

HEALTH RESEARCH GROUP
2000 P STREET, N.W.
WASHINGTON, D. C. 20036
872-0320

[Handwritten initials]
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23

March 8, 1974

Office of Standards
Attention: Docket OSH-36
Occupational Safety and Health
Administration
Room 203
1726 M Street
Washington, D.C. 20210

Dear Sir or Madam:

The enclosed information is submitted (in triplicate) to the Department of Labor in accordance with our request to participate in the Department's oral proceedings on February 15, 1974, with respect to the "possible hazards associated with the manufacture and/or use of vinyl chloride," 38 Fed. Reg., 3874 (January 30, 1974).

The attached petitions, requesting that the Food and Drug Administration, the Consumer Product Safety Commission, and the Environmental Protection Agency prohibit the continued use of vinyl chloride as a propellant in aerosolized products, were filed with the agencies on February 21, 1974. They are submitted for the consideration of the Department of Labor since such use of vinyl chloride presents the possibility of exposure to the chemical by thousands of workers not engaged in the production of vinyl chloride or polyvinyl chloride, but rather who are engaged in the process of packaging aerosols or who use aerosol products on the job (e.g. the use of hair-sprays by hairdressers).

Thank you for your consideration.

Respectfully Submitted,

Bertram R. Cottine

Bertram R. Cottine

Andrea M. Hricko
Andrea M. Hricko

HEALTH RESEARCH GROUP

2000 P STREET, N.W.

WASHINGTON, D.C. 20036

872-0320

February 21, 1974

Mr. Russell Train, Administrator
Environmental Protection Agency
Washington, D.C.

Dear Mr. Train:

As you know, a rapidly rising number of cases of liver cancer (angiosarcoma) are being discovered in workers exposed to vinyl chloride. Combined with other human evidence of liver disease, an earlier study showing cancer in animals, and a recent study in animals demonstrating carcinogenicity with exposures as low as 250 parts per million, it appears that another common chemical has joined the growing list of environmental carcinogens.

Although the major use of vinyl chloride monomer is to make polyvinyl chloride (PVC), several percent of the billions of pounds of vinyl chloride manufactured each year goes into the production of other goods.

We have learned that a significant amount of vinyl chloride is used as an aerosol propellant in consumer products. It is known to have been used as a propellant in insecticide cans in 1964 and there is no indication that its use as such a propellant has been curtailed since that time. (Aerosol Age, April 1964, p. 47.) In that same article, the levels of vinyl chloride, under conditions where hair spray was being used, were shown to exceed 250 parts per million. (See calculations on page 2 of petition.)

Several requests for action are detailed in the attached petition. In addition, we request that you make public the brand names of all aerosol pesticide products presently marketed or marketed at any time in the past which contain vinyl chloride as a propellant. When matters of health and grave danger are at stake, the public has the right to be fully informed about the dangers it faces or has faced from using particular brand name products--regardless of the public relations damage that certain companies may suffer. All those people who have been exposed at any time to products containing vinyl chloride should be made aware of this so that they can inform their physicians.

Thank you for your consideration.

BOR 009822

Sincerely yours,

Andrea M. Hricko
Andrea M. Hricko

Sidney M. Walcott
Sidney M. Walcott

BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

HEALTH RESEARCH GROUP

Petitioner

To: Russell Train, Administrator
Environmental Protection Agency

PETITION TO IMMEDIATELY SUSPEND ALL PESTICIDE PRODUCTS WHICH UTILIZE VINYL CHLORIDE AS A PROPELLANT BECAUSE THERE IS SUBSTANTIAL EVIDENCE THAT VINYL CHLORIDE IS A CARCINOGEN

I. Petitioner

Petitioner Health Research Group is a non-profit organization engaged in public interest research on health issues, including pesticide safety. It is funded by Public Citizen, many of whose members use aerosolized household pesticides.

II. Authority for Petition and Regulation

Petitioner's authority to petition for rule-making is the Administrative Procedure Act, 5 U.S.C. 553 (e). The authority of the Environmental Protection Agency to promulgate this rule is 7 U.S.C. (The Federal Insecticide, Fungicides and Rodenticide Act, "FIFRA", as amended, 1972) §136(q)(1)(G), 136d, 136j(a)(1)(E), and 136K.

