

April 16, 2004

Timothy Adams, Ph.D.
Technical Contact
The International Association of Color Manufacturers
1620 I. Street, NW
Suite 925
Washington, DC 20006

Dear Dr. Adams:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-Naphthalenesulfonic acid, 6-hydroxy-5-[2-methoxy-5-methyl-4-sulphophenyl)azo],-disodium salt posted on the ChemRTK HPV Challenge Program Web site on December 17, 2003. I commend The International Association of Color Manufacturers 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 will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Association 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

**EPA Comments on Chemical RTK HPV Challenge Submission:
6-Hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic acid, disodium salt**

Summary of EPA Comments

The sponsor, The International Association of Color Manufacturers, submitted a test plan and robust summaries to EPA for 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic acid disodium salt, (FD&C Red No. 40, CAS No. 25956-17-6) dated November 21, 2003. EPA posted the submission on the ChemRTK HPV Challenge Website on December 17, 2003.

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

1. Analog justification. The analogs used for the ecological endpoints—2,2'-(1,2-ethenediyl)bis(5-amino)-benzenesulfonic acid and its disodium and dipotassium salts—are not appropriate because they are too dissimilar structurally.
2. Physicochemical Properties. The data for these endpoints are adequate for the purposes of the HPV Challenge Program.
3. Environmental Fate. The data for these endpoints are adequate for the purposes of the HPV Challenge Program. The submitter needs to add input values used in the fugacity model to the fugacity robust summary.
4. Health Effects. The data for these endpoints are adequate for the purposes of the HPV Challenge Program.
5. Ecological Effects. As stated above, the analogs used are not appropriate to satisfy these endpoints; furthermore, EPA does not recommend the use of ECOSAR for anionic dyes. EPA recommends acute toxicity testing for fish and invertebrates, but not for algae because of the shading effect (inhibition of photosynthesis) of this type of dye.

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

EPA Comments on the 6-Hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic Acid, Disodium Salt Challenge Submission

Test Plan

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

The data for all endpoints are adequate for the purposes of the HPV Challenge Program.

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

The data for all endpoints are adequate for the purposes of the HPV Challenge Program.

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

The data for all endpoints are adequate for the purposes of the HPV Challenge Program.

Ecological Effects (fish, invertebrates, and algae)

The analogs—2,2'-(1,2-ethenediyl)bis(5-amino)benzenesulfonic acid and its disodium and dipotassium salts—proposed to meet these endpoints are not appropriate because they bear insufficient structural resemblance to the sponsored chemical. For example, the proposed analog has different substituents such as amino groups, is not an azo compound, and lacks the phenolic group. In addition, EPA does not recommend the use of ECOSAR for anionic dyes. Therefore, the aquatic toxicity endpoints have not been adequately addressed. EPA recommends acute toxicity testing for fish and invertebrates. EPA is not recommending testing for algae because the well-known “shading effect” (toxicity due to physical inhibition of photosynthesis) of this type of dye is expected to interfere with observation of any chemical toxicity to green algae.

Specific Comments on the Robust Summaries

Environmental Fate

Fugacity. The submitter needs to add the input values used in the model to its fugacity robust summary.

Followup Activity

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