

March 3, 2004

William H. Smock
Executive Director
Aromatic Sulfonic Acids Association
1850 M. Street, NW
Suite 700
Washington, DC 20036

Dear Mr. Smock:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Hydroxybenzenesulfonic Acid posted on the ChemRTK HPV Challenge Program Web site on October 23, 2003. I commend the Aromatic Sulfonic Acids Association 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: Hydroxybenzenesulphonic Acid

Summary of EPA Comments

The sponsor, the Aromatic Sulfonic Acids Association (ASAA), submitted a test plan and robust summaries to EPA for Hydroxybenzenesulphonic Acid (CAS No. 1333-39-7) dated September 16, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on October 23, 2003.

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

1. Physicochemical Properties. For the purposes of the HPV Challenge Program, EPA agrees that testing is not necessary for these endpoints. The submitter needs to address minor deficiencies in the robust summaries.
2. Environmental Fate. The submitter needs to provide measured ready biodegradation data and a robust summary for stability in water.
3. Health Effects. EPA believes that, given the strong acidity of this substance, it is unlikely that the submitter's proposed mammalian tests would provide meaningful systemic toxicity information.
4. Ecological Effects. EPA agrees with the submitter's test plan for all ecological endpoints as clarified by EPA.

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

EPA Comments on the Hydroxybenzenesulphonic Acid Challenge Submission

Test Plan

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

The data provided by the submitter are adequate for the purposes of the HPV Challenge Program with the modifications suggested below.

Melting point. Testing for this endpoint is not needed because the substance is an aqueous mixture. While single-isomer melting point information could be useful, the calculated value provided by the submitter (129°C) may not be accurate. EPA found melting point values for two isomers, 2-hydroxybenzenesulphonic acid (CAS 609-46-1), which decomposes at 145°C (Lide, DR (ed.); CRC Handbook of Chemistry and Physics; 81st Edition, p. 3-62 (2000); CRC Press LLC, Boca Raton, FL.), and 4-hydroxybenzenesulphonic acid (with 1 mol water)(CAS 98-67-9), mp 138–142 °C (Beilstein Online database; searched January 29, 2004). EPA recommends that the submitter add these values to the robust summary.

Boiling point. Testing for this endpoint is not needed because the substance is an aqueous mixture. The submitter provided a boiling point value of 270 °C, obtained from an MSDS. EPA located a value of 171 - 172 °C (0.13 hPa) for benzenesulphonic acid (Lindner O. 1985; Ullmann's Encyclopedia of Industrial Chemistry. 5th Edition, A3: 515, 517-518 (1985); W. Gerhartz, Ed. VCH Verlag). Using NOMO5 (Mitre Corporation, Version 2.0, 12/4/87), this boiling point is estimated to be 403 °C at atmospheric pressure. EPA recommends that the submitter include this value in the robust summary. Furthermore, the submitter

needs to indicate whether the value it reported is measured or calculated.

Water solubility. The submitter provided an estimated water solubility value of 1000 g/L at 25 °C obtained from EPIWIN, and a value of 100 vol % at 25 °C from an MSDS. The submitter needs to indicate whether the value from the MSDS is measured or estimated.

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

Adequate data are available for photodegradation, stability in water, and fugacity for the purposes of the HPV Challenge Program.

Stability in water. The submitter correctly concludes that this chemical has no hydrolyzable groups, but needs to state this fact in a robust summary.

Biodegradation. The submitter provided limited measured data and modeling results for p-hydroxybenzenesulphonic acid (CAS No. 98-67-9), one of the components of hydroxybenzenesulphonic acid. The submitter proposes additional inherent biodegradation testing. However, EPA believes that the available test data and modeling results are inadequate to support the sponsor's conclusion that the substance(s) will not significantly degrade in a ready biodegradation test. The submitter needs to conduct a ready biodegradation test following OECD Guideline 301.

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

The submitter proposed to conduct a combined repeated-dose/reproductive/developmental screening test and genetic toxicity studies following OECD guidelines (OECD TGs 422, 471, and 473). However, because the chemical is a strong acid EPA believes that it is unlikely that the proposed mammalian tests would provide meaningful systemic toxicity information. Therefore, the submitter needs to reconsider the testing proposal before conducting such studies and better characterize the corrosivity with available in vitro methods.

Acute toxicity. The data submitted for this endpoint are inadequate because they are from secondary sources with limited information to assess the data adequacy. The omitted information includes test doses, vehicle (if used), number and sex of animals per dose, length of the observation period, incidence of mortality by dose and sex, systemic toxicity in target organs by dose and sex (if any), and a range or 95% confidence interval for the LD₅₀.

Ecological Effects (fish, invertebrates, and algae).

EPA agrees with the test plan provided that the submitter meant that two endpoints will be tested (two species were mentioned) and that the results will be compared to the ECOSAR predictions. If there is close agreement with the test results and ECOSAR predictions, then the remaining endpoint can be addressed with ECOSAR.

Followup Activity

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