

June 22, 2004

Janet M. Mostowy, Ph.D
Vice president
Product Safety & Regulatory Affairs
Bayer Corporation
100 Bayer Road
Pittsburgh PA 15205-9741

Dear Dr. Mostowy:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for N-phenyl-1-naphthalenamine posted on the ChemRTK HPV Challenge Program Web site on February 19, 2004. I commend Bayer CropScience LP for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. EPA agrees with the test plan for these endpoints.
2. Health Effects. EPA believes that the submitter has not adequately justified not conducting reproductive and developmental testing. The same level of documentation needed to support a "closed system intermediate" claim for reduced testing is needed here. Even if that were met, a developmental toxicity test is needed in any event.
3. Ecological Effects. EPA is in partial agreement with the test plan for these endpoints. The submitter needs to provide a robust summary for the algal endpoint indicating an effect value of <1 mg/l (i.e., highly toxic) based on the fish and algae data or conduct an algal toxicity test..

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that Bayer advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

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 "Contact Us" link on the HPV Challenge Program Web site pages 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.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber