



CHEMICAL MANUFACTURERS ASSOCIATION

November 12, 1996

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency (CalEPA)
P.O. Box 942732
Sacramento, CA 94234-7320

Re: Developmental and Reproductive Toxicant Identification Committee's Review of Vinyl Chloride: Developmental and Reproductive Toxicity Data Summary

Dear Ms. Oshita:

The Chemical Manufacturers Association (CMA) Vinyl Chloride Panel submits these comments for consideration by the Science Advisory Board's Developmental and Reproductive Toxicant (DART) Identification Committee at its December 4, 1996 meeting. The Panel consists of the following U.S. manufacturers of vinyl chloride: Borden Chemicals and Plastics, Inc.; CONDEA Vista Company; The Dow Chemical Company; Formosa Plastics; The GEON Company; Georgia Gulf Corporation; Occidental Chemical Corp.; PPG Industries, Inc.; and Westlake Polymers. The Panel appreciates this opportunity to participate in the review of the draft document titled *Vinyl Chloride: Developmental / Reproductive Toxicity Data Summary*.

After careful review of the draft *Data Summary* and available toxicological literature on vinyl chloride, the Panel believes that the available evidence suggests that vinyl chloride is unlikely to be a developmental or reproductive toxicant. However, the Panel is sponsoring an combined two-generation reproductive and developmental toxicity study of vinyl chloride in CD rats which is expected to provide important data needed to evaluate these endpoints. This study is being conducted under a Memorandum of Understanding between the Panel and the Agency for Toxic Substances and Disease Registry (ATSDR) to meet the research needs of ATSDR and the U.S. Environmental Protection Agency. The study protocol is enclosed for examination by the DART Identification Committee.

The Panel recommends that the DART Identification Committee extend its review period for the *Draft Summary* until the combined reproduction and developmental toxicity study has concluded. At that time, the Panel would be pleased to make available to CalEPA the results of the research.

Langley A. Spurlock, Ph.D., CAE
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The CMA Vinyl Chloride Panel hopes that this information will be of assistance to the DART Identification Committee. If you have any questions, please call Dr. Robert A. Venezia of my staff at (703) 741-5639.

Sincerely,



Langley A. Spurlock, Ph.D., CAE
Vice President, CHEMSTAR

Enclosure



A Division of The Society of The Plastics Industry, Inc.

November 18, 1996

Ms. Cynthia Oshita
California Environmental Protection Agency
Office of Environmental Health Hazard Assessment
Post Office Box 942732
Sacramento, California 94234-7320

**Re: SPI Vinyl Institute; Comments on Consideration of Vinyl
Chloride as a Developmental/Reproductive Toxicant Under
California Proposition 65**

Dear Ms. Oshita:

The Vinyl Institute (VI), a division of The Society of the Plastics Industry Inc. (SPI), appreciates this opportunity to offer its views on a proposal by the California Environmental Protection Agency (Cal EPA) Office of Environmental Health Hazard Assessment (OEHHA) to consider vinyl chloride (CASRN 75-01-4) for priority consideration as a developmental/reproductive toxicant under the California Safe Drinking Water and Toxic Enforcement Act (Proposition 65, California Health and Safety Code 25249.5 et seq.).^{1/}

^{1/} Members of the VI are responsible for the majority of the domestic production volume of vinyl chloride monomer (VCM) and polyvinylchloride (PVC). VI's members include: Borden Chemicals and Plastics Limited Partnership, CertainTeed Corporation, Colorite Polymers, Condea-Vista Company, The Dow Chemical Company, The Geon Company, Georgia Gulf Corporation, Occidental Chemical Corporation, PPG Industries, Inc., Shintech, Inc., Union Carbide Chemicals and Plastics, and West Lake PVC Corporation.

SPI is a 2,000 member not-for-profit trade organization representing all segments of the plastics industry in the United States. The Society's members include processors and manufacturers of plastics and plastics products, suppliers of raw (continued...)

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As explained below, OEHHA should postpone consideration of vinyl chloride because:

- (1) the available toxicological literature does not show clearly that vinyl chloride is a developmental or reproductive toxicant;
- (2) ongoing toxicological and epidemiological studies will clarify the scientific data on the potential reproductive and developmental effects of vinyl chloride; and
- (3) the potential for exposure to vinyl chloride from the manufacture and particularly the fabrication of PVC is low, and is minimized by applicable federal, state, and local laws, as well as voluntary programs.

**I. OEHHA SHOULD DEFER CONSIDERATION OF VINYL CHLORIDE
PENDING THE COMPLETION OF ONGOING EPIDEMIOLOGICAL AND
TOXICOLOGICAL STUDIES**

The results of two studies, which are now underway and have already produced findings, could well have significant bearing on OEHHA's proposal to consider vinyl chloride a developmental/reproductive toxicant under Proposition 65. Both studies are sponsored by the Vinyl Chloride Panel of the Chemical Manufacturers Association (CMA). CMA is filing separate comments in this matter, which the Vinyl Institute supports.

The first study is an update of a large epidemiology study of workers in the vinyl industry. This study is expected to be completed in the fall of 1997. Because OEHHA's proposed action is based, in part, upon the results of epidemiological studies, we are also enclosing a copy of a 1987 technical report prepared by the Medical Subcommittee of the VI's Technical Committee, which discusses how many earlier developmental/reproductive toxicity studies of vinyl chloride (particularly epidemiological studies), do not withstand critical scientific review. We

^{1/}(...continued)

materials, processors and converters of plastics resins, and manufacturers of accessory equipment for the plastics industry. Founded in 1937, SPI is the major national trade association of the plastics industry.

