

40 CFR Part 773

[OPTS-42055 TSH 2571-4]

Dichloromethane; Decision To Withdraw a Proposed Rule**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule; withdrawal.

SUMMARY: In the Federal Register of June 5, 1981 (46 FR 30300), EPA proposed the testing of dichloromethane, nitrobenzene, and 1,1,1-trichloroethane under section 4(a) of the Toxic Substances Control Act for certain health and environmental effects. A notice on nitrobenzene appears elsewhere in this issue of the Federal Register; 1,1,1-trichloroethane will be addressed at a later time in another Federal Register document. The Agency has decided not to proceed with rulemaking for dichloromethane. Data received subsequent to the proposal are sufficient to reasonably determine or predict human dermal sensitization, and testing initiated subsequent to the proposal is expected to provide sufficient data to reasonably determine or predict the effects on human reproduction. Data received subsequent to the proposal on cardiovascular effects indicate the such effects are unlikely and do not support a finding of "may present an unreasonable risk." Also, evaluation of the comments submitted and re-evaluation of the available data and the reasoning behind the proposal have caused the Agency to conclude that there is a sufficient basis to reasonably determine or predict that the current manufacture, processing, distribution in commerce, use, or disposal of this substance does not present an unreasonable risk of adverse effects to the environment.

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Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:**I. Background**

Section 4(a) (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) of the Toxic Substances Control Act (TSCA) authorizes the Administrator of EPA to promulgate rules which require manufacturers and processors to test chemical substances and mixtures. Data developed through these test programs are used by EPA in assessing the risks that the chemicals may present to health and the environment.

Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend chemical substances or mixtures for priority testing consideration by EPA under section 4(a) of the Act. The ITC designated dichloromethane (DCM) for priority testing consideration in April 1978. The ITC recommended testing of DCM, on the basis of substantial exposure, for carcinogenicity, mutagenicity, teratogenicity, other chronic effects testing, environmental effects testing, and for epidemiology studies. The ITC designation was published in the Federal Register of April 19, 1978 (43 FR 16684).

EPA's response to this designation was published in the Federal Register of June 5, 1981 (46 FR 30300) as a proposed rule on dichloromethane, nitrobenzene, and 1,1,1-trichloroethane. Nitrobenzene is addressed elsewhere in this issue of the Federal Register, 1,1,1-trichloroethane will be addressed in a future Federal Register document. EPA proposed that the following tests be performed on dichloromethane by industry and the Agency.

PROPOSED TESTING

	Industry-required	EPA-sponsored
Health Effects		
Reproductive effects	X	
Dermal sensitization	X	
Mutagenicity		X
Subchronic cardiovascular	X	
ENVIRONMENTAL EFFECTS		
Aquatic vertebrate, chronic		
Freshwater, coldwater	X	
Freshwater, warmwater	X	
Marine, coldwater		X
Marine, warmwater	X	
Aquatic invertebrate, chronic		
Freshwater	X	
Marine	X	
Birds, acute:		
Terrestrial	X	
Waterfowl	X	

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PROPOSED TESTING—Continued

	Industry- required	EPA- sponsored
Birds, chronic:		
Terrestrial.....	X	
Waterfowl.....	X	
Terrestrial invertebrates.....		X
Aquatic plants, vascular:		
Freshwater.....		X
Marine.....		X
Terrestrial plants:		
Early seedling growth.....	X	
Life-cycle.....		X
Bioconcentration:		
Aquatic vertebrates.....	X	
Terrestrial plants.....	X	
Alteration of microorganisms function.....	X	
Ecosystem effects.....		X

The industry-conducted tests were proposed on the basis of a TSCA section 4(a)(1)(B) finding of substantial production and substantial or significant human exposure or substantial environmental release, except for the subchronic cardiovascular testing which was proposed under TSCA section 4(a)(1)(A) on the basis that DCM may present an unreasonable risk to health. In addition, EPA stated in the proposal that it intended to sponsor a number of mutagenicity and environmental effects tests on DCM. EPA planned to sponsor these tests because standards for environmental and mutagenicity testing and the criteria for sequencing mutagenicity testing had not yet been developed at the time of the proposal. EPA did not propose oncogenicity testing of DCM because it believed that inhalation and gavage studies being performed by the National Toxicology Program (NTP) were sufficient to reasonably determine or predict the oncogenicity of DCM.

