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File UCM

Attached for your information is a good summary of the OSHA Conference on Vinyl held in March. It does a good job of explaining the state of the art.

A handwritten signature in cursive script, appearing to read "J.J. Hall".
J.J. Hall

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cc: PVC File

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Summary of Conference to Reevaluate the Toxicity of Vinyl Chloride, Polyvinyl Chloride and Structural Analogues

The conference was a review of the real or alleged health hazards from vinyl chloride and polyvinyl chloride, in relation to the workplace and the community. There was little new information. Both industry and government have been long familiar with the important animal and epidemiological studies on vinyl chloride which formed the basis of this symposium.

Some issues as possible future concern to the industry did arise:

- o The alleged relationship between vinyl chloride monomer and brain cancer: the possible new evidence, and new reorganizations of older evidence might be interpreted to give added strength to the argument for a link between VCM and brain cancer.
- o The evidence for teratogenic effects of vinyl chloride, while not terribly persuasive, cannot be discounted because of the media value of such an issue. For the same reason, reports of links between VCM and breast cancer cannot be ignored.

- o There was a great deal of evidence presented to demonstrate that polyvinyl chloride dust does indeed cause pneumoconiosis, and perhaps a number of other pulmonary diseases. From the volume of material presented, it would appear that OSHA has become very interested in PVC dust as a workplace hazard.
- o Of particular interest to industry were two papers presented on the use of power, which is a quantification of a study's sensitivity or ability to detect an increase in risk. Negative studies which have a high power, ability to detect a small increase or decrease in an effect, would carry greater weight. Strategic use of power could enhance industry ability to gain acceptance of test results where effects have not been seen and may provide a factual weapon for demonstrating non-validity in studies of poor design. All of these concerns are discussed in greater detail below.

The symposium thoroughly reviewed the carcinogenicity of vinyl chloride monomer, and attempts were made to link VCM with brain and lung cancer, as well as hepatic angiosarcoma, in both animal and epidemiological studies (see discussion below.)

Several papers attempted to show a relationship between vinyl chloride and birth defects or other reproductive problems.

In the sessions dealing with polyvinyl chloride, the primary emphasis was on the relationship between PVC dust and pneumoconiosis. (See discussion.) Participants reported on the results of animal testing with PVC dust in addition to epidemiological and case studies of PVC workers. There was also a dubious report on PVC as a carcinogen, by Dr. Chris Wagner of Wales. An epidemiological study by Richard Waxweiler of NIOSH suggested a link between PVC dust and lung cancer.

The conference also dealt briefly with effects of vinyl chloride and polyvinyl chloride in communities where plants are located. Industry was given a clean record on environmental exposure except in the area of alleged teratogenic effects. Reviews of the literature by Downs et al. and MacMahon have clearly established the numerous flaws in these studies. However, neither these reviews nor the deficiencies were mentioned.

The final sessions of the conference discussed, rather inconclusively, the carcinogenicity of structural analogues

of vinyl chloride and attempted to discuss the role of public health agencies in dealing with toxic substances.

Observations:

- o VCM and brain cancer: Dr. Maltoni's testing suggested a causal relationship between VCM exposure and cancers of the brain, although Maltoni was not able to show a dose-response relationship. However, epidemiological studies, in particular the industry-sponsored EEH study, also showed a somewhat higher incidence of brain cancer in workers with heavy VCM exposure.

These findings were confirmed by tests of the power of epidemiological studies by Dr. Jay Beaumont of NIOSH: studies with positive results had a higher power than negative studies (i.e., had a statistically better chance of being accurate), and when plotted, showed the expected trend for a carcinogenic response.

The results suggest the need for further studies on VCM as a possible brain carcinogen.

- o VCM and breast cancer: As reported in an earlier summary, Maltoni has produced breast tumors in

mice in exposures as low as 10ppm. At this time, there is no other data to support these results.

- o VCM, PVC, and lung cancer: A study by Dr. Y. Suzuki of Mt. Sinai Medical School, attempted to link VCM exposure with tumors of the lung in twenty-six mice (out of 27 exposed.) The study has not been reproduced, and is not supported by most epidemiological data. Furthermore, tests of power for lung cancer results showed a lower power for studies with positive results and a higher power for those that were negative. So there is no valid statistical increase in risk of lung cancer for VCM workers at this time.

Similarly, Dr. Richard Waxweiler's case-control study of lung cancer among vinyl chloride and PVC workers, purportedly showing an increased risk for workers exposed to PVC dust, cannot at this time be considered significant.

- o Reproductive Effects of Vinyl Chloride: Results of studies by Dr. Jackie John of Dow Chemical showed that exposure to vinyl chloride in doses high enough to cause maternal toxicity did not

produce teratogenic effects in the mice, rats or rabbits tested. Dr. Jill Fabricant of the University of Texas sought to show teratogenicity by proving mutagenicity (a dubious linkage). Tests of power, by Maureen Hatch of Columbia, showed that most studies with negative results were of greater validity than tests that showed a greatly increased risk of reproductive anomaly.

There is little hard data suggesting vinyl chloride is a teratogen. However, there is fuel for controversy in this issue, and its attractiveness for the media cannot be discounted.

- o PVC Dust and Pneumoconiosis: Results of animal testing and epidemiological studies presented by several participants in the conference strongly suggested that there is a link between PVC dust and pneumoconiosis. Conference reports indicated that PVC dust is respirable and that it lodges in the lung and can decrease breathing capacity. The study sponsored by ICI showed that the group of workers who smoked and were exposed to heavy concentrations of PVC dust showed a significant decrease in breathing capacity. A perceptible but not significant decrease occurred in workers who didn't smoke.

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It is possible that the government will move to lower the limit for concentration of PVC dust in the workplace. At this time, the limit is $10\text{mg}/\text{m}^3$ of respirable dust, although the exposure levels at many plants are well below this. Community exposure to dust could also be perceived as a potential health hazard.

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