Monsanto

FROM (NAME & LOCATION): Medical, A2SC

DATE: April 4, 1974

SUBJECT: Industry Briefing of EPA Task Group on Vinyl Chloride

REFERENCE:

cc: R. L. Bourget - 1870
H. Corbett - E3SH
W. Easley - 1920
C. Eby - 1920
J. Ellsworth - 1870
G. W. Ingle - 1920

TO: George Roush
A2SA

Industry representatives with varied interests in Vinyl Chloride briefed EPA representatives with regard to manufacturing practices, sources of environmental contamination and the potential health effects of VCM. The program that was followed and lists of EPA and Industrial attendees are attached.

It was stated that total US manufacture of VCM was 5.2 billion pounds per year, 95 percent is used in PVC manufacture. US production represents 25 percent of world-wide VCM production. In average PVC production, saleable product represents 94 percent of the starting VCM. One-half of this loss is estimated to be scrap polymer loss and one-half (3% of total VCM) is estimated to be free VCM. The content of free VCM in the polymer is generally in the range of 10 to 2000 ppm. One weighted average (Barr) was placed at 500 ppm with an estimated 60 to 80 percent release during fabrication preceding final product formulation.

Air concentrations within 0.8 mile of the Goodrich, Louisville plant (Holbrook) ranged from 0.17 to 2.2 ppm, the majority of the approximately 50 samples taken contained <0.5 ppm. Dow (Rsuch) data indicated that VCM dissolved in water was very rapidly released. The half-life was approximately 25 minutes in mildly stirred (200 RPM) water. VCM undergoes photolytic decomposition with an estimated halflife of 5 hours in an atmosphere with 2.5 times the untraviolet intensity present at sea level.

The animal toxicity data that has been published was reviewed (Torkelson). There are some major inconsistencies in the results and interpretations of the various studies. In the Dow studies, the major effects were liver weight changes at 500 and 150 ppm. Other US investigators discounted any liver effect even at levels above 500 ppm. Maltoni's review of Viola's (Italian) study confirmed only the Zymbal gland (ear) tumors. No major effects on the liver were detected. In Maltoni's own study, major incidences of tumors in the liver and ear were reported. The

absence of any tumors of any type in Maltoni's ~~study~~ Cancer remains unexplained. Maltoni has a total of 13 experiments underway with VCM.

Twelve cases of angiosarcoma in the livers of workers in plants using VCM were reported (Dernehl). At present, information relating to the level, duration or chronology of exposure has not been summarized. Previous work-related diseases, such as acro-osteolysis, in these individuals have not been described.

EPA Representatives expressed interest in several specific areas. These areas and the consensus of the industrial representative responses are outlined.

1) What manufacturing practices contribute to VCM loss? How much of this loss could be eliminated by good manufacturing practice?
   The response indicated that each manufacturer was already evaluating these areas and no reliable answer was currently available.

2) Are methods available for removing VCM from plant effluent air streams?
   a) Charcoal absorption not efficient because of polymerization on surface.
   b) Incinceration not efficient because of low fuel load.
   c) Solvent scrubbers capable of 90-95% VCM recovery at Carbide.
   d) Cold traps in line with solvent scrubber may increase efficiency.

3) Does technology exist to reduce monomer content in PVC?
   It is feasible. VCM is not highly soluble in PVC and will migrate outward at temperatures above the glass transition point. In general, the greater density and larger the particle, the higher VCM content. Emulsion produced material should be nearly VCM-free.

4) What is the environmental fate of VCM?
   Little definitive infomation is available. Partial pressure, solvent partition, and photostability information would suggest that neither environmental nor biological accumulation would be expected.

Glen Schweitzer stressed the importance of industries approach to the PVC/VCM situation and indicated it will become a model for future materials.

Paul L. Wright

/bkp

Monsanto

FROM (NAME & LOCATION) J. T. Garrett - A2SA

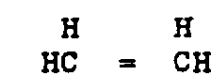
DATE February 26, 1974

COPIES G. Roush
R. E. Kelly ✓
G. J. Levinskas

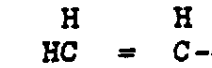
TO E. P. Wheeler
A2SA

The mechanism of the oncogenic response to Vinyl Chloride Monomer (VCM) has not been elucidated to the best of my knowledge. Based on past experience the workers in the cancer field following the Edisonion principal that they have followed in the past will bracket the whole halogenated olifin field. More important, some thoughtfull workers will wonder, as I have, if the mechanism is not more of a function of the olifinic linkage than what specified substituent occupies the alpha carbon. Consider the following series of materials:

