

**"VINYL CHLORIDE: COMBINED INHALATION TWO-GENERATION REPRODUCTION
AND DEVELOPMENTAL TOXICITY STUDY IN CD RATS" (PROTOCOL)**

PEER REVIEWER COMMENT FORM

August 1995

Name Ronald D. Hood, Ph.D.

1. Are the study objectives clearly stated and appropriate?

☒ **Yes**

☐ **No**

☐ **Unsure**

Why?

This is a relatively routine type of study, and the protocol concisely states what is to be done.

2. Is the study design appropriate for the study objectives?

☒ **Yes**

☐ **No**

☐ **Unsure**

Why?

The design is typical for studies assessing a chemical's potential for reproductive or developmental toxicity.

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3. Are the methods selected appropriate for the study objectives?

Yes

No

Unsure

Why?

The methods proposed are typical of the proposed types of tests.

4. Any overall comments on the protocol?

The protocol appears to be quite thorough and well planned. It should be quite adequate to carry out the proposed objectives. I did not find any technical flaws in the protocol, but there are a few typographical errors, which I have circled with pencil in the draft. I have only two additional questions/comments:

1. On page 6, first paragraph, the statement is made that the high inhalation dose of 1012 mg/kg/day "was selected based on the oral equivalent of the limit dose of 1 mg/kg body weight/day." Shouldn't that have been 1000 mg/kg body weight/day instead of 1?
2. The value in mg/kg/day that I obtain when I use the example on page 6 is 1009.8, which rounds to 1010, not 1012. The difference is trivial, but someone might want to check on the discrepancy.

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Select the appropriate category below (List recommended changes or reasons for not recommending:

A. Recommend (☒)

B. Recommend with Required Changes (☐)

C. Not Recommended (☐)

Ronald D. Hood 8-3-95
Signature Date

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5. Any comments on ATSDR's peer review process?

The review process seems appealingly simple and straight forward.

6. Any other comments?

Call on me again if I can be of assistance.

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