

V I N Y L C H L O R I D E

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This report is not intended as a complete treatise on vinyl chloride but is rather designed to acquaint UNIROYAL'S health related personnel with what went on at UNIROYAL in the years when we produced PVC at Painesville and vinyl chloride first, at Painesville and later in the Monochem Plant at Geismar, Louisiana.

U. S. Rubber's Naugatuck Chemical Division grew almost exponentially in the 1940's. Prior to World War I, it had produced sulfuric, nitric and hydrochloric acids for use in the Naugatuck brass and metals industries.

During World War I, shipments of dyestuffs from Europe were cut off by German submarines. Naugatuck Chemical began to manufacture aniline and later various rubber chemicals based on aniline as well as dithiocarbamates and other chemicals developed by The General Laboratories in New York City and later in Passaic, New Jersey.

Synthetic rubber production was started during World War II and agricultural chemical sales began in a very small way at about the same time. During the 40's, research was going on at The General Laboratories and at Naugatuck on various synthetic rubbers and plastics. While we researched our way into

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rubber chemicals and agricultural chemicals, management decided that purchase of a plant was the preferred way to enter the rapidly expanding PVC field. The purchase of the Glenn L. Martin PVC Plant at Painesville, Ohio resulted in 1950. This plant, which started production in 1947, initially made its own vinyl chloride monomer by additions of HCl to acetylene. The HCl was purchased under a favorable contract with a neighboring Diamond Alkali Plant. During the 50's and early 60's volume was doubled and redoubled. Production of VC at Painesville stopped after the Monochem Plant came on stream in 1961.

As was true in most companies at this time, we assumed that vinyl chloride was of very low toxicity. In retrospect, the only animal toxicology studies were acute studies aimed at its possible use as an anesthetic. Because of poor performance, fire hazard and toxic side effects, this use did not develop to any appreciable extent. Nevertheless, everyone "knew" that exposure to vinyl chloride gas was not dangerous so long as you didn't get anesthetized. It was inexpensive so most of the research and development effort on PVC was directed at achieving a better product for various end uses. Most monitoring was aimed at preventing fire and explosion hazards, levels approximately 100 times higher than the TLX. Torkelson and coworkers at Dow conducted a six month vapor exposure study at levels

T. R. Torkelson, F. Oyen, and V. K. Rowe, Am. Ind. Hyg. Assoc. J. 22, 354 (1961)

from 50 to 500 ppm on rats, dogs and guinea pigs. As a result of these studies, Dow recommended a 50 ppm exposure limit which

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they adopted in their own plants. These and other studies are reviewed briefly in Patty and in IARC's Vol. 7 (pages 291-318 (1974)).

Patty's Industrial Hygiene and Toxicology 3rd. ed. Vol. 2B. Toxicology, pages 3537-3542. John Wiley & Sons. New York (1978).

Because most management people in the chemical industry had little experience in the rapidly developing field of industrial toxicology and because of the apparently good health experience among workers heavily exposed to VC, these early warning signals were largely ignored. ACGIH had set a TLV at 200 ppm which remained in effect in 1974. However, OSHA had adopted the 1968 ACGIH level of 500 ppm. These levels were somewhat academic since few companies were equipped to do adequate monitoring of worker exposure before 1974 because VC was considered to be safe at levels prevalent in the industry.

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ACROOSTEOLYSIS:

In the early 60's, a problem began to develop in some plants in Europe and primarily at Goodrich in the U. S. (Goodrich and Union Carbide were two of the earliest manufacturers of PVC resins and Goodrich had become by far the largest by the 70's.) The end bone of the fingers became flattened and in some cases virtually disintegrated. The companies set up a study group at MCA and the Institute of Environmental and Industrial Health at the University of Michigan was chosen to conduct an epidemiological study, the results of which were published in Archives of Environmental Health (22,61-73 (1971)).

The problem was confined to workers involved in hand cleaning reactors. Although the study did not prove that vinyl chloride was the cause, it was generally considered to be.