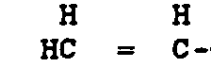
1. ETHYLENE



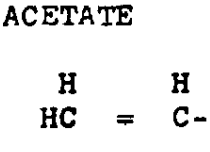
2. VINYL CHLORIDE (VCM)



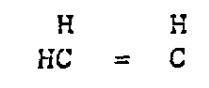
3. VINYL CYANIDE - ACRYLONITRILE (AN)



4. VINYL ACETATE

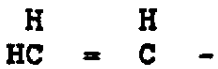


5. VINYL BENZENE - STYRENE (SM)

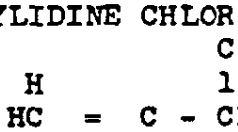


RSV 0011014

6. VINYL BROMIDE



7. VINYLIDINE CHLORIDE



There are a number of these compounds some of which are of very great importance to Monsanto.

The VCM cancer problem came to light through long term vapor inhalation studied in laboratory animals. Vapor inhalation studies, although not new, are somewhat new in the field of occupational carcinogenisis. Future studies for carcinogenisis on gases, volatile liquids and readily sublimable solids will have to be conducted in the vapor phase.

In an effort to be ahead instead of behind the problems created by our products I would strongly recommend that vapor inhalation long term studies be conducted, preferably in concert with other producers, on acrylonitrile (AN), and styrene monomer (SM). I would recommend that Monsanto take the lead with the other producers in this area and do it <u>right</u> now.

I would further recommend that the Italian work on VCM inhalation studies be acquired if possible and the reference to Vinyl Acetate be checked. I understand that the work outlined for the MCA meetin in Chicago showed a single reference to Vinyl Acetate exposure and that these data indicated no problems. It might also be wise to determine from these Italian workers what other olifins they have worked on in the past, are actively working on now, and what they intend to work on in the immediate future.

Jack T. Gerrett

/cm

Monsanto

FROM (NAME & LOCATION): R. M. Sherwood - St. Louis E3SJ

DATE: July 31, 1974

SUBJECT: VCM ANGIOSARCOMA

REFERENCE:

TO: Mr. L. P. Paradis

cc: D. E. Colombo - St. Louis
W. J. Heberle - St. Louis
G. W. Ingle - Washington, D.C
R. E. Murray - Detroit
T. R. VanAcker - St. Louis
E. P. Wheeler - St. Louis A2S

Concerning the excellent questions raised by your memo of July 9, the answers as of July 31 appear to me to be as follows:

1. Question: "How clearly has it been established that VCM is a clear cause of angiosarcoma versus potential for other monomer contaminates?"

   Answer: Most of Washington's career apologists and career alarmists had prior commitments to cover the impeachment proceedings, therefore the VCM question is viewed objectively by responsible observers as follows: Beginning with the early reports from Italy and then the clarifying results from the MCA-funded tests at Bio-Test, it appears that inhalation of some concentration of VCM for some long period of time is associated with an angiosarcoma fate for some mice, some rats, and some humans. No mechanism is known, therefore the consensus on the causal effect of VCM is based on statistical inference. One of the leading theorists, Dr. Maltoni, has been quoted as being "suspicious of all compounds of the carbon-chloride group" which would lead investigation away from decomposition product HCl and away from vinyl benzene.

2. Question: "What exposure levels of VCM are alleged to be causing the problem?"

   Answer: Latest reports have been on mice and rats inhaling concentrations between 50 PPM and 2,500 PPM. After seven months the mice in the USA study and the rats in the European study both have shown tumor incidence at 50 PPM. Tests to prove a "negative proposition," i.e., to quantify a threshold VCM concentration below which no deleterious effects occur, will be done on mice and rats. Extrapolation of any of these rodent data to humans will be contentious in the scientific fraternity, but it's the best we have.

   Concerning the two dozen people who were exposed to VCM and then known to have died from angiosarcoma, the best industry estimates are that most were exposed for years to levels of VCM exceeding several hundred PPM. Furthermore, to our current knowledge no worker has suffered

liver function impairment at levels of 50 PPM of VCM, or less. (It is worth mention at this point that numbers quoted are "time-weighted average" unless otherwise stated. This allows transient "excursions" to a higher level if the average is kept within limit.)

