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January 4, 1979

To: SPI-PVC Safety Group
SPI-VCM/PVC Mailing List
SPI Plastic Bottle Institute
SPI Plastic Beverage Container Division
SPI-AN Polymers Group
SPI-PET Safety Group
SPI Food, Drug and Cosmetic Packaging Materials Committee
SPI Ad Hoc Packaging Risk Assessment Committee
SPI Plastic Bottle Institute
SPI Plastic Pipe Institute
SPI Vinyl Dispersions Group
SPI-PVC Meat Film Wrap Group
SPI Rigid Plastic Container Group
SPI Vinyl Film and Coated Fabrics Group
SPI Vinyl Siding Group

Re: OSHA Request for Information on Vinyl Chloride and Polyvinyl Chloride, 44 Fed. Reg. 74928 December 18, 1979

Ladies and Gentlemen:

The Occupational Safety and Health Administration (OSHA) published the above-referenced Notice requesting information on vinyl chloride and on polyvinyl chloride. Because of the probable interest of all segments of the industry that manufacture, use or process PVC, we are circulating this letter as widely as possible.

According to the Notice, research which has occurred since 1975 has provided more information concerning

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the carcinogenic and other toxic effects of both vinyl chloride and PVC. By February 10, 1980, OSHA wants to accumulate any outstanding information related to this further research.

OSHA's Notice says that experimental bioassays have demonstrated the induction of cancer associated with vinyl chloride at levels of exposure lower than those previously reported. Mutagenic and transplacental effects have also been reported. In addition, PVC has reportedly induced non-malignant respiratory disease in experimental animals exposed to PVC dust. The Notice reports that, in addition to liver cancer, the National Institute for Occupational Safety and Health has identified an excess number of deaths due to cancer of the lung, lympho-hematopoietic system and the central nervous system. Also of concern to OSHA is the fact that it has received reports that PVC processing may subject workers to a carcinogenic risk as well as a risk of pneumoconiosis from PVC dust. Finally, OSHA proports to have information which demonstrates that vinyl chloride is both mutagenic and fetotoxic in humans.

Based on the foregoing, OSHA is starting a reassessment of the health effects of vinyl chloride and polyvinyl chloride and, to begin this process, has asked for the results of all experimental studies which have taken place since the original OSHA rule making was concluded in 1974.

In following up on this matter with the OSHA staff, we were informed that this request for information should not be regarded as an Advance Notice of Proposed Rule Making but that it is merely an indepth survey about the health effects of both vinyl chloride and polyvinyl chloride especially with regard to cancer at sites other than the liver and the possible carcinogenicity of PVC dust. Further, they are interested in any need for added regulatory controls and the feasibility thereof. As one staffer put it, this is a reevaluation of the adequacy of the current standard.

In addition, OSHA hopes to gather a considerable amount of data for use in a symposium it plans for March 20 and 21, 1980 in Washington, D. C.. That symposium, dedicated exclusively to vinyl chloride and polyvinyl chloride, is presently slated to cover the following topics:

1. carcinogenesis bioassays of vinyl chloride
2. morbidity studies of vinyl chloride workers
3. mortality studies of vinyl chloride workers
4. industrial hygiene measurements of PVC dust - characterization and control techniques
5. toxicology of PVC
6. mortality studies concerning PVC
7. morbidity studies concerning PVC
8. reproductive effects of exposure to vinyl chloride and PVC
9. community exposures to vinyl chloride and PVC
10. structural analogs of vinyl chloride
11. further research needs.

The symposium will feature speakers from OSHA, NIOSH, and the National Institute for Environmental Health Services (NIEHS). In addition, both the Chemical Manufacturers' Association (CMA) and SPI were asked whether they would wish to offer speakers for the symposium.

In talking with OSHA, we have asked informally on behalf of both SPI and CMA about the possibility of an extension of the February 10, 1980 filing date. Although we must follow up on this with a formal request for an extension of time for answering the OSHA inquiry, the initial indications are that the Agency would be receptive to such a request but no commitment as to the amount of time that would be granted was given. The date for the symposium will not be changed.