In Italy, one company retained a Dr. Viola from a local university as its medical adviser. They had asked him to try to develop an animal model to study the acroosteolysis problem. They agreed on a long term vapor exposure study on rats at 30,000 ppm. At this high level, Dr. Viola ran into an unexpected problem -- zymbal gland tumors. All his animals died before the end of the year. He reported the results of his study at a meeting in Houston in 1970. The Environmental Health (not sure of exact title) Committee of MCA, of which UNIROYAL'S Medical Director, Dr. Jack Wolfsie was a member, invited Dr. Viola to meet with them. (I am not sure if this was in New York or Washington.) Initially, Dr. Viola's work was taken rather lightly because the dose was so high that the animals were lethargic and did not live long. It was felt that the dose was so far removed from practical exposure as to be meaningless. Man does not have any organ corresponding to the rat's zymbal gland. However, during the following winters and spring, Dr. Wolfsie and I discussed the problem with each other from time to time and became convinced that the industry should study it further to determine whether a real health problem might exist. UNIROYAL moved its corporate offices from New York to Middlebury about July 1, 1971, and Dr. Wolfsie chose not to move. We were without a medical director until November 1971, when Dr. J. D. Forbes took the position. In the meantime, realizing that we

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had lost our contact at MCA, I suggested that I be designated as UNIROYAL'S representative on a VC committee being formed at MCA. In my letter of October 5, 1971, to B. R. Leach, then Plant Manager at UNIROYAL'S PVC plant at Painesville, Ohio, I recommended an industry animal study to determine dose-response relationships and an epidemiological study of VC exposed workers. It is important to realize that at this time we did not know that VC was causing cancer in workers. We were just encouraging a responsible approach. There is always a tendency for others to judge actions based on later knowledge or beliefs.

We did not have a representative at the November 16, 1971, VC meeting at MCA but received the minutes. I attended the December 14 meeting as a guest.

During the Winter and Spring of 1972, a great deal of effort went into securing financial support for the toxicology and epidemiological studies, designing protocols and selecting contractors. We knew that an animal study was most likely in progress in Europe and we wanted to learn as much about that study as possible so that we could design a study which would further extend our and their knowledge. The minutes of the April 20, 1972, meeting listed me as a member and from that time until the closing of our Painesville Plant in late 1975 I was deeply involved.

During the late Summer of 1972, ICI relayed the willingness of the European group to impart information on the European

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study if suitable confidential arrangements could be made. George Best's (MCA) letter of September 20, 1972, to R. O. Lindsell of ICI indicated that I would meet with him in England in mid-October. When I called Mr. Lindsell, he said that they would want me to attend their meeting in Milan on October 19, which I did.

My letter of October 20, 1972, to George Best describes my meeting and my visit to Maltoni's office and laboratory. At this meeting the European group advised that they could not give data but they wanted me to understand thoroughly the nature and scope of their study and invited the U. S. group to support studies aimed at rounding out Maltoni's work. They did tell me that the dosage series covered the range from 10,000 to 50 ppm and that they were surprised to find "toxicity as low as 250 ppm". From the comments made and from what I saw at Maltoni's laboratory, I concluded that Maltoni was finding what appeared to be VC caused cancer at levels as low as 250 ppm, but I had no data so could not in good conscience give this information to any government agency. If NIOSH, OSHA, or EPA were given such preliminary information it would have been made public at once (FOI) and Maltoni would have been hounded for details, jeopardizing completion of the study. The industry was subsequently criticized for withholding information, whereas Dr. Duffield of ICI accompanied representatives of our committee in July 1973 and gave such data as was then available to Dr. Marcus Key, head of NIOSH. He expressed appreciation and asked that we keep him informed once the study was completed.

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There had been some delay in disclosing data to MCA because of concern over confidentiality on the part of the Europeans.