III. Summary of Reasons for This Petition

Vinyl chloride is a toxic substance known to be commonly used as a propellant in aerosolized products. It is known to have been used as a propellant in insecticide cans in 1964, and there is no indication that its use as such a propellant has been curtailed since that time. No regulations currently prohibit such use of vinyl chloride.

BOR 009823

Vinyl chloride monomer is a colorless gas which can cause acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness at high concentrations. It has been linked to osteolytic (bone destructive) lesions of the hands, liver disease, and liver cancer in workers engaged in the polymerisation of polyvinyl chloride from vinyl chloride monomer. In one study of industrial workers exposed to vinyl chloride 30% were found to have liver enlargement. At exposure levels as low as 250 ppm, vinyl chloride has produced liver cancer in rats. Of greatest significance, since 1964 five workers engaged in making polyvinyl chloride from vinyl chloride monomer at one plant have died from a rare and invariably fatal form of cancer of the liver. The most recent death was December 19, 1973. This cancer has recently been diagnosed in a sixth worker in the same plant.

IV. The Use or Presence of Vinyl Chloride in Pesticide Products

Vinyl chloride is among the most often-used propellants in aerosols (Postgraduate Medicine, p. 65; Report of the Committee on Aerosol Toxicity, p. 19) and is known to have been used in the past as a propellant in insecticide sprays (Aerosol Age, p. 47).

A 1964 report estimated that an aerosol product sprayed in a tiny room of 282.5 cubic feet for 30 seconds would result in 0.025% vinyl chloride by volume (Aerosol Age, p. 47.) This level would correspond to over 250 ppm vinyl chloride in the air of a room that size,* not unlike the size of many bathrooms in small apartments.

*Using Aerosol Age's reference that 16.5% by volume corresponds to 460 g. vinyl chloride/M³, and a conversion factor of 500 ppp = 1300 mg/M³ (ACGIH.)

V. Prior Regulatory Actions on Vinyl Chloride

1971. In 1971 under Section 6(a) of the Occupational Safety and Health Act of 1970, the Department of Labor adopted as a Federal standard a ceiling level of 500 ppm (1300 mg/m³) for occupational exposure to vinyl chloride, based on the recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH), (Federal Register, May 29, 1971). The ACGIH has since recommended 200 parts per million as a revised voluntary ceiling value for occupational exposure to the chemical. (Documentation of Threshold Limit Values, p. 477).

1973. On May 15, 1973, the Food and Drug Administration published a notice of proposed rule-making for the "prior-sanctioned polyvinyl chloride resin." The notice proposed that the resin not be used as a component of food packaging material for use in contact with alcoholic foods, since both industry and FDA laboratory analyses had found that the vinyl chloride monomer migrates to alcohol from PVC bottles used to package distilled spirits and wine. Analytical results from industry confirmed that levels of up to 20 ppm of vinyl chloride were found to have migrated to the alcohol from the container after it had been stored for up to one year. The FDA concluded: "Vinyl chloride monomer as such is a poisonous and deleterious substance. FDA knows of no studies which establish a safe level of consumption when this monomer is leached from containers into alcoholic foods." (Federal Register, May 15, 1973).

1973. A July 13, 1973, FDA notice in the Federal Register extended the time for filing comments on the FDA proposal for restrictions on polyvinyl chloride packaging, at the request of the plastics industry. The notice stated that the Bureau of Alcohol, Tobacco and Firearms of the Treasury Department (which had first authorized experimental use of PVC bottles for liquor in November, 1968) had terminated the use of PVC containers for alcoholic beverages pending final

action by the FDA on the proposal. As of this date (2/21/74) the Food and Drug Administration has not finalized its proposal of May 17, 1973.

1974. In direct response to the deaths from a rare form of liver cancer of four workers at one 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 8-12% 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 polymerisation 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

<u>Exposure level- vinyl chloride, by inhalation</u>	<u># of animals exposed</u>	<u># of animals developing liver angiosarcomas</u>
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	54	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 163 workers engaged in the production of PVC found liver enlargement in 30% of the cases studied (Suciu 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 1-1/2 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

The Administrator of the Environmental Protection Agency regulates pesticides under the Federal Insecticide, Fungicide and Rodenticide Act, as amended in 1972 ("FIFRA.") "Pesticides" are defined in FIFRA, 7 U.S.C. 136 (u) as including "any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest...." As a propellant of such a pesticide, vinyl chloride is necessarily included in the mixture of substances.

