August 26, 2002

Mr. John Morris
American Chemistry Council
Aliphatic Esters Panel
1300 Wilson Boulevard
Arlington, VA 22209

Dear Mr. Morris:

We have conducted a review of the Aliphatic Esters category submitted by the Aliphatic Esters Panel as part of their commitment made under the HPV Challenge Program. Our analysis focused initially on the category justification and implementation strategy with the aim of determining the feasibility of achieving the stated objective of characterizing members of this group with the proposed design.

Our analysis concluded that, while the category proposal appears to be a reasonable approach to characterize the category, the implementation strategy was difficult to grasp. The organization and presentation of data in the document should be improved to increase clarity and facilitate analysis. A major problem in evaluating this proposal is the poor documentation provided for both category components and analogs. There are incomplete or missing robust summaries.

Some examples include the following:

1. The proposed test plan could have been five separate submissions since it consists of one category with five subcategories. Although not explicitly stated, it appears that the subcategories are unrelated because there is no proposal to use data from one category for use in another category (e.g., data in Group A chemicals will not be used for any other group).

2. Although some information is provided regarding the intention of developing a “technical discussion” to show why either no genetic toxicity (for chromosomal effects) or developmental/reproductive toxicity studies are necessary for subcategories A, C, D, and E, it is difficult to evaluate whether this is a reasonable approach unless the discussion is presented.

3. There are 45 HPV substances and approximately 17 non-HPV substances in the five categories. In all of the “non-IUCLID” robust summaries, references are not provided for the studies summarized.

These deficiencies make it difficult to understand how the implementation strategy will lead to the desired characterization.

I encourage the Aliphatic Esters Panel to take the necessary steps to make this category viable. We are prepared to proceed to data adequacy determinations as soon as we get your response.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site “Submit Technical Questions” button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

Sincerely,

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Oscar Hernandez, Director
Risk Assessment Division