Upon my return from Italy, I called a meeting of management people at UNIROYAL to alert them to the possibility that VC would be found to be an animal carcinogen and if so, OSHA would be forced to drastically reduce its VC standard (500 ppm) and that it would be necessary to start monitoring workers' exposure. The Painesville Plant Management agreed to undertake the monitoring task with guidance from L. F. Dieringer and me. I also urged management to take a hard look as to whether it would be good business to retrofit the Painesville Plant in view of reactor size and design.

During the late Summer of 1973 we got approval to purchase a Miran infrared analyzer. After it was delivered, C. B. Westerhoff came from Painesville and went with Larry Dieringer and me to S. Norwalk to be instructed in its use. In early January, I took it to Painesville and worked for a couple of days with Westerhoff to get started on monitoring. This is an elegant study instrument. When NIOSH came into the plant, a couple of months later, they were most impressed by the data which was presented to them.

On January 19, Dr. Mac Roy Gasque, Medical Director of Olin, Dr. Richard Kociba, Pathologist at Dow and Dr. Theodore Torkelson, Toxicologist at Dow, met with the European group and

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received preliminary results. They were as well impressed as I had been. Dr. Duffield of ICI attended our meeting on January 30, 1973.

The next several months were devoted to developing detailed protocols and negotiations with Industrial Bio-Test for the animal (rat, mice, hamster) study and selecting a contractor for the epidemiological studies. Tabershaw-Cooper were chosen for the epidemiological study. This study was announced on June 28, 1973, and got underway promptly. It is unfortunate that Industrial Bio-Test which had had a good reputation over-expanded and never completed the animal study, although, we did get some preliminary results. Part of the money was recovered. The Tabershaw-Cooper study was completed and an update is currently underway by Environmental Health Associates. There is no question but that VC caused angiosarcoma. This study will seek to find whether other malignancies such as brain tumor are elevated.

It has been interesting to me that my recommendation not to go ahead with the Industrial Bio-Test study and to support Maltoni was vetoed by Goodrich. They are the company which has had most of the acroosteolysis and angiosarcoma. In recent years, they have really worked at improving their toxicology, industrial hygiene and medical capability and their image.

On January 22, 1974, Goodrich informed NIOSH that three deaths due to angiosarcoma of the liver had occurred at their Louisville PVC Plant. Since this was one of the main cancers,

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Maltoni found in his animals, the odds were overwhelming that VC was the cause. This started a process which was unprecedented in the U.S. and probably in the world. In January 30, 1974, Federal Register, OSHA began a fact finding procedure which included both written and oral comments, the latter before an administrative law judge beginning on February 15. This process gave everyone from scientist to laborer and general hell raisers a chance to say his piece. Scientific meetings, literature reviews and industry meetings blossomed everywhere. My files are extensive during this period and I have not tried to summarize them.

On April 5, 1974, OSHA published an Emergency Temporary Standard for VC of 50 ppm. This automatically locked them into a six month schedule to issue a final standard.

UNIROYAL presented its testimony concerning the proposed standard on June 21. It is interesting to review what we said at that time. It has held up very well in the light of subsequent findings. Although we suggested a 25 ppm standard, OSHA set the limit at 1 ppm. We will never know for sure whether any lives have been saved by this low level.

The final report by Tabershaw-Cooper was submitted on May 3, 1974, but was revised several times as careful study by committee members enabled the authors to clarify certain issues and further records were found by Union Carbide. This enlarged the cohort. The real final report issued on January 1978. By

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this time, Tabershaw-Cooper had been purchased by Equitable Environmental Health, Inc. (Their report is filed in a separate folder in my vinyl chloride toxicology file with a yellow label, "Equitable Epidemiol".) In addition to the angiosarcoma, brain tumors were in excess (12 vs. 5.9 expected). A great deal has been made of the brain tumor data but at this time we really don't know whether this is a real effect or a chance variation. Hopefully, the updated study will be more definitive.

