP bioassay are the most appropriate for use in conducting a quantitative risk assessment for methylene chloride. NIOSH also maintains that when conducting such modeling, all tumors, both benign and malignant, should be used. This practice is consistent with the OSHA cancer policy.

OSHA should also examine the results of the HSIA study which was conducted at exposure concentrations over the range of 0 to 500 ppm and 500 to 3,500 ppm. In those studies the investigators reported that carboxyhemoglobin in the blood of the methylene chloride-exposed animals increased as the exposure dose increased up to 500 ppm but remained constant in animals exposed between 1,000 and 3,500 ppm. No evidence of a carcinogenic response was observed in these animals except those exposed at 3,500 ppm.

These results need to be viewed in the context of the information on methylene chloride's metabolism which was described by OSHA in the ANPR. The saturation of carboxyhemoglobin production demonstrated by the HSIA at high exposures is consistent with the possibility of two pathways for methylene chloride metabolism described by OSHA, and may offer some insight regarding the carcinogenic response observed among animals exposed at higher concentrations in the NTP bioassay.

OSHA has also asked a series of questions concerning the technical aspects of conducting quantitative risk assessments. These questions concern selection of scaling factors, expression of dose, and model selection. In response to these questions we have attached a copy of the NIOSH comments on the OSHA proposed revisions to the cancer policy, 29 CFR 1910.1000 (April 5, 1982).

OSHA has also requested information that would support a dose rate effect for methylene chloride. NIOSH is not aware of any data that is currently available that supports a dose rate effect for methylene chloride. The absence of such data should not prevent the incorporation of a limit on short term exposures to prevent production of carboxyhemoglobin which can lead to short term impairment of functional capacity.

B. Permissible Exposure Levels

- (1) Should a revised standard be developed to include an 8-hour time weighted average, ceiling limit, an action level or a combination of limits?
- (2) What permissible exposure limits should be proposed and what support, in the health evidence, is available for these numbers?
- (3) What data support the feasibility for measuring the lower permissible limits (including accuracy and precision of collection and analytical procedures)?

The following comment responds to items (1), (2), and (3) above.

As stated previously, NIOSH recommends that exposure to methylene chloride be controlled so that no worker is exposed at a concentration greater than 1.0 ppm. This should be determined in an 8-hour air sample.

Since 1.0 ppm of methylene chloride appears to be the lowest quantifiable limit (using OSHA method no. 59) for which there is storage stability data and adequate precision and accuracy, a recommendation for an action level is not appropriate. Based on data presented in the 1976 criteria document, concurrent exposure to carbon monoxide concentrations lower than 35 ppm should not present an additional health hazard.

- (4) What data support the technological feasibility for achieving the lower permissible exposure limits for the major industrial sectors?

In response to this question, NIOSH is submitting copies of 25 Health Hazard Evaluation reports from a variety of workplaces where methylene chloride is used. Although not all of these operations report exposures at or below 1.0 ppm, in most cases, the exposures were well below the prior NIOSH recommended exposure limit of 75 ppm. However, in those operations where methylene chloride is used as the primary solvent, such as degreasing and furniture or paint stripping, exposures were much higher, often exceeding 1,000 ppm.

- (5) How should the standard deal with the effects of occupational exposures to DCM in conjunction with those of carbon monoxide (metabolite to DCM), and possibly phosgene (product of DCM heat decomposition)? Should the PEL for DCM be lower when these other substances are present? How should an air monitoring strategy deal with such combined exposures?

As stated above, at the NIOSH recommended exposure limit of 1.0 ppm, there should be no additive effects due to the simultaneous presence of carbon monoxide. However, if OSHA should select a higher PEL for methylene chloride, then in order to consider the additive toxicity of simultaneous

exposure to carbon monoxide and methylene chloride, the concentration of methylene chloride as carbon monoxide should be reduced to satisfy the relationship:

$$\frac{C(\text{CO})}{L(\text{CO})} + \frac{C(\text{CH}_2\text{Cl}_2)}{L(\text{CH}_2\text{Cl}_2)} \leq 1$$

Where:

C(CO) = TWA exposure concentration of CO in ppm

L(CO) = The NIOSH recommended exposure limit of CO, e.g., 35 ppm

C(CH₂Cl₂) = TWA exposure concentration of methylene chloride in ppm

L(CH₂Cl₂) = The TWA exposure limit of methylene chloride in ppm

In qualitative terms, as can be seen from the graphical presentation in Figure XII-1 of the NIOSH Criteria Document (attached), the allowable methylene chloride concentration should be reduced by about 10 ppm for every 5 ppm carbon monoxide.

Since phosgene is so acutely toxic, every effort should be made in the standard to prohibit use of methylene chloride in those situations likely to produce phosgene, such as open flames and heat sources. NIOSH suggests that OSHA also require that the labels on containers of methylene chloride contain information on the possibility of phosgene formation. OSHA may also want to consider requiring that monitoring for phosgene be conducted in those areas where its formation is likely.

C. Production and Control Systems

The four references cited below can be used as sources of information for those installing methylene chloride controls.