7 U.S.C. §136d(c) imposes upon the Administrator the duty to issue a suspension order for any pesticide if the Administrator determines that action is necessary to prevent an imminent hazard...."

7 U.S.C. §136d(b) imposes upon the Administrator a duty to cancel a pesticide if it "appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with provisions of this Act or when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment...."

A pesticide is "misbranded" if the "label does not contain a warning or caution statement which may be necessary, and if complied with, together with any requirements imposed under Section a(d) of this title, are adequate to protect health and environment." Therefore, a "misbranded" pesticide does not "comply with provisions of this Act." A pesticide must be deemed "misbranded" if no directions for use on a label would be adequate to protect the health of the user or those exposed to a pesticide.

The chronic toxicity and evidence of carcinogenicity of vinyl chloride monomer for human beings has been documented by experimental studies and by clinical reports. Further use of vinyl chloride

monomer as a propellant for aerosolized products must be prohibited since there is no evidence that human beings can safely be exposed to the chemical. Therefore, no label directions can be considered adequate to protect the public health and any pesticide product containing vinyl chloride as a propellant must be deemed "misbranded."

Further, under 7 U.S.C. § 136K the Administrator of the Environmental Protection Agency has the authority to stop the sale of or to seize any pesticide that is "misbranded."

Respectfully submitted,

Andrea M. Hricko

Andrea M. Hricko

Sidney M. Wolfe

Sidney M. Wolfe, M.D.

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

Dated: Washington, D.C.
21 February 1974

BOR 009830

~~CONFIDENTIAL~~

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Federal Register, Vol. 38, No. 134, July 19, 1973, p. 18684.

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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.

Suciu, 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).

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Wilson, R. H., et al., "Occupational Acetabulolysis: Report of 31 Cases," JAMA, 201:577-583, 1967.

BOR 009831

HEALTH RESEARCH GROUP

2000 P STREET, N.W.

WASHINGTON, D. C. 20036

872-0320

February 21, 1974

Dr. Alexander M. Schmidt, Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Dr. Schmidt:

As you know, a rapidly rising number of cases of liver cancer (angiosarcoma) are being discovered in workers exposed to vinyl chloride. Combined with other human evidence of liver disease, an earlier study showing cancer in animals, and a recent study in animals demonstrating carcinogenicity with exposures as low as 250 parts per million, it appears that another common chemical has joined the growing list of environmental carcinogens.

Although the major use of vinyl chloride monomer is to make polyvinyl chloride (PVC), several percent of the billions of pounds of vinyl chloride manufactured each year goes into the production of other goods.

We have learned that a significant amount of vinyl chloride is used as an aerosol propellant in consumer products including hair sprays. According to one published report (Aerosol Age, April 1964, p. 47), the levels of vinyl chloride, under conditions where hair spray was being used, can exceed 250 parts per million. (See petition, p. 2)

Several requests for action are detailed in the attached petition. In addition, we request that you make public the brand names of all aerosol cosmetic products presently marketed or marketed at any time in the past which contain vinyl chloride as a propellant. When matters of health and grave danger are at stake, the public has the right to be fully informed about the dangers it faces or has faced from using particular brand name products--regardless of the public relations damage that certain companies may suffer. All those people who have been exposed at any time to products containing vinyl chloride should be made aware of this so that they can inform their physicians.

Thank you for your consideration.

Sincerely yours,

Andrea M. Hricko Sidney M. Wolfe, M.D.

Andrea M. Hricko Sidney M. Wolfe, M.D.

BOR 009832

BEFORE THE FOOD AND DRUG ADMINISTRATION

HEALTH RESEARCH GROUP

Petitioner }

TO: Alexander H. Schmidt, Commissioner
Food and Drug Administration

PETITION TO IMMEDIATELY PROHIBIT THE CONTINUED USE OF (1) VINYL CHLORIDE AS A PROPELLANT FOR AEROSOLIZED COSMETICS, AND OF (2) POLYVINYL CHLORIDE AS A CONTAINER FOR ANY COSMETIC PRODUCT WHICH CAN LEACH OUT DETECTABLE AMOUNTS OF VINYL CHLORIDE FROM THE PVC, BECAUSE THERE IS SUBSTANTIAL EVIDENCE THAT VINYL CHLORIDE MONOMER IS CARCINOGENIC

I. Petitioner

Petitioner Health Research Group is a non-profit organization engaged in public interest research on health issues, including cosmetic safety. It is funded by Public Citizen, many of whose members use aerosolized cosmetics and polyvinyl chloride bottles which contain cosmetics and toiletries.

