November 13, 2001

Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116
Attn.: Chemical Right-To-Know Program

Dear Ms. Whitman,

The Industrial Health Foundation Cyclic Anhydride Committee appreciates the comments received by the U.S. Environmental Protection Agency (EPA), People for Ethical Treatment of Animals (PETA), and Environmental Defense concerning the test plan submitted by the Cyclic Anhydride Committee in response to the EPA's HPV Challenge Program. The purpose of this letter is to respond to all interested parties. The majority of EPA's specific comments will be addressed in the revised test plan and robust summaries for phthalic anhydride accompanying this correspondence.

Due to the limited data available for these chemicals and the lack of hydrolysis information, the test plan will be modified as necessary dependent upon results from physicochemical tests. Testing results for ecotoxicity, repeat dose and reproductive toxicity will actually reflect the anhydride, the diacid, or a combination of the two. Regardless of hydrolysis results, the anhydride will be used as the starting material for dose application with the possible exception of ecotoxicity tests. ICCA information for MTHPA will be incorporated into the test plan as it becomes available.

General Comments:

The Committee understands that the category approach for these chemicals needs to be supported by more toxicological data and intends to revise the test plan and submit additional information as test data becomes available.

The committee has planned additional testing to fulfill HPV requirements for ecotoxicity data and clarified the committee's position concerning the repeat dose and reproductive toxicity tests planned for NMA. PETA has raised concerns about the necessity of the animal tests planned. Aside from the combined repeat dose and reproductive toxicity test performed under ICCA for MTHPA, to date, the committee has not located definitive information concerning repeat dose and reproductive toxicity. The committee's position concerning the available data is stated more clearly in the test plan. Due to lack of information, and the limited information that indicates phthalic anhydride may have the potential for reproductive toxicity, the committee feels that definitive results will be necessary to evaluate the toxicity of this category.

The committee is aware of the need for valid physicochemical data for these compounds and as stated in the initial test plan, has planned testing for all chemical/physical properties that were not adequately referenced. On the EPA's recommendation the log P value will be calculated and EQC Level III modeling will be used for estimating transport and distribution. The committee does not feel that testing is warranted for vapor pressure as available data indicates these compounds have a low vapor pressure. The committee has planned modeling based on Pitzer's method as opposed to actual testing.

The THPA and HHPA robust summaries for genetic toxicity were considered deficient in the original test plan due to lack of detailed information. These studies were only available to the committee as tables and "summaries". The original studies were unpublished and are not available. The Committee agrees with the EPA that the information is inadequate and has proposed testing an additional chemical, HHPA, for in vitro (bacterial) genetic toxicity.

The committee appreciates this opportunity to respond to comments from EPA and PETA. Please address any questions or comments concerning this letter or test plans to: Dr. Henry Trochimowicz, Sc.D., Delaware Toxicology Associates, Inc., 14 Lamatan Road, Newark, DE 19711; Phone: (302)239-4725; E-Mail: hjtroch@aol.com.

Sincerely,

Janice M. O'Polka
Project Coordinator

cc:
Karen Florini, Senior Attorney
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Jessica T. Sandler
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