

November 16, 2000

Richard Balcomb
Director, Toxicology and Environmental Assessments
Ciba Specialty Chemicals
540 White Plains Road
Tarrytown, NY 10591

Dear Mr. Balcomb:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plans for 3,5-Di-*tert*-butyl-4-hydroxyhydrocinnamic acid octadecyl ester (CAS # 2082-79-3), 3,5-Di-*tert*-butyl-4-hydroxyhydrocinnamic acid neopentetetrayl ester, (CAS # 6683-19-8) and 2,4-Di-*tert*-butylphenyl phosphite (3:1) (CAS # 31570-04-4), received by EPA July 10, 2000. I commend Ciba Specialty Chemicals for its commitment to the HPV Challenge Program and encourage you to take appropriate steps to make your submission a successful contribution.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program Web site EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

As detailed in the enclosed comments, EPA identified many weaknesses in the robust summaries submitted for the three chemicals. The robust summaries are not acceptable as final public information documents. EPA accepts the Ciba submissions conditionally, believing that the issue pertains to poorly documented conclusions intended to support the proposed test plans. Eventual acceptance of the plans is contingent upon the submission within the next 90 days of substantially improved robust summaries that meet the standard set out in EPA's guidance documents. EPA will post this letter and the enclosed Comments on the Chemical RTK Web site within the next few days.

In addition, a set of comments received by EPA during the comment period was forwarded automatically to Ciba.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-260-3470. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button 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

Attachments

cc: W. Sanders
C. Auer
N. Patel

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