

Copied by MCA

DEPARTMENT OF LABOR

**Occupational Safety and Health
Administration**

[29 CFR Part 1910]

[Docket OSH-36]

**VINYL CHLORIDE; OCCUPATIONAL
EXPOSURE STANDARD**

Hearing

On May 10, 1974, notice of proposed
rulemaking with regard to a permanent

standard for occupational exposure to vinyl chloride was published in the *Federal Register* (39 FR 16896). The notice provides an opportunity for public participation in the proceeding, by means of written submissions to be mailed to the given address, postmarked no later than June 10, 1974. The notice also permits interested persons to file objections to the proposed standard set out in the notice and request a hearing thereon. The objections must specify the provisions of the proposed standard to which objections are made, state the grounds for the objections, be accompanied by a summary of the evidence to be adduced at the requested hearing, and must be postmarked no later than June 10, 1974.

Informal contacts with Occupational Safety and Health Administration staff have disclosed widespread interest in the proceeding, a probability of requests for a hearing, and an alleged need for more time for the submission of written comments and the formulation of objections in accordance with the requirements of the notice.

Accordingly, it has been decided to waive the requirements for objections and request for a hearing thereon and instead to set for hearing the entire proposed standard, set forth in the May 10 notice. It is hoped that this decision will: (1) Eliminate the possible difficulty of formulating appropriate objections within the short period of time fixed in the notice; (2) permit full participation at the hearing, without limitation as to issues; and (3) expedite the proceeding, in view of the six-month provision in section 6(c) of the Williams-Steiger Occupational Safety and Health Act of 1970, and the expectation that a hearing would be requested and scheduled anyway.

Therefore, pursuant to sections 6(b), 6(c), and 8(c) of the Occupational Safe-

ty and Health Act of 1970 (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657), Secretary of Labor's Order No. 12-71 (36 FR 8754) and 29 CFR Part 1911, the notice of the proposed rulemaking on vinyl chloride published on May 10, 1974 at 39 FR 16896, is hereby amended in the following respects: (1) The part of the notice concerning the filing of objections and requests for hearing, in the third full paragraph of the middle column of page 16897 of the May 10 issue of the *Federal Register*, is withdrawn; and (2) in lieu thereof the following paragraphs are added:

Data, views, and arguments concerning the proposed standard will be received by an administrative law judge, to be appointed by the Chief Administrative Law Judge of the Department of Labor at an informal hearing to begin at 9:30 a.m. June 25, 1974 in the Departmental Auditorium on Constitution Avenue, between 12th & 14th Streets, NW., Washington, D.C.

The hearing shall be conducted in accordance with the rules of procedure in 29 CFR Part 1911. Any interested person desiring to participate at the hearing must file a notice of intention to appear with Ms. Joanne Goodell, Attn: Docket OSH-36, Occupational Safety and Health Administration, 1726 M Street, NW., Room 200, U.S. Department of Labor, Washington, D.C. 20210 no later than June 17, 1974. A notice must state the name and address of the person to appear, the capacity in which he will appear, and the approximate amount of time required for his presentation. In addition, to the extent practicable, the notice should contain a general statement of the position to be taken with respect to any provision of the proposed standard, and of the evidence to be adduced in support of the position.

In all other respects, the May 10, 1974 notice of proposed rulemaking remains unchanged.

Signed this 22d day of May 1974.

JOHN H. STENDER,
Assistant Secretary of Labor.

[FR Doc. 74-12188 Filed 5-23-74; 11:15 am]

Copied by MCA.

CONSUMER PRODUCT SAFETY COMMISSION

[16 CFR Part 1500]

SELF-PRESSURIZED HOUSEHOLD SUB- STANCES CONTAINING VINYL CHLORIDE

Proposed Classification as a Banned Hazardous Substance

In response to recent information on the toxicity of vinyl chloride monomer and in response to a petition received on February 21, 1974, from the Health Research Group, Washington, D.C., the Consumer Product Safety Commission proposes to ban as a hazardous substance any self-pressurized product (aerosol product) for household use containing vinyl chloride monomer. By notice published May 9, 1974 (39 FR 16511), the Commission determined that consumer products containing vinyl chloride monomer as a propellant or ingredient are products which could create a substantial product hazard and required manufacturers of such products to submit certain information to CPSC.

