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R. N. WHEELER

PPG INDUSTRIES, INC. / ONE GATEWAY CENTER / PITTSBURGH, PENNSYLVANIA 15222

November 23, 1971

Mr. R. N. Wheeler, Jr.
Union Carbide Corporation
Chemicals & Plastics Division
P. O. Box 8004
South Charleston, W. Va. 25303

Dear Mr. Wheeler:

It was requested at the Washington, D. C. meeting of vinyl chloride producers that we submit comments to you on the proposed research program on vinyl chloride carcinogenesis and a method for sponsoring such a study.

We feel that the objectives of the test program are three-fold.

- (1) To duplicate using one exposure level the test results obtained and published by Dr. Viola. This test would be on material obtained from the same source used by Dr. Viola.
- (2) To determine whether ethylene derived vinyl chloride (U. S. VCM) is carcinogenic. This data should be obtained by employing one animal species using either male rats only or male and female rats. The exposure level should be comparable to that tested in (1) above (5000 ppm V/V).
- (3) Contingent upon positive confirmation of carcinogenesis from U. S. VCM, it would be necessary to establish a "no effect" level by introducing lower exposure levels.

We do not see the advantage of using both rats and mice in order to establish whether U. S. VCM is carcinogenic. In Dr. Viola's study he used male rats only. The study need not necessarily contain females. It is our desire to have a protocol designed to determine first whether U. S. VCM of the purity normally encountered in U. S. production is carcinogenic. This study should include one exposure level to male rats and maybe female rats (Wistar Strain) for each material, as well as, a non-exposed control group. This protocol should answer the

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question of carcinogenesis of U. S. VCM and also confirm or fail to confirm Dr. Viola's observation using acetylene derived vinyl chloride containing 2-3% impurities. This study should clarify the importance of VCM impurities in the observed formation of tumors.

We feel that this protocol is reasonable and should be undertaken as soon as possible in the event pressure is brought on the manufacturers by governmental agencies because of Dr. Viola's publication on this subject. We feel it is not necessary to initiate an extensive study involving numerous exposure levels until the primary objective has been determined. The second phase of the study would depend upon the results obtained from the first phase. Should U. S. VCM produce tumors, it would be necessary to establish a "no effect" level where tumor formation did not occur. This would be accomplished by expanding the study and introducing lower exposure levels of U. S. VCM. On the other hand, if the incidence of tumor formation were not increased, then there would be little value in expanding the study to include lower exposure levels. Phase III would be an epidemiological study also predicated on positive findings of increased incidence of tumor formations employing U. S. VCM.

We would like to comment on the purity and analytical methods. There is probably very little difference in the purity of U. S. VCM among manufacturers in this country, therefore, the supplier can be one of many. The test material should come from only one supplier in one ton cylinders (one ton cylinders are the most practical containers for various reasons). The purity of the test material supplied should be well documented by an analytical method agreed upon in advance by the sponsors. The material should be purchased so that the quality is reliable and within agreed upon specifications. The purchase price for the test material should be included in the program cost to be shared by the sponsors.

We favor pro-rated sponsorship based upon published production capacity from manufacturers and published consumption of VCM for PVC manufacturing. Our participation, of course, would be contingent upon sufficient interest in other companies to share the costs. We would hope that the above comments will be favorably considered and incorporated in the final protocol. We are not rigid in our position, however, we feel that the objectives can be fulfilled by a program as outlined above. We will be pleased to assist the Ad Hoc members in any way we can to arrive at a practical and technically sound study.

Yours very truly,



Zeb G. Bell, Jr., Sc.D.
Director Environmental Control

ZGB/hab

Cc: M. V. Anthony, Stauffer Chemical Co.
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