

May 23, 2008

Ms. Nancy Sandrof, Manager
Fatty Nitrogen Derivatives (FND) Panel
Amides Task Group
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. Sandrof,

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for the revised Fatty Nitrogen Derived Amides Categories posted on the ChemRTK HPV Challenge Program Web site on October 18, 2004. I commend the Amides Task Group of the American Chemistry Council's Fatty Nitrogen Derivatives (FND) Panel 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.

The revised fatty nitrogen-derived amides categories test plan contains three categories and two single chemicals. This letter addresses the two single chemicals: Naphthenic acids, reaction products with diethylenetriamine (CAS # 68131-13-5) and Tall oil fatty acids, compounds with triethanolamine (CAS # 68132-46-7).

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

1. General Comments. For clarity and better characterization of the two single chemicals, an individual test plan is needed for each chemical. For tall oil fatty acids, compounds with triethanolamine: These should not be designated as Fatty Nitrogen Derived Amides. The only straightforward reaction products are the amine salts and the fatty acid mono-, di- and triesters (the structural formula shown in the test plan, is obviously incorrect and does not correspond to salt or ester formation). The test plan needs to clearly state the nature of the substance, including whether or not ester groups are present. Likewise, for the naphthenic acids reaction products, the test plan needs to characterize the nature of the substance, including the structural variations in the naphthenic acid moieties.
2. Analog Justification. EPA agrees with the use of specific FND amides as analogs to characterize the ecological hazard for the two individual chemical submissions (see item 6 below).
3. Physical-chemical Properties. EPA agrees that the nature of the substances (mixtures of ionic surfactants) precludes meaningful measurements for these endpoints.
4. Environmental Fate. (1) Tall oil fatty acids, compounds with triethanolamine. Data for photochemistry and fugacity are adequate for the purposes of the HPV Challenge Program (fugacity modeling does not apply if the substance contains solely amine salts). EPA agrees with the proposed biodegradation testing. Stability in water testing is needed if ester groups are present.

(2) Naphthenic acids, reaction products with diethylenetriamine. Data for photochemistry, stability in water, and fugacity are adequate for the purposes of the HPV Challenge Program. EPA agrees with the proposed biodegradation testing, provided that sufficient additional information is provided on the various structure types present.

5. Health Effects. EPA agrees with the submitter that testing is needed for the repeated-dose, genetic, reproductive and developmental toxicity endpoints for both substances. For the acute toxicity endpoint, the submitter proposes using available acute toxicity data from chemicals in the various FND categories. EPA believes a better approach would be to report the results of the range-finding tests for the planned repeated-dose toxicity studies to satisfy this endpoint.

6. Ecological Effects. For both substances, acute fish, invertebrate and algal toxicity data are adequate for the screening purposes of the HPV Challenge Program, when judged as follows. Because the proposed analogs imperfectly match the sponsored substances, EPA believes that the best approach is to use data from the worst case analogs: CAS Nos. 61791-39-7, 61789-40-0, and 68910-93-0. This approach can apply to the non-amide CAS # 68132-46-7 only because of the common surfactant properties involved. Where possible, missing data elements (e.g., pH, total organic carbon, water hardness, dissolved oxygen, temperature, and purity) in ecotoxicity robust summaries need to be provided.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that the Task Group 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 me at 202-564-8617. 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 tsc-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Mark Townsend, Chief
HPV Chemicals Branch

cc: O. Hernandez
R. Lee
J. Willis