Section 2(f)(1)(A) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f)(1)(A)) defines "hazardous substance" as "any substance or mixture of substances which is toxic . . . if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." Section 2(g) of the act states that "the term toxic shall apply to any substance . . . which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." Section 2(q)(1)(B) of the act defines a "banned hazardous substance" as "any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Secretary [now the Commission] by regulation classifies as a 'banned hazardous sub-

stance' on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under this Act for the substance, the degree of nature of hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce."

The Commission has determined that reasonable grounds exist to propose the banning of self-pressurized products for household use containing vinyl chloride on the basis of toxicity. These grounds include the following:

(1) *Human data.* On January 22, 1974, the Occupational Safety and Health Administration was informed by the National Institute for Occupational Safety and Health (NIOSH) that the B. F. Goodrich Chemical Company reported that deaths of several of its employees from a rare form of liver cancer may have been occupationally related.

The employees of the B. F. Goodrich Chemical Company who died from angiosarcoma of the liver had an average exposure of approximately 19 years of vinyl chloride, at unknown concentrations, and variable exposures to other volatile chemicals. Some employees of Union Carbide Company and Goodyear Company are also reported to have had exposure to vinyl chloride and to have died from angiosarcoma of the liver. Finally, autopsies of four deceased employees revealed that liver angiosarcoma tumors were histologically indistinguishable from the angiosarcoma tumors observed in Professor Maltoni's experimental animals (see below).

(2) *Animal data.* Professor Cesare Maltoni, of the Instituto di Oncologia, Bologna, Italy, reported on a series of experiments on the effect of exposure of rats, mice, and hamsters to vinyl chloride at concentrations of 10,000; 6,000; 2,500; 500; 250; and 50 ppm for varying period of time. Some of the experiments have been concluded, and others are still ongoing. The experimental results so far reported are that tumors have been observed in groups of animals exposed to vinyl chloride at concentrations as low as 250 ppm.

These data are contained in the transcript of an "Informal Fact Finding Hearing on Possible Hazards of Vinyl Chloride Manufacture and Use," U.S. Department of Labor, Occupational Safety and Health Administration, February 15, 1974. A copy of this document is available for public inspection at the Office of the Secretary, 1750 K Street NW., Washington, D.C. 20207.

The Commission is in receipt of a petition from the Health Research Group, set forth below, "to immediately prohibit the continued use of vinyl chloride as a propellant for aerosolized consumer products and to remove all products containing vinyl chloride as a propellant from the market because there is substantial evidence that vinyl chloride is

the polyvinyl chloride plant, the Department of Labor published on January 30, 1974, a request for information and a notice of a fact-finding hearing on the possible hazards associated with the manufacture and/or use of vinyl chloride (Federal Register January 30, 1974). At the hearing held on February 15, 1974, the Industrial Union Department of the AFL-CIO petitioned for an emergency temporary standard to prevent any worker exposure to vinyl chloride.

VI. The Grave Danger Resulting from Exposure to Vinyl Chloride—A. Acute Effects. Vinyl chloride is a gas which can cause unconsciousness at extremely high concentrations. Inhalation of a 2.5% concentration of vinyl chloride can cause dizziness, disorientation and headache (ILO, p. 1466). At an 8.2% concentration cardiac arrhythmias have been observed in experimental dogs (ACGIH, p. 477). The Committee on Aerosol Toxicity has voiced concern over the use of certain gases—including vinyl chloride—as components of propellant/solvent systems in aerosols because they are capable of producing "cardiac sensitization" (Committee Report, p. 19).