II. EPA's Response to Public Comments

The Agency received comments from six sources: The Halogenated Solvents Industry Alliance (HSIA), Dow Chemical Company, Celanese Corporation, Vulcan Materials Company, Procter and Gamble Company and Atlantic Richfield Company. These comments questioned the Agency's basis for proposing dermal sensitization, subchronic cardiovascular, and environmental testing. The comments in general supported the Agency's proposal to test for reproductive effects.

Comments on dermal sensitization were made by all six commentors. Atlantic Richfield Company and Celanese Corporation objected to the testing because of the lack of historical evidence for the effect and the limited potential for dermal exposure due to dichloromethane's rapid evaporation from skin. Procter and Gamble and Celanese Corporation objected to the

proposed test protocol. HSIA, Vulcan Materials Company, Procter and Gamble, and Dow Chemical Company took exception to the testing because they believed that existing unpublished data were sufficient to evaluate dermal sensitization. The unpublished data were submitted to the Agency by Dow Chemical Company (Ref. 15). The Agency has reviewed these data and agrees with the commentors that the data are sufficient to evaluate dichloromethane's potential for dermal sensitization and is therefore withdrawing the proposal to test for this effect.

Comments on subchronic cardiovascular testing were received from all the commentors except Procter and Gamble, stating that the Agency had failed to demonstrate the need for such testing in evaluating the hazards of dichloromethane. Further, industry disapproved of the proposed test protocols stating that they were not expected to produce meaningful data. The Agency, upon the receipt of additional data on the cardiovascular effects of dichloromethane (see Unit III.A), is withdrawing the proposal for cardiovascular testing.

Comments of environmental testing were received from all six commentors. Celanese Corporation commented that since environmental testing protocols were not well established, the Agency would not be warranted in requiring these tests. The other five commentors questioned the Agency's decision to require environmental testing solely on the basis of substantial release. The commentors stated that they believed that the Agency had sufficient data to reasonably determine that releases of dichloromethane are not expected to present an unreasonable risk. The Agency has re-examined the available data, and on the basis of the rationale given in Unit III.B, agrees with the commentors and is withdrawing the proposal for environmental testing.

The comments received on reproductive effects testing acknowledged, with some reservations, the need for such testing. Dow Chemical Company, HSIA, and Vulcan Materials Company commented that there was no history of reproductive effects from the use of dichloromethane but agreed testing was necessary. Celanese Corporation commented that based upon the metabolism of dichloromethane it did not expect it to cause reproductive effects but also agreed with the need for testing. Following the Agency's testing proposal, HSIA informed EPA that it was

sponsoring a 2-generation reproduction study (see Unit III.A).

III. Decision Not To Require Testing

EPA has decided not to promulgate a rule to require the testing proposed for this substance, for the reasons stated below.

A. Health Effects

Subsequent to the proposed rule, HSIA initiated a 2-generation reproductive study in rats on dichloromethane. EPA reviewed the protocol and concluded that the study would be adequate to determine the reproductive effects of dichloromethane (Refs. 2 through 6). The study was initiated in the first quarter of 1983 and exposures will be completed during the second quarter of 1984 with a final report issued by June 1985 (Ref. 11). The Agency expects to receive the final report by that date.

Although this testing is not part of a negotiated testing agreement, the HSIA agreed to adhere to the Good Laboratory Practice Standards issued by the U.S. Food and Drug Administration as published in the Federal Register of December 22, 1978 (43 FR 59986). The HSIA agreed to permit laboratory inspections and study audits in accordance with the provisions outlined in TSCA section 11 at the request of authorized representatives of EPA. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to Good Laboratory Practice provisions.

The HSIA further agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of each study will be retained for at least 10 years from the date of publication of this notice, and made available during an inspection or submitted to EPA if requested by EPA or its designated representative. Documentation which will be retained includes correspondence and other documents relating to the general conduct of the testing and the interpretation or evaluation of data other than that included in the final report. The HSIA understands that the Agency plans to publish quarterly in the Federal Register a notice of the receipt of any test data submitted for this study. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section

14, any data submitted will be made available by EPA for examination by any person.

Finally, the HSLA understands that failure to conduct the testing according to the specified protocols or failure to follow Good Laboratory Practice procedures may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to require further testing.

Dow Chemical Company has submitted to EPA the results of a human skin sensitization study of dichloromethane which provide sufficient information to reasonably predict that dichloromethane does not cause dermal sensitization (Ref. 15).