3. Question: "What VCM levels are the various groups seeking to get regulated?"

Answer: First OSHA instituted an Emergency Temporary Standard of 50 PPM which is valid until October 5. Then OSHA proposed a Permanent Standard of "no detectable using measurements accurate to 1 PPM" and put it out for comment. Thereupon:

A. A. D. Little under contract to SPI estimated that the proposed permanent standard of 1 PPM ("no detectable level") would shut down the domestic PVC producing plants which ultimately could result in a loss of 1.7 - 2.2 million jobs.

B. The AFL-CIO representative said industry was using "scare tactics" and "hysteria;" but further said they "would not trade lives for jobs" and would "get along without PVC" if necessary.

C. OSHA said "There isn't any likelihood that we're going to put the industry out of business;" but also indicated that this would be a precedent-setting case and "any doubt must be resolved on the side of the employee."

D. SPI on behalf of the VCM and PVC producers proposed a sliding scale from 25 PPM in 1974 down to 10 PPM in 1976. OSHA appeared to accept the sliding scale principle without commenting on the levels or on the two year time interval.

E. The National Cancer Institute confirmed that VCM "fulfills the requirements for a proven carcinogen."

F. NIOSH presented preliminary data taken from unannounced measurements taken on PVC kettle floors. NIOSH also stated that there is "no way to demonstrate the safe level of a carcinogen."

G. General Motors stated that its suppliers could not meet the "no detectable level" standard and estimated that shut-down of GMC car production would cost perhaps 1.8 million jobs nationwide.

4. Question: "What's the consensus of most probable VCM level that will be regulated? Near term and long term?"

Answer: There is no consensus, just speculation. If OSHA accepts the industry proposal of 25/10 it probably will be sued by Ralph Nader for dereliction of duty to the worker. If OSHA keeps its "no detectable" stance it must be sued by the producers for acting against the intent of Congress when the law was enacted. On the third hand, if OSHA were to try to make a political compromise by perhaps specifying TWA's of 20 PPM in '74, 10 PPM in October '75, and 5 PPM in October '76 it conceivably could get sued by both sides.

My guess is that OSHA will make no commitments until October so that it will have whatever information surfaces in the interim. Then OSHA will specify the level it feels is necessary to protect the worker. At that point the producers will probably have to get an injunction to produce at the 25 PPM they themselves proposed, the courts will in subsequent months interpret the law for us, and the time period of the proceeding will be spent by everyone continuing to try to develop the "engineering controls and workpractice methods" necessary to minimize usage of respiratory protection equipment.

5. Question: "What VCM levels are involved in polymerization, compounding, and in the finished product?"

Answer: It varies from "no detectable" to more than several hundred PPM.

The responsibility must finally devolve upon the resin producer to make and ship a low-VCM product. The resin customer still will have to provide ventilation where bags are opened or hopper cars unloaded, since the air space above resin will have VCM in it if any is present in the resin as shipped. Proper ventilation over mill rolls will continue to be necessary, and perhaps also at extruder die openings. The SPI proposes that resin with less than 1000 PPM will not be a problem for fabricators. Armstrong Cork sets the number at 2000 PPM. I have not seen supportive data from either one.

In finished products the FDA is considering an interim "food additive" order for PVC which would limit VCM to 10 PPM in rigid PVC, 1 PPM in flexible film, and 50 PPB in food. If issued in present form it will apply also to potable water pipe. I gather that this would vacate PVC's GRAS and prior sanction stati.

6. Question: "What are the affected industries' abilities to conform to these various levels?"

Answer: No one wants to volunteer to be the first to be quoted. Surely the vinyl-asbestos floor tile people are a step ahead of the phonograph record people on VCM and VAM ventilation due to the longer-established asbestos problem. The principal determinant in conformation probably will be getting delivery on the needed hardware.

7. Question: "What's the likelihood that PVC will be wiped out of food packaging, potable water, etc.?"

Answer: Concern about angiosarcoma from VCM extracted from PVC potable water pipe is in my judgement asinine. I feel sure that PVC producers supplying the pipe industry will be able to supply resin with VCM low enough to permit pipe to be made to FDA's reasonable standards. Concerning PVC for food applications like Oscar Mayer bologna rack-display packages, PVC-Saran bacon wrap, flexible meat wrap film, rigid produce wrap, half-gallon Bourbon bottles, and other food bottles; comments as follows:

A. By pulling vacuum on vents of extruders Oscar Mayer probably can continue making PVC bologna packages. If not they probably will look to ABS for the yellow bases and perhaps clear ABS for the tops. (This should be clarified by mid-August.)