B. Evidence of Carcinogenicity. On January 22, 1974, the B. F. Goodrich Company announced that three—and it is now known five—of its Louisville, Kentucky, vinyl-chloride workers had died of angiosarcoma (or hemangioendothelioma) of the liver, an exceedingly rare form of liver cancer. The five deaths occurred between 1964 and 1973, with the time of development of liver cancer after the onset of exposure to vinyl chloride in the four workers for whom this information is known from 14 to 27 years.

The National Institute for Occupational Safety and Health, estimating that only twenty to thirty people die in the United States every year from this particular type of cancer, has announced the discovery of a new occupational cancer associated with the polymerization of polyvinyl chloride from vinyl chloride, with vinyl chloride as the chief causative suspect (Statement of Dr. Marcus Key, February 1, 1974). The disease is invariably fatal, once cancer has been initiated (Statement of Dr. Irving Selikoff, February 15, 1974).

The carcinogenic effects of exposure to vinyl chloride have been demonstrated by Viola and Maltoni, in separate experiments. Viola produced angiosarcomas of the liver in rats when exposed to 30,000 ppm for 4 hours/day, 5 days/week, for 12 months (Viola, p. 20). Maltoni has produced the same type of cancers when exposing rats to much lower doses (Statement of Prof. Cesare Maltoni, February 15, 1974). After 127 weeks of exposure to vinyl chloride (4 hours/day, 5 days a week, by inhalation), Maltoni reported liver tumors in Sprague-Dawley rats at exposures as low as 250 ppm. (See table below).

RESULTS OF MALTONI'S EXPERIMENTAL STUDY

Exposure level— vinyl chloride, by inhalation	Number of animals exposed	Number of animals developing liver angiosarcomas
10,000 ppm.....	69	6
6,000 ppm.....	72	11
2,500 ppm.....	74	9
500 ppm.....	67	7
250 ppm.....	67	2
50 ppm.....	64	0

Dr. Maltoni reported that he is currently conducting an experiment using 300 rats exposed to 50 ppm, since the failure of the low dose of vinyl chloride to induce cancer may be a function of the small number of animals tested.

In addition, Maltoni has observed two fibrosing angiosarcomas in the offspring of pregnant rats exposed to vinyl chloride. He stated that such fibrosing angiosarcomas have never been observed as occurring spontaneously in Sprague-Dawley rats.

C. Other Evidence of Liver Disease. As early as 1961 Torkelson et al. reported that abnormal histologic changes were noted in the livers of rabbits after repeated exposures to 200 ppm of vinyl chloride. Slight liver enlargement was noted at doses as low as 100 ppm (Torkelson et al.).

A 1967 French study of 168 workers engaged in the production of PVC found liver enlargement in 30% of the cases studied (Suci et al.).

A later report of the health experience of Dow Chemical's vinyl chloride workers revealed no overt illness, but did determine that certain blood tests of liver function (e.g. beta lipoprotein, the icterus index, and bromosulfalein retention time) were abnormally altered. On the basis of their findings, the authors concluded that some degree of liver dysfunction might result from a TLV for vinyl chloride of 300 ppm (Mutchler et al.).

Marsteller et al. reported within the past few months that 19 out of 20 workers who had been exposed to vinyl chloride for 1½ to 21 years at a PVC producing plant in Germany had some type of liver disease, including gross changes of the liver and spleen. Direct inspection of the liver and spleen (by surgical operation) showed disease to be present in 14 out of the 20 workers (Marsteller et al.).

D. Evidence of Other Chronic Effects. In October 1963 osteolytic lesions were first observed in two Belgian plastics workers who were also suffering from Raynaud's phenomenon due to constriction of the local blood vessels in their hands (ILO, p. 1466). This hand syndrome—termed acroosteolysis—has since been observed in over 30 workers in the United States employed in the manufacture of PVC resins (Wilson et al.).

