

June 15, 2004

Sarah Loftus McLallen
ACC Petroleum Additives Panel
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. McLallen:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Nitric acid, 2-ethylhexyl ester posted on the ChemRTK HPV Challenge Program Web site on February 17, 2004. I commend the Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG) 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 cannot comment on these endpoints without the necessary details (robust summaries and references) on the physicochemical properties of the the sponsored substance. EPA agrees with the proposed test plan, but the submitter needs to provide the test protocols that will be used to measure boiling point (assumed to be OECD TG 103) and vapor pressure (OECD TG 104). It is suggested that the fugacity model be run using Level III instead of Level I and that OECD TG 301 is followed for assessing biodegradation.

2. Health Effects. Data provided on acute toxicity and repeat-dose toxicity are sufficient for the purposes of the HPV Challenge Program. EPA agrees with the proposed test plan and suggests that the developmental and reproductive toxicity endpoints be met using OECD TG 421 and that the chromosomal aberration endpoint be met by using the in vitro cytogenetic assay (OECD TG 473). EPA believes the bacterial gene mutation study may not be adequate for the purposes of the HPV Challenge Program.

Genetic toxicity. The bacterial gene mutation test provided was performed at relatively low doses (0.1 microliters/plate, which is equivalent to approximately 100 micrograms/plate) given that most protocols for this test suggest testing up to 5000 micrograms/plate. Please provide information on whether higher concentrations were attempted but could not be sustained because of cytotoxicity, precipitation, etc.

3. Ecological Effects. Data provided on the aquatic toxicity to fish, invertebrates, and algae appear sufficient for the purposes of the HPV Challenge Program, however, EPA reserves judgment pending the receipt of more information on water solubility.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that HERTG 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