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Hasmukh Shah, Ph.D.
Manager,
Vinyl Chloride Health Committee
Chemical Manufacturers Association
1300 Wilson Boulevard
Arlington, VA 22209

Dear Dr. Shah:

My comments on ATSDR's Draft Toxicological Profile for Vinyl Chloride (dated August 1995) are listed below. All of the comments refer to the Health Effects section and in particular, the Adequacy of the Database subsection.

- 1) The profile suggests that there is concern about the oral route of exposure and the present lack of toxicology data by this route of exposure. On p. 120 -121 of the profile, it is stated that acute and intermediate duration studies should be performed using the oral route of exposure in order to examine developmental, neurological, and systemic effects. The profile indicates that this research would be useful in determining whether any effects would occur when vinyl chloride contaminated ground water or food products are consumed. However, there is little evidence in this profile to indicate that this route of exposure is relevant to human health. On p. 3, the profile states that most drinking water supplies do not contain vinyl chloride and the extent of contaminated wells is unknown. Furthermore, the profile goes on to state that because the U.S. government now regulates the amount of vinyl chloride that goes into food packaging, basically no vinyl chloride is present in food which comes into contact with these products. Thus, it seems the focus of data gathering should be to gain a greater understanding of the potential for exposure by the oral route. If there is no potential exposure by this route, then there is no justification to perform these toxicology studies.

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- 2) On p. 123-124, the profile states that reproductive and developmental toxicity studies with inhalation as the route of exposure should be performed in rodents. A memorandum of understanding will be signed shortly between ATSDR and CMA for a voluntary research project which will address both of these data needs.
- 3) In the last sentence on p. 119, the profile indicates that acute inhalation studies examining the threshold for cardiac irregularities would be useful. Following a recent reevaluation of the data, William Cibulas of ATSDR (in a letter to CMA dated November 8, 1996) states that there is no need to conduct additional inhalation studies of acute duration. This should be reflected in the profile.
- 4) On p. 56 of the profile, it is stated that studies of acute and intermediate duration by the oral route have not been conducted. However, on p. 118, there is a table indicating that there are published studies of intermediate duration by the oral route.

If you have any questions concerning my comments, please do not hesitate to call me at (412) 434 - 2245.

Sincerely,

Heather D. Burleigh-Flayer

Heather D. Burleigh-Flayer, Ph.D.

cc: Dr. J. Barter - GO

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