VII. Relief Requested. We request that the Chairman of the Consumer Product Safety Commission declare aerosolized consumer products containing vinyl chloride to be "banned hazardous substances," under the definition of 15 U.S.C. § 1261(q)(1) and under the authority granted the Chairman in § 1262. Moreover, under the authority of § 1265, the Chairman is requested to remove from sale such consumer products containing vinyl chloride as propellants and to prohibit the introduction of such aerosolized products containing vinyl chloride into interstate commerce.

The chronic toxicity and evidence of carcinogenicity of vinyl chloride monomer for humans has been documented by scientific studies and clinical reports. Further use of vinyl chloride monomer as a propellant for aerosolized consumer products must be prohibited since there is no evidence that human beings can safely be exposed to the chemical.

Dated: Washington, D.C. February 21, 1974.

Respectfully submitted,

ANDREA M. HICKO

SIDNEY M. WOLFE, M.D.,
2000 P. Street, N.W. #708
Washington, D.C. 20036.

REFERENCES

- American Conference of Government Industrial Hygienists (ACGIH), *Documentation of Threshold Limit Values*, 1971, pp. 477-478.
- Bernstein, I. L., "Medical Hazards of Aerosols," *Postgraduate Medicine*, December 1972, pp. 62-68.
- "Consumer Packaging," *Chemical and Engineering News*, April 12, 1971, p. 22.
- Federal Register*, Vol. 36, No. 105, May 29, 1971, p. 10508.
- Federal Register*, Vol. 36, No. 95, May 15, 1973, p. 12931.
- Federal Register*, Vol. 36, No. 134, July 13, 1973, p. 18684.
- Federal Register*, Vol. 39, No. 21, January 30, 1974, p. 3874.
- International Labour Organization (ILO), *Encyclopedia of Occupational Safety and Health*, 1972, p. 1468.
- Kubler, Hans, "The Physiological Properties of Aerosol Propellants," *Aerosol Age*, April 1964, pp. 44-50, 90-91.
- Maltoni, Prof. Cesare, *Instituto di Oncologica*, Bologna, Italy, Testimony at Department of Labor Hearing on Vinyl Chloride, February 15, 1974.
- Marsteller, H. J., et al., *Deutsche Med. Wochenschrift* 98:2311, 1973, cited by Dr. Irving Selikoff at February 15, 1974, Department of Labor Hearing on Vinyl Chloride.
- Mutchler, J. E., Kramer, C. G., Report on Relation of Exposure to State of Health of Dow Chemical Workers, Gordon Conference, Tilton, New Hampshire, August, 1968, cited in *Documentation of Threshold Limit Values*, p. 278.
- Report of the Committee on Aerosol Toxicity, August 4, 1972, p. 19 (Chairman: Dr. Albert C. Kolbye, Jr.).
- Samuels, Sheldon, Industrial Union Department, AFL-CIO, Testimony presented February 15, 1974, at Department of Labor Hearing on Vinyl Chloride, citing figures supplied by industry sources.
- Selikoff, Irving, Professor, Mt. Sinai School of Medicine, Testimony at Department of Labor Hearing, on Vinyl Chloride, February 15, 1974.
- Suci, I., Drejman, I., and Valaski, M., "Etude des Maladies dues au Chlorure de Vinyle," *Clinique des maladies professionnelles*, Vol. 58, No. 4, 1967 (English abstract.)
- Torkelson, T. R., Oyen, F., Rowe, V. K., *Amer. Indust. Hyg. Assn. J.*, 22:354 (1961), cited in *Documentation of Threshold Limit Values*, p. 277.
- Viola, P. L., "Carcinogenic Effect of Vinyl Chloride," *Abstr. 10th. International Cancer Congress*, Houston, Texas (1970), p. 20.
- Wilson, B. H., et al., "Occupational Acroosteolysis: Report of 31 Cases," *JAMA*, 201:577-581, 1967.

[FR Doc.74-11936 Filed 5-22-74; 8:45 am]