The cardiovascular effects of acute exposure to dichloromethane have been adequately characterized (Ref. 27). EPA has re-evaluated the need for subchronic cardiovascular testing on dichloromethane. The Agency's basis for proposing subchronic cardiovascular testing was the reported observation of increased arterial pressure and myocardial contractility in dogs exposed to 500 ppm dichloromethane for 2 hours. The report was contained in an abstract of a doctoral dissertation (Ref. 1). The full text of the dissertation was unavailable for the Agency's analysis until after the publication of the proposed rule. Upon evaluation of the full report, Agency scientists concluded that while a statistically significant cardiovascular effect was seen at 500 ppm, the effect was not observed at 1,000, 2,000 or 5,000 ppm (Ref. 17). The lack of a dose response leads the Agency to question the significance of this finding.

In contrast to the above study, other animal studies and occupational epidemiology studies have not reported cardiovascular effects. Chronic and subchronic animal tests have shown that long term exposure to concentrations of dichloromethane greater than 1,000 ppm produces effects in the liver and kidney but not in the cardiovascular system (Refs. 18 and 19). Epidemiologic studies of workers exposed to approximately 100 ppm dichloromethane have found no increase of cardiovascular effects over age-matched controls (Refs. 10 and 12). One of the studies (Ref. 10) investigated 29 subjects and, based upon clinical histories and electrocardiogram examinations, did not find evidence of exposure-related cardiovascular toxicity. Further, industrial hygiene studies with long-term exposure of workers to 300 to 600 ppm dichloromethane have not reported cardiovascular effects (Refs. 7, 8, 14). EPA now believes that the weight of the

evidence does not support a finding that anticipated human exposures to dichloromethane "may present an unreasonable risk" of long term cardiovascular effects that would be identifiable through a subchronic study. Furthermore, the Agency believes that it can reasonably predict the cardiovascular effects of dichloromethane on the basis of the above occupational and animal studies. Therefore, EPA has decided not to proceed with rulemaking to require subchronic cardiovascular effects testing of dichloromethane.

EPA decided not to propose oncogenicity testing because it believed at the time that the NTP studies should be sufficient to characterize the oncogenic hazards of dichloromethane. The NTP studies consist of two sets of bioassays, one by gavage and one by inhalation. The two bioassays were conducted by different laboratories under different schedules. The NTP announced that cancellation of publication of the final report on the gavage assay in the Federal Register of August 4, 1983 (48 FR 35508) due to problems in recordkeeping. The inhalation study is unaffected by this announcement. The inhalation study is expected to be completed by late 1984, with peer review tentatively scheduled for the first quarter of 1985. EPA believes at this time that the remaining inhalation test should be sufficient to characterize the oncogenic hazards of dichloromethane. The majority of human exposure to dichloromethane occurs by air, which suggests that inhalation is the preferred route of exposure for testing. Further, the pharmacokinetics of dichloromethane are largely independent of the route of exposure (Ref. 24). The Agency reserves the right to propose an oncogenicity testing requirement if at some future date the inhalation study is found inadequate.

In the proposed rule EPA stated that it was not requiring epidemiology studies because the Agency wished to review the results of a then ongoing industry study. This study has been completed and published (Refs. 19 through 22). The Agency is currently reviewing the study and will propose further epidemiology studies in the future if it believes that they are necessary.

B. Environmental Effects

EPA is withdrawing the proposal to require environmental studies for dichloromethane. The Agency has decided after further considering the data that neither a section 4(a)(1)(B) nor a section 4(a)(1)(A) finding is supportable for this substance. EPA acknowledges that dichloromethane

enters the environment in substantial quantities, 451 million pounds estimated for 1980 (Ref. 23), but finds that there are sufficient data to reasonably determine or predict the distribution and effects of these releases in the environment. Therefore, further testing is not necessary. This conclusion by the Agency is based upon a re-evaluation of available information on the environmental fate, actual environmental levels, acute toxicity, and bioaccumulation.

The environmental fate of dichloromethane is fairly well characterized, and is discussed in detail in the dichloromethane support document (Ref. 23). Releases to air degrade fairly rapidly, and releases to water tend to partition to the atmosphere where they, too, degrade. Dichloromethane is not believed to bioaccumulate. Actual measurements of dichloromethane are reported to be 30 to 100 parts per trillion in air and less than 30 ppb in water (Ref. 24). These data indicate the dichloromethane does not accumulate in the environment. Production levels are not anticipated to increase drastically, and in 1983, in fact, production decreased (Ref. 25). The Agency thus concludes that environmental concentrations are not likely to increase.

