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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DEC 20 1985

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Triphenyltin hydroxide (TPTH): Company response to Toxicology Branch's request to analyze the tissue samples from the dog long term toxicity studies.

TOX CHEM No. 896E

FROM: John D. Doherty *John Doherty 12/19/85*  
Toxicology Branch  
Hazard Evaluation Division (TS-769)

TO: Henry Jacoby  
Product Manager #21  
Registration Division (TS-767)

THRU: Edwin Budd  
Section Head  
Toxicology Branch  
Hazard Evaluation Division (TS-769)

*Budd 12/19/85*  
*12/19/85*  
*17/22/85*

In a previous memo from Toxicology Branch (TB) concerning the review of the protocol for the dog subchronic dosing study (see J. Doherty review dated June 18, 1985), the registrants of TPTH were requested to analyze the tissue from the dogs on this study for the presence of TPTH.

In a letter recently received from Mr. Don Lawatsch of the American Hoechst Co. dated October 24, 1985 and addressed to Mr. Henry Jacoby, Mr. Lawatsch replied that the number of samples to analyze was extremely large and that there would not be sufficient sample to analyze several tissue types. Mr. Lawatsch also proposed to analyze for TPTH and its di- and mono- phenyl tin metabolites rather than the total tin content because this would be more meaningful than analyzing for the total tin content which may vary due to the natural tin content of the tissues.

The problems related to the analysis of the tissue samples were discussed among other issues at a meeting held between EPA and the American Hoechst and the M&T Companies held December 12, 1985. The following is copied from TB's memo addressing the Proceedings of that meeting:

"TB concurred that the companies may present a paper outlining a series of alternate plans or approaches to determine the bioaccumulation of TPTH and its metabolites in animal tissues. This paper should include:

- a. description of the method to be used to analyze for TPTH and its metabolites and including the sensitivity of the method,
- b. justification that analysis for TPTH and its metabolites is more meaningful than analysis for total tin,
- c. which tissues/organs will be analyzed to assess for the bioaccumulation of TPTH,
- d. summary of what is known about the bioaccumulation, metabolism, tissue retention of TPTH and its metabolites in animal tissues based on available studies and what studies are currently in progress to assess this problem.

TB will wait for the submission of this report from the companies."

No further action will be taken by TB related to recommendations for analysis of the tissues until the above report is provided and reviewed.