- 1) Hughes RT (1986): Design Criteria for Plating Tank Push-Pull Ventilation. In: Proceedings of Ventilation '85, edited by H.D. Goodfellow, Elsevier Science Publishers, B.V. Amsterdam, pp. 521-527.
- 2) Huebener DJ and Hughes RT (1985): Development of push-pull ventilation. Am Ind Hyg Assoc J 46(5):262-267.
- 3) Anastas MY (1984): Engineering and other health hazard controls in oral contraceptive tablet-making operations. NTIS Publication No. PB 5 220739/AS.
- 4) Zey JN and Anastas MY (1986): Health hazard evaluation report HETA 85-105-1689, Fiber-Glass Development Corporation, Dayton, Ohio. National Institute for Occupational Safety and Health.

Two of these reports provide criteria for push-pull ventilation which may be used for degreasing operations where open surface tanks are in use. One report describes typical controls found in the pharmaceutical industry and the fourth report is HETA 85-105-1689 (one of the 25 HHE reports referred to above). The HHE report describes ventilation systems that can be used during resin mixing operations.

D. Substitution Availability

In some situations, such as degreasing operations, freon may be a reasonable substitute for methylene chloride. In other operations, such as furniture stripping, there may not be reasonable alternatives to the use of methylene chloride; therefore, adequate engineering controls and personal protective equipment and clothing must be used.

E. Protective Equipment and Clothing

Since NIOSH regards methylene chloride as a potential occupational carcinogen, only the most protective respirators are recommended. These include:

1. Self-contained breathing apparatus with a full facepiece operated in the pressure-demand mode.
2. A combination respirator which includes a Type C supplied-air respirator with a full facepiece operated in the pressure-demand mode and an auxiliary self-contained breathing apparatus operated in the pressure-demand mode.

It must also be remembered that workers may become adapted to the odor of methylene chloride; therefore, air-purifying respirators should not be used.

As can be seen from the data presented below, commercially available chemical protective clothing for use against methylene chloride does not provide adequate protection. Since these data were obtained using only methylene chloride, it is reasonable to assume the permeation times will be reduced if methylene chloride is present in a mixture with other solvents. NIOSH recommends that users of methylene chloride evaluate candidate protective clothing against methylene chloride or the methylene chloride mixture to be used under actual work conditions. NIOSH also recommends that the thickest PVA or Viton be selected as candidate materials since they appear to have the longest breakthrough times and seem to degrade less rapidly than other materials.

The following data have been obtained from the Internal NIOSH Chemical Protective Clothing Data Base:

<u>Breakthrough Time (minutes)</u>	<u>Material</u>
17->480	PVA
30-120	Viton
<15	Butil
	Neoprene
	Natural Rubber
	Nitrite Polyethylene
	Acrylonitrile
	PVC

F. Workers Exposure and Monitoring

In response to this category, a printout from the NIOSH National Occupational Health Survey (NOHS) data base is attached. This printout list trade names of commercially available products that contain methylene chloride and the percentage of methylene chloride in those products. The second printout, also from NOHS, lists by standard industrial classification code the number of facilities in which methylene chloride was present and the number of workers in those facilities.

We have also attached a summary of unpublished data collected by NIOSH investigators from several small furniture refinishing facilities in the Cincinnati, Ohio area. These facilities were selected because they appear to be representative of small furniture refinishing facilities throughout the nation. In general, the facilities investigated by NIOSH all had a small number of employees. In one facility, no controls were used; in another, an inadequate ventilation system was in use.

In the first facility, furniture was placed in a small tank which was in a garage; the tank was open and there was no ventilation. Methylene chloride concentrations ranged from 287 ppm to 2,160 ppm. After installation of what is described as primitive ventilation, exposure concentrations ranged from 12 ppm to 234 ppm.

At the second facility, a medium-sized warehouse, a stripping tank similar to that in use at the first location was partially closed and ventilated. Methylene chloride concentrations at this facility ranged from 90 ppm to 297 ppm.

At the third facility, stripping was performed by application of methylene chloride through a low-pressure nozzle and the work was conducted on a bench. Ventilation at this facility was described as poor, and concentrations ranged from 131 ppm to 139 ppm in adjacent areas, to 899 ppm at the work station.

G. Workers Training

As stated in the NIOSH CIB on methylene chloride, a worker education program should be designed so that workers are informed about the potential health risks from exposure to methylene chloride, the proper use of personal protective equipment and clothing, smoking cessation programs, and proper work practice procedures. Workers should also be trained in the recognition of the symptoms of methylene chloride exposure.

H. Medical Surveillance

NIOSH recommends that the final methylene chloride standard include a program that will detect methylene chloride-induced health effects including: eye or skin irritation, dizziness, incoordination, nausea, tingling or numbness of the extremities, irritability, lethargy and stupor. Physicians should also be provided with all toxicological information, industrial hygiene sampling data, and a listing of protective devices or equipment that the worker may be required to wear. A medical evaluation to determine the worker's ability to wear a respirator should also be conducted. The physician should also conduct periodic medical examinations that focus on the respiratory, cardiovascular, and nervous systems, and on the liver, pancreas, blood, and skin since these organs are the primary targets of methylene chloride exposure.

NIOSH has no comment on the following sections:

- I. Control Measures and Benefits
- J. Environmental Effects
- K. Impact on Small Entities
- L. Duplication/Overlapping/Conflicting Rules

31 Attachments

Enclosures and/or attachments that are not included are available free of charge from the NIOSH Docket Office [513/533-8450].