B. For bacon wrap, Saran PVDC's monomer must be considered just as suspect as VCM until proved innocent. Undoubtedly Dow has thought of this and is acting.

C. For food-grade PVC meat wrap and produce wrap there may be difficulties getting the VCM out at the PVC resin dryer and at the film extruder without exceeding heat stability limitations. (We should ask ourselves if we have any patent position on prestabilized PVC resin, i.e. calcium-zinc or epoxydized soya oil charged in the slurry tank, so that resin may be stripped harder in the drier.) This VCM problem may prove an Achilles heel in food film applications such that Reynolds, Borden, etc. cast around for replacement films that will heat seal and handle on automatic equipment satisfactorily as well as have desirable barrier properties to oxygen. If we have film ambitions for our barrier resins we

should work with Borden and Reynolds to define the market and put our opening thrust against PVC where its use is technically or toxicologically borderline.

D. In FDA bottles the game is essentially over for PVC. Barrier resins, glass, clear polypropylene, and polyethylene all can take pieces out of the PVC market. In 1970 my 1975 forecast for PVC bottles total food/non-food was the most pessimistic in the industry. In 1973 it looked on the nose. Now it looks optimistic.

8. Question: "What are the volumes involved in the above question? What polymers are substitutable? What would be the impact on the plastics industry and our market as a whole?"

Answer: We are not staffed for this degree of omniscience.

If we have reason to believe that barrier resins could compete with Saran and PVC films in performance, we should:

A. Start to find out more about the toxicity of these barrier resins than we ever thought we would need to know.

B. Pick likely markets and then go out and do the work to get the market answers to these questions.

9. Question: "What are the signs of similar federal or societal concerns in other polymer areas? For example, the aforementioned AN or HCN in ABS, SAN, or barrier resins?"

Answer: All responsible men are trying within their own pervue to apply this startling lesson learned from VCM.

A. The EPA has a task force looking at VCM-PVC at each stage in its life cycle from birth through disposal/-destruction. Measurements of VCM concentrations in neighborhoods near PVC plants have to date been satisfactorily low values. EPA also is looking at VCM half-life in sunlight, decomposition products, and so forth.

B. The FDA is moving quickly but quietly to "be sure we know all we should" and then take effective, responsible action on plastics now having prior sanction or GRAS status.

C. Our chemical industry is initiating and funding feeding studies and inhalation studies on monomers

and polymers related and unrelated to PVC without any outside suasion. Costs will be in the hundreds of thousands of dollars.

RECOMMENDATION

I know you are interested in my suggestions about the listening posts we need and the role we should play in this matter.

I. This monomer carcinogenicity problem is so basic and so important that every function in our business is touched -- medical, manufacturing procedures, engineering design, legal, research, marketing, and the others. In my opinion there should be for marketing two partially redundant sources of information:

A. Medical Department leading a high-level task force in the best interests of our employees, neighbors, and customers. Exchange of information within our industry as necessary and proper. Sensitive information handled. Reports written to the General Manager or functional Director levels, with the Director of Marketing passing the information downwards per his judgement.

B. Our Washington office keeping themselves informed of activities of SPI, Keller & Heckman, FDA, OSHA, CPSC, NOISH, and so forth. Generally non-sensitive information handled. Reports passed on as developments happen, to the manager level of interested groups as well as to the Director of Marketing.

II. As to what Market Development action should be initiated I feel this PVC packaging problem should be considered an opportunity for barrier resins in existing oxygen-sensitive applications, therefore Commercial Development gets to carry the ball.

III. Finally, while I have this blank page in front of me, I want to suggest for consideration the application of the Rand Corporation's "Think Tank" technique, more formally known as the Delphi method. Envisioned is a Scientist and Senior Scientist peer group considering the questions:

A. "What is it about VCM which could initiate cancer?"

B. "What other chemicals share this feature with VCM?" (Especially consider styrene monomer, acrylonitrile, and butadiene.)

C. "What chemicals are completely unlikely to act similar to VCM?"

D. "For each mechanism elicited from Question A above, can we predict the existence of an anticarcinogen, or perhaps an inhibitor for VCM which renders it harmless at body temperatures?"

E. "Is there a type of radiation which will give 50 PPM of VCM a half-life of seconds?"

F. Other derivative questions.

I have attached a Harvard Business Review article about the Delphi method.

Roger

R. M. Sherwood

RMS/bh

attach.