II. Authority for Petition And Regulation

Petitioners' authority to petition for rulemaking is the Administrative Procedure Act, 5 U.S.C. 553(e). The authority of the Food and Drug Administration to promulgate this rule is 21 U.S.C. 371(a); 361(a),(d); 331(a),(g).

III. Summary of Reasons for This Petition

Vinyl chloride is a toxic substance known to be used as a propellant in aerosolized cosmetics and suspected to be present in cosmetics containing alcohol that are packaged in polyvinyl chloride (PVC) bottles. No FDA regulations currently prohibit such uses of vinyl chlorida or PVC.

BOR 009833

Vinyl chloride monomer is a colorless gas which can cause acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness at high concentrations. It has been linked to osteolytic (bone destructive) lesions of the hands, liver disease, and liver cancer in workers engaged in the polymerisation of polyvinyl chloride from vinyl chloride monomer. In one study of industrial workers exposed to vinyl chloride 30% were found to have liver enlargement. At exposure levels as low as 250 ppm, vinyl chloride has produced liver cancer in rats. Of greatest significance, since 1964 five workers engaged in making polyvinyl chloride from vinyl chloride monomer at one plant have died from a rare and invariably fatal form of cancer of the liver. The most recent death was December 19, 1973. This cancer has recently been diagnosed in a sixth worker in the same plant.

IV. The Use or Presence of Vinyl Chloride in Cosmetic Products

Vinyl chloride is among the most often-used propellants in aerosols (Postgraduate Medicine, p. 65; Report of the Committee on Aerosol Toxicity, p. 19.), and is a propellant in hairsprays (Aerosol Age, p. 47 and an industry source, January, 1974.)

A 1964 report estimated that spraying hairspray in a tiny room of 282.5 cubic feet for 30 seconds would result in 0.025% vinyl chloride by volume (Aerosol Age, p. 47). This level would correspond to over 250 ppm vinyl chloride in the air of a room that size,* not unlike the size of many bathrooms in small apartments.

Polyvinyl chloride (PVC) is produced by the polymerisation of vinyl chloride. About 46 million pounds of PVC were used in plastic bottles in 1970. Plastic bottles (PVC and polyethylene together) comprise about 35% of the toiletries and cosmetics

*Using Aerosol Age's reference that 16.5% by volume corresponds to 450 g. vinyl chloride/M³, and a conversion factor of 500 ppm = 1300 mg/M³.

packaging market (Chemical and Engineering News, April 12, 1971, p. 22).

After the manufacture of PVC, about 500 to 3000 ppm of vinyl chloride is entrapped in the PVC resin (Statement of Sheldon Samuels, February 15, 1974). The vinyl chloride monomer--in FDA's own tests--has been found to migrate out of PVC containers into the alcoholic beverages they contain. (See following discussion). To our knowledge, no tests have been conducted to determine whether other alcohol or organic solvent-containing liquids (e.g., bath lotion or perfume can also leach detectable amounts of vinyl chloride from their polyvinyl chloride containers.

V. Prior Regulatory Actions on Vinyl Chloride

1971. In 1971 under Section 6(a) of the Occupational Safety and Health Act of 1970, the Department of Labor adopted as a Federal standard a ceiling level of 500 ppm (1300 mg/m³) for occupational exposure to vinyl chloride, based on the recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH), (Federal Register, May 29, 1971). The ACGIH has since recommended 200 parts per million as a revised voluntary ceiling value for occupational exposure to the chemical. (Documentation of Threshold Limit Values, p. 477).

1973. On May 15, 1973, the Food and Drug Administration published a notice of proposed rule-making for the "prior-sanctioned polyvinyl chloride resin." The notice proposed that the resin not be used as a component of food packaging material for use in contact with alcoholic foods, since both industry and FDA laboratory analyses had found that the vinyl chloride monomer migrates to alcohol from PVC bottles used to package distilled spirits and wine. Analytical results from industry confirmed that levels of up to 20 ppm of vinyl chloride were found to have migrated to the alcohol from the container after it had been stored for up to one year. The FDA concluded: "Vinyl chloride monomer as such is a poisonous and deleterious substance. FDA knows of no studies which establish a safe level of consumption when this monomer is leached from containers into alcoholic foods." (Federal Register, May 15, 1973).

