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

NOV 5 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: EPA Id # 8340-17. Triphenyltin hydroxide: Verification of the content of the test material used in the chronic toxicity study in dogs (RCC study # 047013/047024, June 1987). Reclassification of the study to GUIDELINE.

TOX CHEM No.: 896E
PC No.: 083601
TOX PROJECT No.: 2-0117
Submission No.: S405010

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THROUGH: Marion Copley, DVM, Section Head
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CONCLUSION

The registrant has provided information previously requested by HED regarding the identification of the test material used in the chronic feeding study with dogs. A copy of the certificate of analysis of the test material is attached and indicates that the test material was 97.2% active ingredient. The classification of the chronic feeding study with dogs (RCC #047013/047024, June 1987, see also document #6351 for the DER) is changed to GUIDELINE.

Action Requested

The Hoechst Celanese Corporation has submitted (refer to letter from Dr. Berthold Volger dated October 8, 1991) a copy of the certificate of analysis of the test material used in the chronic feeding study with dogs (RCC # 047013/047024, June 1987, MRID #402855-01, see also HED document #6351 for DER). This information was requested in the original review of the study and on later occasions. The study was originally classified as RESERVED pending receipt and review of additional information including the certificate of analysis of the test material.

Toxicology Branch I (TB-I) has reviewed the information provided by the registrant and the following comments apply.

Toxicology Branch Comments

1. In the letter accompanying the certificate of analysis for the test material used in the chronic feeding study with dogs, Dr. Berthold Volger states that "this information was also provided to you with the study report (MRID #40285501), see confidential attachment page 3 of 3)."

The copy of this study as submitted to TB did not contain this information and the section of the data package where it was said to be was deleted. Instead of the certificate of analysis there was a message that the section was deleted so as not to "disclose the identity of percentage inert ingredients". Since the study was supposed to have been conducted with technical grade TPTH, there should not have been any added inerts (unless the technical product contains stabilizers). Thus it was important to clarify the exact content of the test material since it was implied that a formulation may have been used as the test material.

The certificate of analysis as submitted (attached) clarifies this issue and attests that technical grade TPTH and not a formulation was tested.

2. Other issues related to this study including providing additional information on the nervous system (refer to review dated November 3, 1988 for EPA Reg. # 8340-17) and on the analysis of tin content in tissue (refer to review dated Sep. 6, 1991 for EPA Reg $ 8340-17) have been resolved.

Thus, the chronic feeding study with dogs (RCC #047013/047024 dated June 1987, MRID #402855-01) is reclassified to CORE GUIDELINE.

3. The conclusions for this study remain unchanged as follows:

NOEL > 18 ppm (highest dose tested)

Levels tested: 0, 2, 6, and 18 ppm. Beagle dogs.

This memo takes the place of a DER supplement.

TOXR 008256

Page 4 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

X Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.