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understand that the CMA Vinyl Chloride Panel can provide further information or updates if that would assist in Cal/EPA's review.

The second ongoing study is a two-generation developmental and reproductive toxicity study in rats that is being conducted at Huntingdon Life Sciences Laboratories. Among other things, this study is expected to provide valuable mechanistic data that should be examined by OEHHA. The study is being conducted under a Memorandum of Understanding between the CMA Panel and the Agency for Toxic Substances and Disease Registry (ATSDR) to meet the needs of ATSDR and the U.S. Environmental Protection Agency (EPA). The CMA Panel has indicated that it would make the results of this study available to OEHHA upon its completion.

In the absence of a clear and sound toxicological database, it would not be prudent for OEHHA to consider vinyl chloride as a potential developmental/reproductive toxicant before the results of the above-mentioned studies are completed. In addition, vinyl chloride is already listed as a carcinogen under Proposition 65. Thus, warning statements are already required for instances when there may be exposures to vinyl chloride above the no-significant risk level.

II. EXPOSURE TO VINYL CHLORIDE FROM THE MANUFACTURE AND FABRICATION OF PVC IS LOW AND STRINGENTLY REGULATED

The VI generally disagrees with OEHHA's statement that: "Major exposures [to vinyl chloride] can occur in manufacturing or fabrication of PVC."^{2/} While we agree that non-routine or emergency situations can, under certain circumstances, result in major short-term exposures to vinyl chloride, lifetime exposure of workers and the population at large to vinyl chloride is exceedingly low.

As noted by OEHHA, approximately 97% of vinyl chloride manufactured in the U.S. is used as a chemical intermediate in the manufacture of polyvinyl chloride (PVC). In workplaces in which vinyl chloride is so used (and in other workplaces), workers are protected from exposure to vinyl chloride under the Occupational Safety and Health Administration's (OSHA) vinyl

^{2/} "Draft Prioritized Candidate Chemicals Under Consideration for Developmental/Reproductive Toxicity Evaluation" OEHHA (October 4, 1996) at 56.

chloride standard.^{3/} For over 20 years since the standard was promulgated, industry has been subject to a stringent 1 part per million (ppm) permissible exposure limit (PEL). Today, the entire PVC production process is essentially closed, with most activities taking place within closed vessels, further minimizing potential exposure to vinyl chloride.

With respect to air emissions, U.S. ethylene dichloride (EDC), vinyl chloride monomer (VCM), and PVC manufacturing facilities are subject to a Clean Air Act (CAA) National Emission Standard for Hazardous Air Pollutants (NESHAP) (40 C.F.R. § 61.60 et seq.), which is one of the most stringent standards of its kind. The vinyl chloride NESHAP contains detailed criteria (e.g., numerical emission limits, equipment specifications, and work procedures) to minimize emissions from various points in the manufacturing process. Besides using new technologies and innovative procedures, and complying with federal, state and local standards, the industry has also instituted a number of voluntary pollution prevention and worker safety and health programs. As a result, EPA estimates that the vinyl industry has reduced vinyl chloride emissions over 99 percent since the early 1970's.

Manufacturing process improvements have resulted in reduced residual vinyl chloride concentrations in PVC resin, which, in turn, reduces the potential for exposure of downstream fabrication workers and the public. All producers of PVC suspension resins use some type of stripping system to remove residual vinyl chloride. According to the "Encyclopedia of PVC," most general purpose PVC suspension resins (which comprise over 80% of the PVC resin produced in the U.S.) exit the stripping column at the manufacturing site at a low ppm residual vinyl chloride concentration. For well over ten years, this amount has been well under 5 ppm at the time of shipment^{4/}, and we understand that resins typically contain only a fraction of this amount today. With respect to food contact PVC, the Food and Drug Administration (FDA) observed in a 1986 rulemaking that although prior to 1975 residual vinyl chloride levels in food-use

^{3/} 29 C.F.R. § 1910.1017. Under the standard, manufacturers must reduce or eliminate worker exposure to vinyl chloride by using a combination of engineering controls, work practice controls, and personal protective equipment.

^{4/} Encyclopedia of PVC, Nass, L.I., Heiberger, C.A., eds.; Second Edition, Marcel Dekker, Inc., New York, 1986, Volume 1.

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PVC of 1,000 ppm were common, improved manufacturing procedures had lowered that amount by more than five orders of magnitude.^{2/} Indeed, a recent study estimating emissions from PVC pipe extrusion operations detected no vinyl chloride.^{3/} Therefore, there is negligible employee and general population exposure to vinyl chloride as a result of handling or processing PVC resin.

* * *

We appreciate the opportunity to provide input in this regard and trust that you find these comments useful. Should you have any questions concerning this matter, or desire more detailed information or comments, please do not hesitate to contact us.

Sincerely,

Robert H. Burnett/PLP
Robert H. Burnett

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Enclosure

^{2/} 51 Fed. Reg. 4177, 4178 (February 3, 1986).

^{3/} "Sampling and Analytical Test Report; Emission Factor Development for the PVC Pipe Manufacturing Industry," Rosengarten, Smith, and Associates (January 1996). This report was submitted to U.S. EPA.