

May 20, 2005

Mark Mayes
Product Risk Manager
R.T. Vanderbilt Company, Inc.
P.O. Box 5150
30 Winfield Street
Norwalk, CT 06855

Dear Mr. Mayes:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Dibutylcarbomodithioic acid, methylene ester posted on the ChemRTK HPV Challenge Program Web site on June 1, 2004. I commend R.T. Vanderbilt Company, Inc. 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 notes that a number of OECD Guideline animal studies were conducted in 2003 and 2004 after Vanderbilt agreed to sponsor Dibutylcarbomodithioic acid methylene ester in the HPV Challenge Program. If Vanderbilt supported these studies, and the reason for this testing was to satisfy the requirements of the HPV Challenge Program, the company should have waited until the close of the public comment period before initiating any needed testing, in accordance with Program guidance.

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 Vanderbilt 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 Mark Townsend, Acting Chief of the HPV Chemicals Branch, 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 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: M. E. Weber
J. Willis

**EPA Comments on Chemical RTK HPV Challenge Submission:
Dibutylcarbamodithioic acid, methylene ester**

Summary of EPA Comments

The sponsor, R. T. Vanderbilt Company, Inc., submitted a test plan and robust summaries to EPA for dibutylcarbamodithioic acid, methylene ester (CAS No. 10254-57-6), on May 11, 2004. EPA posted the submission on the ChemRTK HPV Challenge Web site on June 1, 2004.

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

1. Physicochemical Properties. Data are adequate for the boiling point, vapor pressure, water solubility, and partition coefficient endpoints. The estimated melting point value provided by the submitter is inadequate.
2. Environmental Fate. Data are adequate for the photodegradation and fugacity endpoints. The data provided for the biodegradation and stability in water endpoints are inadequate.
3. Health Effects. Data are adequate for the acute, repeated-dose, reproductive and developmental, toxicity endpoints, as well as for gene mutations. However, more details are needed in the robust summaries. EPA agrees that data are needed to address the chromosomal aberrations endpoint.
4. Ecological Effects. Data appear adequate for acute toxicity to fish and invertebrates and toxicity to algae pending receipt of revised robust summaries. EPA recommends that a chronic daphnia test be conducted.

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

**EPA Comments on the Dibutylcarbamodithioic Acid, Methylene Ester
Challenge Submission**

Test Plan

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

Data are adequate for the boiling point, vapor pressure, water solubility, and partition coefficient endpoints for the purposes of the HPV Challenge Program.

Melting Point. The estimated melting point of 202.6 °C for this substance and its description in the robust summaries as an amber liquid are inconsistent. The submitter needs to provide a measured melting point.

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

Data are adequate for the photodegradation and fugacity endpoints for the purposes of the HPV Challenge Program.

Biodegradation. The submitted biodegradation test is not valid because the biodegradation of the reference compound, sodium benzoate, did not meet the test validity criteria. Therefore, the measured biodegradation data are inadequate and testing is needed for this endpoint.

Stability in Water. The submitter did not provide a robust summary for this endpoint. The submitter stated in the test plan that this endpoint is not applicable because the chemical “does not contain common hydrolyzable...functional groups.” As thioesters may hydrolyze, the no-hydrolysis claim needs to be supported with measured data on a structural analog. Otherwise, testing of this diester needs to be performed.

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

Data submitted for acute toxicity, repeated-dose toxicity, reproductive toxicity, developmental toxicity, and gene mutations are adequate. However, some additions to the robust summaries are needed. Although the information provided for acute effects is insufficient, information from the repeated-dose studies gives credence to the undocumented LD₅₀ values and indicates that the substance does not exhibit a high degree of acute toxicity (no mortalities or extreme toxicity were observed at 20,000 ppm). This information is sufficient for the purposes of the HPV Challenge Program. EPA agrees with the submitter’s proposal to conduct an *in vitro* chromosomal aberration assay.

Ecological Effects (fish, invertebrates, and algae)

Data appear adequate for the acute toxicity to fish, acute toxicity to invertebrates, and toxicity to algae endpoints pending receipt of revised robust summaries that provide missing study details.

Given the estimated log K_{ow} of 6.73, EPA recommends a 21-day daphnia reproduction test (OECD TG211), particularly if the submitter’s claim of no hydrolysis is confirmed.

Specific Comments on the Robust Summaries

Health Effects

Repeated-Dose Toxicity. The summary needs to include a list of the hematology and clinical chemistry parameters examined, as well as the specific organs weighed and examined for histopathology.

Reproductive and Developmental Toxicity. The summary needs to include specific information for the organs weighed and histopathologically examined, as well as the parameters described in Annex 3 of the guideline for OECD TG 422 including the number of pregnant females per group, number of pups with grossly visible abnormalities, number of runts, etc.

Ecological Effects

Fish. Details missing include the mean length of the fish, information on the use of a control, and water chemistry parameters such as water hardness, pH, and dissolved oxygen concentration.

Invertebrates. Details missing include water chemistry parameters such as water hardness, pH, and dissolved oxygen concentration.

Algae. Details missing include pH and biomass results.

Followup Activity

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