Our contacts at OSHA also indicate that they have a number of additional references which were not cited in the Federal Register. Since those listed in the Notice were only meant to be examples, the Agency has committed to preparing a bibliography of those materials for us.

As to the next step, we can report that both the PVC Safety Group Steering Committee and the Group's Health Committee will be meeting in the near future to discuss the possibility of both an SPI response to the request for information and participation in the symposium. In the meantime, after you review the information requested, we would appreciate being informed whether you have information which would be responsive to the questions posed by OSHA, and whether you would be interested in such information being submitted to the Agency by The Society's

Polyvinyl Chloride Safety Group.

As always, should you have any questions, comments, suggestions or need any further information, copies of documents or the like, please do not hesitate to let us know.

Cordially yours,

Joseph E. Hadley, Jr.

Joseph E. Hadley, Jr.

Enclosure

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3-0889

Dated: December 10, 1979.

Frank H. Madden,

AID Advisory Committee Representative, Joint Committee on Agricultural Development, Board for International Food and Agricultural Development.

[FR Doc. 79-38585 Filed 12-17-79; 8:45 am]

BILLING CODE 4710-02-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Occupational Exposure to Vinyl Chloride and Polyvinyl Chloride

AGENCY: Occupational Safety and health Administration, Department of Labor.

ACTION: Request for information on vinyl chloride and polyvinyl chloride.

SUMMARY: This notice requests information on vinyl chloride (CAS No. 75-01-4) and on polyvinyl chloride (CAS No. 9002-86-2). Vinyl chloride (VC), a synthetic chemical, was once synthesized by the addition of hydrogen chloride to acetylene. Currently, the most common route of production is by the halogenation of ethylene. In this latter process, ethylene is reacted with hydrogen chloride and oxygen to give ethylene dichloride, which is subsequently cracked thermally to produce vinyl chloride and hydrogen chloride. Vinyl chloride is used primarily to produce polyvinyl chloride (PVC), a plastic resin, through conversion of the VC monomer into a polymer or copolymer form. Vinyl chloride is also used in the production of methyl chloroform and in the production of resins as a comonomer with vinylidene chloride. PVC is used in the manufacture of a variety of industrial and consumer products, such as containers, wrapping film, electrical insulation, and pipes.

In 1975, OSHA regulated vinyl chloride as a carcinogen, based primarily on evidence of excess liver angiosarcoma incidence following VC exposure (29 CFR 1910.1017). OSHA did not regulate exposure to PVC dust in the same standard. Therefore, it continues to be regulated as an inert or nuisance air contaminant (29 CFR 1910.1000, Table Z-3).

Research since 1975 has provided considerably more information concerning the carcinogenic and other toxic effects of VC and PVC exposure. OSHA is currently in the process of evaluating the available evidence pertaining to the potential occupational health hazards of VC and of PVC and, by this notice, is requesting information related to several important issues.

DATE: The information requested in this notice must be submitted in quadruplicate on or before February 10, 1980.

ADDRESS: The information requested in this notice should be submitted to the Docket Officer, Docket No. H-034, Room S6212, U.S. Department of Labor, OSHA, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202-523-7894).

FOR FURTHER INFORMATION CONTACT: Dr. Peter Infante, Office of Carcinogen Identification and Classification, Directorate of Health Standards Programs, Room N3718, U.S. Department of Labor, OSHA, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202-357-0325).

SUPPLEMENTARY INFORMATION:

Background

Vinyl chloride (C_2H_3Cl; CAS No. 75-01-4; chloroethene) is a colorless gas at room temperature and pressure. After synthesis from VC monomer, polyvinyl chloride ($(C_2H_3Cl)_n$; CAS No. 9002-86-2; chloroethene homopolymer) is in the form of white or colorless granules. Residual vinyl chloride monomer can become trapped in the PVC particles. However, recent processing methods can reduce considerably the amount of residual VC trapped in the polymer resins.

