November 8, 2002

William J. Greggs
Product Safety and Regulatory Affairs
The Procter & Gamble Company
Miami Valley Laboratories
11810 E. Miami River Road
Cincinnati, Ohio 45253

Dear Mr. Greggs:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Nonanoic acid, sulfophenyl ester, sodium salt, posted on the ChemRTK HPV Challenge Program Web site on July 11, 2002. I commend The Procter & Gamble Company 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 HPV 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 will post this letter and the attached comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The Procter & Gamble Company advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

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

Attachment

cc: C. Auer
A. Abramson
M. E. Weber
W. Penberthy

EPA Comments on Chemical RTK HPV Challenge Submission:
Nonanoic Acid, Sulfophenyl Ester, Sodium Salt

SUMMARY OF EPA COMMENTS

The sponsor, The Procter & Gamble Company, submitted a test plan and robust summaries to EPA for nonanoic acid, sulfophenyl ester, sodium salt (nonanoyloxybenzene sulfonate, NOBS, CAS No. 91125-43-8) dated June 28, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on July 11, 2002. Data on the analogs, sodium octanoyloxybenzene sulfonate (C_8 AOBS) and sodium decanoyloxybenzene sulfonate (C_{10} AOBS) are also included.

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

1. Physicochemical Properties and Environmental Fate. EPA agress that adequate data are available for all endpoints except for photodegradation. The submitter needs to provide an estimate for phodegradation.

2. Health Effects. All appropriate SIDS-level tests have been performed for the purposes of the HPV Challenge Program.

3. Ecological Effects. Aquatic toxicity test data for fish, aquatic invertebrates, and algae are adequate for the purposes of the HPV Challenge Program.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON NONANOIC ACID, SULFOPHENYL ESTER, SODIUM SALT CHALLENGE SUBMISSION

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

EPA agrees that adequate data are available for stability in water, biodegradation, and fugacity for the purposes of the HPV Challenge Program.

Photodegradation. The submitter needs to provide an estimate for atmospheric photodegradation.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate data are available for all health endpoints for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to use data from analogs, sodium octanoyloxybenzene sulfonate (C_8 AOBS) and sodium decanoyloxybenzene sulfonate (C_{10} AOBS), based on similar chemical structure and toxicity profiles, to support the test plan. The submitter needs to address deficiencies in the robust summaries.

Ecological Effects (fish, invertebrates, and algae).

Aquatic toxicity test data for fish, aquatic invertebrates, and algae are adequate for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

Environmental Fate.

Fugacity. The submitter needs to incorporate the actual input values utilized in its estimation for this endpoint.

Health Effects.

Information missing in the robust summaries for repeated-dose, genetic (*in vivo* cytogenetics study), and developmental toxicity is the purity of the test material.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.