



CHEMICAL MANUFACTURERS ASSOCIATION

June 30, 1987

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Gerald A. Emison
Director
Office of Air Quality Planning & Standards
United States Environmental Protection Agency
Research Triangle Park, NC 27711

Re: Testing of Vinylidene Chloride
Under Section 4(a)(1)(A) of TSCA

Dear Mr. Emison:

I am writing on behalf of the Chemical Manufacturers Association Vinylidene Chloride ("VDC") Program Panel to convey our concerns about the proposed use of Section 4 of the Toxic Substances Control Act to require yet another long-term study of VDC. I would also like to request a meeting to discuss these issues.

As you know, EPA is authorized to require testing of chemical substances under section 4(a)(1)(A) of TSCA only on making the following findings: first, that the manufacture, use, distribution or disposal may present an unreasonable risk; second, that the available data are insufficient to enable EPA to reasonably predict or determine the health effects; and third, that the proposed testing is necessary to enable the Agency to make such a prediction. The VDC panel believes that the present extensive data base is sufficient to enable EPA to make a reasonable prediction of possible carcinogenic effects without the need for another oncogenicity study.

The Agency's ability to make a reasonable determination or prediction of carcinogenic effects of VDC is well established. The air office -- using existing data -- evaluated potential human risk in its consideration of VDC under Section 112 of the Clean Air Act. The agency prepared a Health Assessment Document, which contained a carcinogenicity risk assessment, and concluded that possible risks are extremely small. While the Panel may not agree with all of the details of the EPA risk assessment, it is clear that the Agency can make a reasonable prediction of risks.

We understand your desire to obtain a better data set on which to base an estimate of cancer potency. It is certainly possible to improve the data base for assessing VDC

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carcinogenicity, as it is with any chemical, regardless of how extensive the current data base is. However, a test rule under Section 4(a)(1)(A) of TSCA is not available to the Agency simply to improve the data base, when a reasonable prediction of carcinogenic potential can be made on the basis of the already extensive data.

The CMA VDC Panel has expressed its willingness to work with the Office of Air Quality Planning and Standards to improve the Agency's risk assessment for VDC in a way that does not require that the Agency exceed its authority under Section 4 of TSCA. The Panel has conducted a survey of manufacturers and users of VDC to better estimate emissions and potential exposures to VDC. This information, together with information on pharmacokinetic modeling, may assist the Air Office in improving its risk assessment for this chemical. We would welcome an opportunity to meet with you and your staff at your offices to discuss these issues. We would suggest July 23 or 30 as possible meeting dates.

If you have any questions, please do not hesitate to contact us. We are awaiting your response regarding the meeting.

Sincerely yours,



Robert R. Romano, Ph.D.
Manager, Vinylidene Chloride Panel
Program Panel

cc: Ron Campbell
John O'Connor
Gary Timm

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