The vinyl chloride industry can be divided into three major components: VC synthesis, VC polymerization, and PVC fabrication. It has been estimated that in the U.S., 15 plants manufacture vinyl choride, 43 plants polymerize polyvinyl chloride, and at least 7,500 plants are engaged in the fabrication of PVC. During 1978, 3.47 million tons of VC and 2.94 million tons of PVC were produced.

The present permissible limit for occupational exposure to vinyl chloride is 1.0 ppm averaged over any 8-hour period, and 5.0 ppm averaged over any period not exceeding 15 minutes (29 CFR 1910.1017). For polyvinyl chloride dust, the standard is 15 mg/m^3, averaged over any 8-hour period (29 CFR 1919.1000).

Laboratory Studies

Experimental bioassays have demonstrated the induction of cancer by VC at levels of exposure lower than those previously reported. In VC inhalation studies of rats, Maltoni (1) has induced liver angiosarcomas at 25 ppm and mammary carcinomas at one ppm. In addition, several different test systems have provided evidence for the mutagenic potential of VC, i.e., *E. coli, S. typhimurium, S. pombe,* insects, plants, and cultured mammalian cells (2). VC also has been demonstrated to have a transplacental effect in rats. Inhalation exposure of pregnant rats to VC concentrations of 6,000 and 10,000 ppm have resulted in VC-dependent tumors in their offspring (1).

There is also evidence from animal studies that PVC may induce non-malignant respiratory disease. It has been reported that after seven months of exposure, rats and guinea pigs caged in work areas where sacks were being filled with PVC powder developed pulmonary pathological changes and granulomatous lesions containing foreign particles thought to be PVC dust (3).

Epidemiologic Studies

Several investigations of employee populations have indicated that VC/PVC exposure is associated with an increased carcinogenic risk to several organ sites in addition to the liver. A NIOSH retrospective cohort study of workers from four VC polmerization plant showed an excess number of deaths due to cancer of the liver, lung, lympho-hematopoietic system, and central nervous system (4).

Of further concern is the finding that the carcinogenic risk may extend to industries fabricating polyvinyl chloride. A proportionate mortality study of plastic workers in Great Britain, which included PVC fabricators, demonstrated a statistically significant excess of stomach cancer (5). Also, an excess of mortality from digestive system cancer among PVC fabricators of both sexes was found by Chiazze et. al. in the U.S. (6). Among white females in the study, observed deaths from breast and urinary tract cancers were also greater than expected. Waxweiler et. al. performed a detailed study of the excess lung cancer risk previously observed at a synthetic plastics and rubber plant (7). Analysis of lung cancer cases by cell type demonstrated a greater frequency of adenocarcinomas (Type 3) and large cell undifferented (Type 4) cancer. Neither cell type is believed to be strongly assoicated with cigarette smoking. Of 12 chemicals analyzed, only PVC dust exposure proved to be statistically significant. The authors suggested that the excess of Type 3 and 4 lung cancer cases in this plant was related to PVC dust exposure.

A recent epidemiologic study suggests that PVC may be related to pneumoconiosis (8). Employees of a polyvinyl chloride production factory in Italy were submitted to chest X-ray examination. Twenty subjects were diagnosed as having pneumoconiosis. All of these cases had worked five or more years in departments with demonstrated PVC dust pollution. No

pneumoconiosis was observed in subjects who worked in areas free of PVC dust. These findings are consistent with earlier case reports of pneumoconiosis among workers exposed to PVC dust (9,10). The Institute of Oncology and Tumor Center in Bologna, Italy has demonstrated a higher frequency of cytolgoically abnormal sputum cells among the workers employed in the VC/PVC industry in contrast either to workers in the general chemical industry or to individuals who are heavy smokers (11).

Epidemiologic studies also exist which demonstrate the mutagenicity of VC in humans. Chromosomal aberrations in lymphocytes of male workers, in excess of the number observed in non-exposed workers, have been reported in several studies (2). Morever, a study of miscarriages among wives of men occupationally exposed to VC detected a significant excess in fetal mortality following the husband's exposure to VC (12).

