

201-15302



Aromatic Sulfonic Acids Association

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May 20, 2004

Dr. Oscar Hernandez, Director
Risk Assessment Division
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: ASAA Revised Test Plan for Hydroxybenzenesulfonic Acid (CAS No 1333-39-7) Under the HPV Program.

Dear Dr. Hernandez;

On September 16, 2003, the Aromatic Sulfonic Acids Association (ASAA) submitted a test plan and robust summaries (in IUCLID format) for hydroxybenzenesulfonic acid (HBSA) (CAS No. 1333-39-7). On March 3, 2004, the ASAA received comments from EPA regarding the test plan and summaries. The ASAA thanks the EPA and several public commenters for thoughtful suggestions, which we believe have strengthened our test plan.

The ASAA has revised the test plan and robust summaries as follows:

Introduction – The HPV Assessment Introduction was revised to include synonyms and additional detail on uses of HBSA.

Physicochemical properties

- The data provided by EPA on HBSA analogues for melting point and boiling point have been added to the robust summaries.
- The robust summaries were clarified to indicate which values for boiling point and water solubility were measured and which were estimated.

Environmental fate

- Stability in water – The robust summary was revised to include the statement from the assessment report that no hydrolysable groups are present in HBSA.
- Biodegradation – The test plan was revised to indicate that a ready biodegradation test following OECD Guideline 301 will be performed.

Ecological effects – The test plan was revised to be clear that both a daphnia and an algae test will be performed.

Health Effects

- Acute effects – As several public commenters noted, we also concluded that the acute toxicity of HBSA can be attributed primarily to the fact that it is a strong acid, and as such can be expected to be highly irritating. We found, and noted, in our test plan and

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summaries, several studies indicating corrosive effects in the eye and in the gastrointestinal tract. Because these are secondary studies, we were not able to locate the primary studies in order to fill in all the data elements. Since, however, they are consistent with our expectations of corrosiveness and irritation, and since we do not believe that additional material information would be added to the HBSA data base, we do not plan to perform acute mammalian studies.

- Repeated dose toxicity - The ASAA appreciates the comments of EPA and the public recommending that we re-consider the need for a repeated dose study. The literature was searched for studies investigating skin or eye irritation. We located a skin irritation study for HBSA indicating that the substance is corrosive. We have concluded that testing of systemic toxicity would cause unnecessary harm to laboratory animals without significantly adding to the information base of HBSA. A repeated dose and repro/developmental test (OECD 422) would not add significant information and will not, therefore, be performed.
- Chromosomal aberration – The ASAA recognizes, as one public commenter observed, that the cell strain for the chromosomal aberration test was not specified. The test plan is clear, however, that OECD Test Guideline 473 will be followed. The ASAA will insure the appropriate cells will be used by the testing laboratory so that testing will comply with the OECD test guidelines and HPV program guidelines.

In preparing this test plan, the ASAA gave careful consideration to the principles contained in the letter EPA sent to all HPV Challenge Program participants on October 14, 1999. As requested by EPA, in that letter, the ASAA has sought to maximize the use of scientifically appropriate categories of related chemicals and of structure-activity relationships and to minimize the use of laboratory animals. Additionally, and also as requested by EPA's letter, the ASAA has conducted a thoughtful, qualitative analysis rather than use a rote checklist approach. The ASAA has taken the same thoughtful approach when developing this revised test plan.

If there are any questions regarding our test plan, please contact me at by e-mail at william.smock@verizon.net.

Sincerely,

William H. Smock
Executive Director