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1974. In direct response to the deaths from a rare form of liver cancer of four workers at one 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 8-12% 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 polymerisation 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

<u>Exposure level- vinyl chloride, by inhalation</u>	<u># of animals exposed</u>	<u># of animals developing liver angiosarcomas</u>
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 163 workers engaged in the production of PVC found liver enlargement in 30% of the cases studied (Suciu 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 (Hutchler 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 1-1/2 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

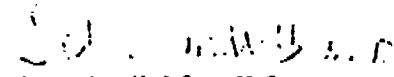
In October 1963 osteolytic lesions were first observed in two Belgian plastics workers who were also suffering from Raynaud's phenomenon due to constriction of the local blood vessels in their hands (ILO, p. 1466). This hand syndrome--termed acroosteolysis--has since been observed in over 30 workers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

VII. Relief Requested

21 U.S.C. § 331(a) prohibits the "introduction or delivery for introduction into interstate commerce of any...cosmetic that is adulterated." As defined by 21 U.S.C. § 361(a), a cosmetic is deemed to be adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to users..." or "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health." Petitioners seek immediate prohibition of vinyl chloride as a constituent or propellant of aerosolized cosmetics and of polyvinyl chloride as a container for any cosmetic product which can leach out detectable amounts of vinyl chloride from the PVC, because there is substantial evidence that vinyl chloride monomer is carcinogenic. Immediate action is necessary to prevent further human exposure to vinyl chloride monomer.

Respectfully submitted,

Andrea H. Hricko


Sidney M. Wolfe, M.D.

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

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

BOR 009840

REFERENCES

- American Conference of Governmental 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. 10505.
- Federal Register, Vol. 38, No. 95, May 15, 1973, p. 12931.
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HEALTH RESEARCH GROUP
2000 P STREET, N.W.
WASHINGTON, D. C. 20036
872 0320

February 21, 1974

Mr. Richard Simpson, Chairman
Consumer Product Safety Commission
Washington, D.C.

Dear Chairman Simpson:

As you know, a rapidly rising number of cases of liver cancer (angiosarcoma) are being discovered in workers exposed to vinyl chloride. Combined with other human evidence of liver disease, an earlier study showing cancer in animals, and a recent study in animals demonstrating carcinogenicity with exposures as low as 250 parts per million, it appears that another common chemical has joined the growing list of environmental carcinogens.

Although the major use of vinyl chloride monomer is to make polyvinyl chloride (PVC), several percent of the billions of pounds of vinyl chloride manufactured each year goes into the production of other goods.

We have learned that a significant amount of vinyl chloride is used as an aerosol propellant in consumer products. According to one published report (Aerosol Age, April 1964, p. 47), the levels of vinyl chloride, under conditions where hair spray was being used, can exceed 250 parts per million. (See petition, p. 2).

Several requests for action are detailed in the attached petition. In addition, we request that you make public the brand names of all aerosol consumer products presently marketed or marketed at any time in the past which contain vinyl chloride as a propellant. When matters of health and grave danger are at stake, the public has the right to be fully informed about the dangers it faces or has faced from using particular brand name products--regardless of the public relations damage that certain companies may suffer. All those people who have been exposed at any time to products containing vinyl chloride should be made aware of this so that they can inform their physicians.

Thank you for your consideration.

Sincerely yours,

Sidney M. Wolfe, M.D.
Sidney M. Wolfe, M.D.

Andrea M. Hricko
Andrea M. Hricko

BOR 009842

BEFORE THE CONSUMER PRODUCT SAFETY COMMISSION

HEALTH RESEARCH GROUP,
Petitioner

To: Richard Simpson, Chairman
Consumer Product Safety Commission

PETITION 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 CARCINOGENIC

I. Petitioner

Petitioner Health Research Group is a non-profit organization engaged in public interest research on health issues, including consumer product safety. It is funded by Public Citizen, many of whose members use aerosolized consumer products.

II. Authority for Petition and Regulation

Petitioner's authority to petition for rule-making is the Administrative Procedure Act, 5 U.S.C. 553 (e). The authority of the Consumer Product Safety Commission to promulgate this rule is 15 U.S.C. (The Federal Hazardous Substances Act), §1261(q)(2), 1262, 1263, and 1265.

