

June 11, 2003

Dr. Ronald Joiner
Manager, Global Toxicology
General Electric Company-Plastics
One Plastic Avenue
Pittsfield, MA 01201

Dear Dr. Joiner:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for N-Methylphthalimide posted on the ChemRTK HPV Challenge Program Web site on January 30, 2003. I commend the General Electric Company-Plastics 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 General Electric Company-Plastics advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

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: N-Methylphthalimide

Summary of EPA Comments

The sponsor, General Electric Company-Plastic, submitted a test plan and robust summaries to EPA for N-methylphthalimide (CAS No. 550-44-7) dated December 30, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 30, 2003.

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

1. Physicochemical Properties. The data provided by the submitter are adequate for the purposes of the HPV Challenge Program. The submitter needs to enter the correct value (1.29) for Log Pow in its robust summary.
2. Environmental Fate. The data provided by the submitter are adequate for the purposes of the HPV Challenge Program. The submitter needs to address some deficiencies in the photodegradation robust summary.
3. Health Effects. Available data were adequate for acute toxicity, repeated-dose and genetic toxicity endpoints for the purposes of the HPV Challenge Program. EPA agrees with the submitter's approach to do a combined screening test for reproduction and developmental endpoints.
4. Ecological Effects. Data submitted for all ecological endpoints are adequate for the purposes of the HPV SIDS-level Challenge Program.

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

EPA Comments on the N-methylphthalimide 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.

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

The data provided by the submitter are adequate for the purposes of the HPV Challenge Program.

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

For the purposes of the HPV Challenge Program, data are adequate for acute toxicity, repeated-dose and genetic toxicity endpoints. Available information does not adequately address the developmental and reproduction toxicity endpoints. EPA agrees with the submitter's proposal that testing is needed for these endpoints and recommends a combined screening test following OECD TG 421.

Ecological Effects (fish, invertebrates, and algae).

Adequate data are available for all endpoints for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

Physicochemical Properties

Octanol/water partition coefficient. In section 4.0 of the robust summaries, the submitter entered the value 19 ± 2 in the first cell, corresponding to Log Pow. The submitter needs to correct this error. The correct value should be 1.29, as the submitter indicates on page 9.

Environmental Fate and Transport

Photodegradation. In the photodegradation robust summary, the submitter included language not pertinent to this endpoint. The submitter needs to remove the paragraphs related to “*Estimation of Environmental Distributions*”, “*Common Features of the Models*”, and “*Model Results*”. These three sections are already covered under Section 8.2-Theoretical Distribution (fugacity calculation). Section 8.2 should be changed to Section 8.1.

Health Effects

General. The substance purity was not always reported in the summaries.

Developmental. There is an error on page 42. The value of 1607 for the control group entry for the “% of litters with anomalous fetuses” should be corrected.

Ecological Effects

Invertebrates. The robust summary did not indicate the number of organisms tested at each concentration.

Followup Activity

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