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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 8340-17. Triphenyltin hydroxide: Registrants response to Toxicology Branch's review of the chronic dosing study with dogs concerning 1) the certificate of analysis of the test material, 2) the qualifications of the pathologist responsible for evaluating the microscopic slides and information regarding the methodology of the histopathological examination, and 3) analysis of the tissues for tin content.

TOX CHEM No.: 896E
TOX PROJECT No.: 8-1073 and 8-1138*
Record No.: 229928
*Same action was sent twice.

FROM: John Doherty 10/25/88
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TO: Lois Rossi
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THROUGH: Edwin Budd
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The American Hoechst Corporation (now the Hoechst Celanese Corporation) previously submitted a chronic feeding (one year) study with dogs to satisfy a data gap as indicated in the registration standard for triphenyltin hydroxide (TPTH). This study was reviewed and the CORE Classification was assigned as RESERVED (refer to memo from J. Doherty dated October 7, 1987 for EPA Reg. No. 8340-17). The October 7, 1987 memo indicated that the study could be upgraded if certain information was provided. The following is a discussion of the three issues

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indicated as being related to upgrading the study together including TB-I's comments on the registrant's response as submitted on August 5, 1988.

1. The certificate of analysis of the test material.

The registrant (refer to the letter from B. Volger dated August 5, 1988) stated that the information regarding the certificate of analysis of the test material is on page 52 of the report "as a Confidential Attachment".

A copy of page 52 is attached. Page 52 does not describe the identity of the test material but refers to a certificate of analysis (#02762) and cites the FIFRA reference 10(d) (1) (C) as a reason for deletion of this information.

The registrant's response does not satisfy the Agency's request to identify the test material used for the study. The results of the analysis of the test material will have to be submitted to the Agency.

Proper identification of the test material is a prerequisite for determining the acceptability of a study submitted to meet a CORE study data gap.

2. Reexamination of the nervous system by a specialist in neuropathology.

The nervous system was not reexamined as requested in the October 7, 1987 memo. The registrant submitted a report from the testing laboratory (RCC, Ltd, Itingen Switzerland) which contained a description of the histopathological techniques and the Curriculum Vitae of Dr. G. Pappritz, the pathologist responsible for evaluating the study.

As per discussion with Dr. Leonard Slaughter, consulting pathologist to Health Effects Division, Dr. Pappritz is considered to be well qualified to assess the nervous system for signs of toxicity to TPTH and the methods used were appropriate for assessment of possible neurotoxicity induced by organotin chemicals.

This issue is considered resolved.

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3. Results of tissue analysis for tin content.

Dr. Volger reports that there have been technical problems with the analysis of TPTH and its metabolites and states that they expect to have an appropriate method and acceptable results by the end of this year.

Overall Conclusion

Upgrading the study to CORE MINIMUM or higher is not warranted based on the information provided by the registrant at this time. The study may be upgraded pending receipt and review of the information regarding the analysis of the test material and the results of the analysis of the tissues for tin (and organotin) content.

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CROSS REFERENCE NUMBER 1

This cross reference number is used in place of the following whole page.

DELETED: Certificate of Analysis No. 02762

PAGE NO.	REASON FOR DELETION	FIFRA REFERENCE
52	Discloses identity of percentage of added inert ingredients	10(d) (1) (C)