

DRAFT

February __, 1987

Mr. Ralph Northrop
Test Rules Development Branch
Office of Toxic Substances
Environmental Protection Agency
Room 101, Northeast Mall
401 M Street, S.W.
Washington, D.C. 20460

Re: Proposed Test Rule for 1,1-Dichloroethylene
(Vinylidene Chloride)
OPTS-42081

Dear Mr. Northrop:

On January 15, 1987, the Chemical Manufacturers Association ("CMA") Vinylidene Chloride Program Panel ("VDC Panel") submitted comments on EPA's proposed test rule for 1,1-dichloroethylene (vinylidene chloride). The comments point out that EPA's proposal raises significant scientific issues regarding interpretation of the extensive existing data regarding vinylidene chloride. The comments also present additional pharmacokinetic and metabolism ^{data} ~~studies~~ and suggest

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that these ^{data}~~studies~~ should be used by EPA in carcinogenicity risk assessment.

The VDC Panel looks forward to discussing these significant scientific issues with EPA scientists at the February 12, 1987 public hearing on EPA's proposed test rule. In that connection, I am enclosing a suggested agenda for the public hearing which is intended to foster and accommodate a scientific dialogue on these issues among scientists from EPA and from industry. The VDC Panel believes that the public hearing will be most productive if it can serve as a forum in which to commence such a discussion among the appropriate scientists.

The VDC Panel will identify those scientists who could best contribute to a discussion of the issues raised in our comments. We request that EPA furnish by February 9 a list of scientific personnel from offices within the Agency such as OAQPS and OTS, as well as from other relevant federal agencies such as NTP, who plan to attend and participate in the public hearing. The Panel will then attempt to bring scientists who can most appropriately engage in a scientific discussion with the government experts.

The VDC Panel would welcome any suggestions you might have on how best to achieve the objective of conducting a

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meaningful and productive scientific dialogue on the issues
raised in our comments. We look forward to seeing you on
February 12, 1987.

Sincerely yours,

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

Enclosure

cc: Carol Glasgow

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PROPOSED AGENDA
FOR FEBRUARY 12, 1987 PUBLIC HEARING
ON PROPOSED TEST RULE
FOR 1,1-DICHLOROETHYLENE (VINYLIDENE CHLORIDE)
OPTS-42082

I. Introduction -- History and ~~Basics~~ of EPA Proposal EPA

II. ~~Introduction~~ ^{Product} Brief Summary of VDC Program Panel Comments on EPA Proposal

III. Discussion and Assessment of Existing Toxicity Database for VDC

A. Adequacy of Existing Oncogenicity Studies

B. Adequacy and Utility of Metabolism and Pharmacokinetic Data in Assessing Existing Oncogenicity Database

1. Interpretation of metabolism and pharmacokinetic data

2. Identification of data gaps regarding pharmacokinetics

C. Discussion of Exposure and Emissions Data

IV. ~~Utility of~~ Metabolism and Pharmacokinetic Data in ~~carcinogenicity risk assessment~~ ^{risk assessment of VDC}

1. ~~Utility of pharmacokinetic data in risk assessment~~ ^{Proposed DEM studies}

2. Identification of ~~additional~~ Pharmacokinetic data which might provide useful information for risk assessment for VDC

3. ~~Proposed modelling~~ (provide description: will proposal be for toxicity modelling, risk assessment modelling, or both?)

V. Discussion of Effects of Additional Data on Risk assessment

*Sackagudo
Lorano*

VI Summary/Conclusion

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