May 21, 1973

INFORMATION ON VINYL CHLORIDE TO BE PRESENTED ORALLY TO NIOSH

I. Description of the Vinyl Chloride and Polyvinyl Chloride Industry

Vinyl chloride is a commodity used in very large quantities to make polyvinyl chloride resins (polymer and copolymer). The following estimated figures for 1972 illustrate the tremendous importance of this industry which has operated for 35 years in the United States and 40 years in Europe.

	Vinyl Chloride	Polyvinyl Chloride
U.S. Production	5.2 billion lbs (0.65 exported)	4.4 billion lbs
U.S. Capacity	5.9 billion lbs	
World Production	22 billion lbs	
Annual growth last 5 years	14%	
Projected annual growth, U.S.	11%	
U.S. Plants	14	37 (23 companies)
U.S. Workers	1500	5000
World Workers	10,000	

URL 22866

Virtually all (>99%) vinyl chloride is used in production of polyvinyl chloride and other polymers. It is difficult to estimate the number of workers employed in converting, molding, and fabricating these polymers but it is of the order of 10's of thousands, working in thousands of plants. It has been estimated that the wholesale value of fabricated products is over $3 billion.

Almost all of the vinyl chloride and polyvinyl chloride producers in the U.S. are participants in the MCA Technical Task Group on Vinyl Chloride Research. Over 95% of the

PLAINTIFF'S EXHIBIT Harris 38

U.S. vinyl chloride capacity and 85% of the PVC capacity are represented by the following 20 companies today.

Air Products	Goodrich
Allied Chemical	Goodyear
Borden Chemical	Monsanto
BP Industries (British)	Olin
Conoco	PPG
Diamond Shamrock	Shell
Dow	Stauffer
Ethyl	Tenneco
Exxon	Union Carbide
Firestone	Uniroyal

II. Summary of Toxicity Studies on Vinyl Chloride Monomer

A. Published Information on VCM

Vinyl chloride monomer was for many years considered to be very low in toxicity, both from single and repeated exposure. Because of its volatility, inhalation was considered the only important route of exposure for workmen. The high flammability of VCM has been considered to be a more serious hazard than inhalation.

From the earliest lists until 1962, the American Conference of Governmental Industrial Hygienists (ACGIH) recommended that the time-weighted average long-term 7-8 hour daily exposure of workmen not exceed 500 ppm v/v (~1300 mg/m^3). This recommendation was based on single exposure studies on animals and on human experience. Recommended time-weighted average concentrations are published by the ACGIH in an annual list of "Threshold Limit Values" (TLV). A TLV was considered by this group to "represent conditions under which it is believed that nearly all workers may be

repeatedly exposed day after day, without adverse effect." In 1963 the ACGIH modified their recommendation so that 500 ppm was to be a maximum concentration (or ceiling) rather than a time-weighted average. This change was in part due to the publication by Torkelson, Oyen, and Rowe (American Industrial Hygiene Association Journal Vol. 22, p 354, 1961) of the results of six-months repeated inhalation studies on laboratory animals. These authors reported ~~slight~~ reversible ~~liver injury~~ in rats exposed 7-hours per day to ~~500~~ ppm and recommended that the time-weighted average exposure of workers not exceed 50 ppm. However, this recommendation was not considered appropriate by Lester, Greenberg, and Adams (ibid. Vol. 24, p 265, 1963) ~~who did not consider significant injury~~ to have resulted in rats which they had repeatedly exposed to ~~500~~ ppm v/v.

About 1963-1964 reports appeared in the European literature describing pain and tenderness in the fingers of polyvinyl chloride workers. X-ray examination showed that the bones of the hand were dissolving. This condition known as acroosteolysis was also investigated by American vinyl and polyvinyl chloride companies and similar disease was found in workers who cleaned polymerization vessels. The epidemiological data from this investigation was published in January 1971. (Archives of Environmental Health, Vol. 22, pp 61-91, 1971). This epidemiological study was directed at workers currently employed by the companies. In May 1970, Dr. P. Luigi Viola, an Italian physician, reported in Houston that he had attempted to create a bone condition in rats similar to human acroosteolysis. (Tenth Intl. Cancer Congress, Houston, Texas, May 22-29, 1970). Dr. Viola observed tumors in the ear canals of rats exposed to 30,000 ppm (3%) vinyl chloride vapor 4 hours per day for 12 months. Viola also reported tumors in the lungs and bones of these rats but these later tumors are of questionable significance.

These data were subsequently published (Viola, P. L., Bigotti, A., and Caputo, A., Cancer Research 31, 516-522, May 1971).

In 1970 the ACGIH proposed reduction of their recommended TLV to a time-weighted average of 200 ppm primarily on the basis of work reported by Kramer and Mutchler at a 1968 Gordon Research Conference on Toxicology and subsequently published in January 1972 (American Industrial Hygiene Association Journal, Vol. 33, p 20, 1972). The authors reported evidence of clinical findings in workers exposed to a time-weighted average concentration of 300 ppm VCM for many years.

In 1972 the ACGIH took vinyl chloride from the list of Intended Changes and changed the value in their regular list to 200 ppm. This value remains the recommended value in the 1973 list. A copy of the Documentation for the ACGIH TLV for vinyl chloride as published in 1971 is attached.

In order to get more details of Dr. Viola's experiments, including additional unpublished studies and observations that he might have compiled, he was invited by the Manufacturing Chemists Association to visit Washington and discuss his findings with MCA's Occupational Health Committee. On May 5 and 6, 1971, he discussed data published in 1971 and referred to other studies completed and underway. Dr. Viola was extremely vague and evasive in giving details. He did report that his vinyl chloride was quite impure and claimed to have seen tumors in rats exposed to 5000 ppm. He thought 2500 ppm would be without such an effect. He produced no data and refused to give details. He claimed he would not be concerned about workers exposed to less than 500 ppm. We are not aware of any further publications by Dr. Viola on this subject.