Some acute toxicity information on aquatic organisms is available for vertebrates, invertebrates, and algae. Effects are seen at concentrations of several hundred ppm (Ref. 23). Because of the thousand-fold difference between effect concentrations and levels in the environment, and because it seems unlikely that environmental levels will increase, EPA believes that dichloromethane is not likely to present an unreasonable risk to aquatic life (Ref. 13). Therefore, EPA is withdrawing the proposed requirements for chronic aquatic toxicity testing of dichloromethane on aquatic vertebrates and invertebrates.

Information on bioconcentration of dichloromethane in aquatic vertebrates and terrestrial plants has not been reported; however, a bioconcentration factor (BCF), a measure of a chemical's potential for bioconcentration, can be estimated for dichloromethane. Based upon its reported octanol/water partition coefficient the BCF for dichloromethane is 5.2. Generally, chemicals with BCFs less than 1000 are not recommended for testing (Refs. 24 and 26). Because the estimated BCF for dichloromethane is very small, the Agency believes that dichloromethane has little or no potential for bioconcentration and, therefore, is

withdrawing the proposed requirement for bioconcentration testing.

Exposure to dichloromethane in air has caused acute effects in terrestrial mammals at several thousand ppm (Ref. 23) and in terrestrial plants at much higher levels (Ref. 16). However, the terrestrial toxicity testing proposed for dichloromethane was based upon exposure to dichloromethane through surface or ground water rather than through the air. It was believed that organisms might ingest dichloromethane either in the water or through the food chain (as a result of original exposure through the water). However, based on low reported concentrations of dichloromethane in water and the low estimate of bioaccumulation (Ref. 24), EPA believes that dichloromethane is not likely to present an unreasonable risk to terrestrial life. Therefore, EPA is withdrawing the requirement for terrestrial environmental effects testing.

IV. Proposed Agency-Sponsored Testing

EPA stated in the proposed rule that it intended to sponsor mutagenicity and environmental effects tests on dichloromethane. The mutagenicity testing is now ongoing and the results are expected by September 1984. The Agency may propose further mutagenicity testing if it believes it to be necessary. The environmental tests will not be performed by the Agency, for the reasons discussed in Unit III.B.

V. Public Record

EPA has established a public record for this decision not to pursue testing under section 4 [docket number OPTS-42023]. This record includes:

- (1) Federal Register notice designating dichloromethane to the priority list.
- (2) Communications before industry consisting of letters, contact reports of telephone conversations, and meeting summaries.
- (3) Testing proposals and protocols.
- (4) Published and unpublished data.
- (5) Federal Register notice requesting comment on the proposed test rule and comments received in response thereto.
- (6) Federal Register notice announcing the final decision not to require testing.

VI. References

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- (2) Bowman CM. 1982 (April 30). Dow Chemical Company, Midland, Michigan 48640. Letter to SD Newburg-Rinn, Assessment Division, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, DC 20460.
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(13) Gilford JH, Ehreth DJ. 1981 (September 21). Health and Environmental Review Division, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, DC 20460. Environmental Risk Assessment of Dichloromethane, Carbon Tetrachloride, Trichloroethylene, Methyl Chloroform, Tetrachloroethylene, Freon-113. Intra-agency memorandum to Marilyn Bracken, Toxics Integration, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, DC 20460.

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(15) IBT. 1972. Industrial BIO-TEST Laboratories. Human repeated insult patch test with four-aerosol antiperspirant products. P.O. No. 530-2032-269 IBT No. F1961.

(16) Lehmann J, Paech C. 1972. Effect of some vaporized lipophilic solvents on carbon dioxide fixation by alfalfa. *Experientia* 28:1415-1416.

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(18) MacEwen JD, Vernot EH, Haun CC. 1972. Continuous Animal Exposure to Dichloromethane. AMRL-TR-72-28. Systemed Corporation Report No. 2-71005. Wright-Patterson Air Force Base, Ohio, Aerospace Medical Research Laboratory. 33p.

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Criteria 32 Methylene Chloride, Draft.
Geneva, Switzerland.

This record, which includes the basic information considered by the Agency in developing this decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday except legal holidays in Room E-107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement the record with additional relevant information as it is received.

The proposal to add 40 CFR 773.1500 to Chapter I of 40 CFR Subpart B, published at 46 FR 30300 June 5, 1981.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: June 11, 1984.

William D. Ruckelshaus,
Administrator.

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T5