III. Summary of Reasons for This Petition

Vinyl chloride is a toxic substance known to be commonly used as a propellant in aerosolized products. No regulations currently prohibit such use of vinyl chloride.

Vinyl chloride monomer is a colorless gas which can cause acute toxicity manifested by dizziness, headache, disorientation, and unconsciousness at high concentrations. It has been linked to osteolytic (bone destructive) lesions of the hands, liver disease, and liver cancer in workers engaged in the polymerisation of polyvinyl chloride from vinyl chloride monomer. In one study of industrial

workers exposed to vinyl chloride 30% were found to have liver enlargement.

At exposure levels as low as 250 ppm, vinyl chloride has produced liver cancer in rats. Of greatest significance, since 1964 five workers engaged in making polyvinyl chloride from vinyl monomer at one plant have died from a rare and invariably fatal form of cancer of the liver. The most recent death was December 19, 1973. This cancer has recently been diagnosed in a sixth worker in the same plant.

IV. The Use or Presence of Vinyl Chloride in Consumer Products

Vinyl chloride is among the most often-used propellants in aerosols (Postgraduate Medicine, p. 65; Report of the Committee on Aerosol Toxicity, p. 19; Aerosol Age, p. 47.) A 1964 report estimated that an aerosol product sprayed in a tiny room of 282.5 cubic feet for 30 seconds would result in 0.025% vinyl chloride by volume (Aerosol Age, p. 47.) This level would correspond to over 250 ppm vinyl chloride in the air of a room that size,* not unlike the size of many bathrooms in small apartments.

*Using Aerosol Age's reference that 16.5% by volume corresponds to 460 g. vinyl chloride/M³, and a conversion factor of 500 ppm = 1300 mg/M³ (ACGIH.)

V. Prior Regulatory Actions on Vinyl Chloride

1971. In 1971 under Section 6(a) of the Occupational Safety and Health Act of 1970, the Department of Labor adopted as a Federal standard a ceiling level of 500 ppm (1300 mg/m³) for occupational exposure to vinyl chloride, based on the recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH), (Federal Register, May 29, 1971). The ACGIH has since recommended 200 parts per million as a revised voluntary ceiling value for occupational exposure to the chemical. (Documentation of Threshold Limit Values, p. 477).

1973. On May 15, 1973, the Food and Drug Administration published a notice of proposed rule-making for the "prior-sanctioned polyvinyl chloride resin." The notice proposed that the resin not be used as a component of food packaging material for use in contact with alcoholic foods, since both industry and FDA laboratory analyses had found that the vinyl chloride monomer migrates to alcohol from PVC bottles used to package distilled spirits and wine. Analytical results from industry confirmed that levels of up to 20 ppm of vinyl chloride were found to have migrated to the alcohol from the container after it had been stored for up to one year. The FDA concluded: "Vinyl chloride monomer as such is a poisonous and deleterious substance. FDA knows of no studies which establish a safe level of consumption when this monomer is leached from containers into alcoholic foods." (Federal Register, May 15, 1973).

1973. A July 13, 1973, FDA notice in the Federal Register extended the time for filing comments on the FDA proposal for restrictions on polyvinyl chloride packaging, at the request of the plastics industry. The notice stated that the Bureau of Alcohol, Tobacco and Firearms of the Treasury Department (which had first authorized experimental use of PVC bottles for liquor in November, 1968) had terminated the use of PVC containers for alcoholic beverages pending final

action by the FDA on the proposal. As of this date (2/21/74) the Food and Drug Administration has not finalized its proposal of May 17, 1973.

1974. In direct response to the deaths from a rare form of liver cancer of four workers at one 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 8-12% 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 type of cancer, has announced the discovery of a new type of cancer associated with the polymerization of polyvinyl chloride from vinyl chloride, with vinyl chloride as a chief causative suspect (Statement of Dr. Vincent Selikoff, 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 angiosarcoma of the liver in rats when exposed to 30,000 ppm for 6 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 (6 hours/day; 5 days a week, by inhalation), Maltoni reported liver cancers 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	# of animals exposed	# 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 fibrotic 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.

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 163 workers engaged in the production of PVC found liver enlargement in 30% of the cases studied (Sucin 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 (Hutchler 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 1-1/2 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.

Respectfully submitted,

Andrea M. Hricko

Andrea M. Hricko

Sidney M. Wolfe

Sidney M. Wolfe, M.D.

Dated: Washington, D.C.
21 February 1974

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

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