While the OSHA law is good in principle, it was written by labor oriented people from the standpoint that industry is not concerned about health and safety and will do nothing to protect the worker unless forced too. OSHA felt pressured to act quickly. While labor was pushing hard for a "non-detectable" level of exposure, we in industry advised that a finite measurable low level was essential if the standard were to be enforceable. OSHA issued its final standard on October 24, 1974, [F.R. 39(194)35890-35898 incl.]. The main features included:

1 ppm TWA permissible exposure limit.

0.5" action level.

Monitoring above action level.

Regulated areas.

Medical program including at least
annual physical exams including
history, blood parameters, etc.

EPA issued its regulation on VC as a Hazardous Air Pollutant on October 21, 1976. This standard has not affected UNIROYAL

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because we stopped production of PVC prior to this.

AIHA published its revised "Hygienic Guide" in February 1978 and set a TLV of 5 ppm that year.

In the period following the announcement of angiosarcoma at Goodrich, VC and PVC manufacturers reviewed medical records and checked pathology of liver cancers. Cases of angiosarcoma were reported to NIOSH. For a time, NIOSH compiled this information and made it widely available during the standards development stage but dropped it shortly thereafter. A few pertinent documents are listed below:

Compilation dated June 25, 1974, Table I listed 15 U.S. cases and 1 Swedish.

Letter dated January 22, 1975, from Dr. Lloyd of OSHA to Dr. Torkelson and appended Tables.

My letter of August 12, 1976, to Torkelson developed the rolling average concept and showed that VC induced angiosarcoma was not increasing after 1968. I could not justify spending a great deal of time on VC because we had dropped out of the business.

Rose Kaminski's (NIOSH) letter to Torkelson asking for information.

Torkelson's letter to Dr. John Stafford of ICI dated April 1, 1977.

Torkelson's letter to Stafford, March 29, 1977. He gives latest NIOSH data and includes an update of my August 12, 1976 letter.

Minutes of January 11, 1978, Item 9.0
Torkelson mentions international registry

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of angiosarcoma cases being developed
by Dr. John Stafford of ICI.

NIOSH update JOM 20:429-428 (1978).

Torkelson updated my earlier figures
9/20/78 -- Same results.

Angiocarcinoma. J. Stafford Worldwide
Summaries:

1. 5/1/80
2. 1/20/82
3. 8/25/82
4. 1/17/84

During 1978 and 1979, we became concerned that we had not received a final report on IBT's animal studies. When a careful audit established that it would be impossible to get a reliable report, MCA asked for a return of part of the money. As indicated in CMA letter of November 8, 1980, we agreed to accept \$110,000. The meeting of 3/18/80, attached to Dr. Shah's letter of 3/19/80 summarizes this problem. This is further summarized in my letter of 3/31/80 to B. R. Leach. (See also EPL Report, dated 5/14/80 and Bob West Associates, Inc. Report received 5/20/80.

In 1979, plans were started for an epidemiological update. A pre-publication release of a study by the Consumer Product Safety Commission was dated April 1, 1979. Rats and mice were exposed for one hour to 50, 500, 5000 and 50,000 ppm of VC. The data muddled the water but in the long run didn't

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change things much. Comments by Dr. Jessie Norris of Dow attached to T. R. Torkelson's letter of November 8, 1979, critiques this study. Maltoni considered it a ridiculous waste of time.

The vinyl chloride experience was a vast educational experience for:

The General Public - Became more aware of OSHA, NIOSH and Toxicology.

Management - Became more aware that chronic effects can be serious even though acute toxicity is low. OSHA has to be reckoned with.

Scientist - Got a better insight into the kinds of data needed to thoroughly evaluate toxicity. Still can't quantify relationship between animal and human toxicity.

Regulatory Bodies - Gained experience in working with industry groups and began to understand that industry is concerned and wants to protect its workers.

Industry Groups - Learned to work more creatively and honestly with regulatory agencies.

Because of the long time from exposure till death from cancer, we will not be entirely clear of the VC problem until early in the next century. Fortunately, UNIROYAL has not had a case of angiosarcoma. On the basis of numbers of workers involved, we might expect one or two cases by the time all those exposed to VC have died.

August 1, 1984

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