Information requested on vinyl chloride and polyvinyl chloride

The date recently received by OSHA suggest that a reassessment of the known health effects of vinyl chloride and polyvinyl chloride is appropriate at this time. Additional information in several areas is needed before a reassessment can be completed. The requested information includes, but is not limited to, the following:

(1) Experimental test results for carcinogenicity of vinyl chloride at atmospheric exposures of less than 50 ppm.

(2) Studies of transplacental carcinogenic and teratogenic effects in humans or animals at any level of exposure to vinyl chloride.

(3) Experimental studies of carcinogenicity and other toxic manifestions for any level of polyvinyl chloride exposure. These effects should include, but are not limited to, mutagenicity, teratogenicity, embryotoxicity, and other transplacental effects, as well as cytotoxic and cytogenetic effects on sperm cells. To the greatest extent possible, complete information concerning the industrial source of the polyvinyl chloride, the size and characteristics of the particles, and exposure levels or concentrations of PVC and residual VC should be included for each study.

(4) Epidemiologic studies of either vinyl chloride or of polyvinyl chloride (i.e. cohort, cross-sectional, or case-control).

(5) Case reports and case series of brain, lympho-hematopoietic, lung, and liver cancers by facility and relevant demographic variables, such as age, sex, race, date of diagnosis, date of death, date of first exposure, and length of exposure for either vinyl chloride or polyvinyl chloride.

(6) Mutagenicity study results of vinyl chloride or polyvinyl chloride as measured by the analysis of human body fluids, e.g., direct mutagenic testing with peripheral blood lymphocytes, non-disjunction in humans with YFF sperm test, and *in vivo* cytogenetics.

(7) Body burden measurements of vinyl chloride in humans.

(8) For operations involving polyvinyl chloride, the types of resin in use, the concentration of vinyl chloride trapped in the resin, and the concentration of VC and PVC dust in the atmosphere where individuals are working. This information should include estimates of the particles sizes and concentrations of particles that fall within the respirable range.

(9) In PVC bagging and milling operations, atmospheric levels of PVC and VC, monitoring devices used to detect VC, and the type of respirator protection program for individuals working in these operations. This should include the sensitivity and validity of analytic techniques in use.

(10) Types of occupations, job classifications, and industries where exposure to either VC or PVC at any level may occur, and the numbers of employees involved in each vinyl chloride and polyvinyl chloride exposure situation, separated by sex and race.

(11) Appropriate engineering controls, work practices, and personal protective equipment available to reduce levels of exposure to VC or PVC below the current standards, or to the lowest levels feasible.

SUBMITTALS OF INFORMATION REQUESTED

Interested persons are invited to submit written data, views, and comments with respect to the issues described abve. All communications should be submitted in quadruplicate, by February 10, 1980, to the Docket Officer, Docket H–034, Room S6212, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210 (202–523–7894).

References

The following documents, referred to in this notice, are available for inspection and copying at the OSHA Technical Data Center, Room S6212, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

1. Maltoni, C. Vinyl chloride carcinogenicity: An experimental model for carcinogenesis studies. *Origins of Human Cancer*, Cold Spring Harbor Laboratory, 1977, pp. 119–146.

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9. Szende, B., K. Lapis, A. Nemes, and A. Pinter. Pneumoconiosis caused by the inhalation of polyvinyl chloride dust. *La Medicina del Lavoro*, 61: 433–436, 1970.

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Signed at Washington, D.C. this 12th day of December 1979.

Eula Bingham,

Assistant Secretary of Labor.

[FR Doc. 79–38858 Filed 12–17–79; 8:45 am]

BILLING CODE 4510–26–M

Pension and Welfare Benefit Programs

(Prohibited Transaction Exemption 79–79; Exemption Application No. D–837)

Exemption from the Prohibitions for Certain Transactions Involving College Retirement Equities Fund

AGENCY: Department of Labor.