

US EPA ARCHIVE DOCUMENT



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

004573

JUL 22 1985

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: EPA Reg. No. 1812-279. Triphenyltin hydroxide (TPTH):  
Skin diffusion test-humans (in vitro).

TOX CHEM NO. 896E

FROM: J.D. Doherty *J.D. Doherty 7/22/85*  
Toxicology Branch, HED (TS-769)

TO: H.A. Jacoby, PM #21  
Registration Division (TS-767)

THRU: E.R. Budd  
Section Head  
Toxicology Branch, HED (TS-769)

*Budd  
7/22/85*

## Background:

The Griffin Corporation (P.O. Box 1847 Valdosta, Georgia) has submitted an in vitro human skin diffusion test using triphenyltin hydroxide (TPTH) as the test chemical (refer to EPA Acc No. 258298). The study was not accompanied by a cover letter and it could not be determined why this particular test which is unconventional was conducted to support registrations for products containing TPTH.

Dr. Robert Zendzian of Toxicology Branch (TB) who is recognized as having the most relevant background for evaluating dermal absorption studies was asked to review this study. A copy of Dr. Zendzian's review is attached.

Other Comments: [Note to Product Manager]

Additional dermal absorption data with radiolabelled TPTH submitted by the American Hoechst Corporation (EPA Acc. No. 258231)\* indicate that TPTH is absorbed by animal skin although to a small degree. Thus, the conclusion made by the investigator in the study with human skin that "TPTH is completely not absorbed" is called into question.

\*Data may be Confidential Business Information.



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JUL 17 1985

MEMORANDUM

SUBJECT: Triphenyltin, Review of Dermal Absorption Studies

TO: John Doherty PhD *[Signature]* 7/17/85  
Toxicologist  
Review Section II  
Toxicology Branch

FROM: Robert P. Zendzian PhD, Acting head  
Review Section IV  
Toxicology Branch  
HED (TS-769)

Per your request of July 7, 1985 the following dermal absorption studies of triphenyltin have been reviewed. DERs are attached.

Citation

Triphenyltin Hydroxide (TPTH) Skin diffusion tests,  
I. Blank, Biosearch Laboratories Ltd. April 1985

Core classification Unacceptable

Conclusion

The report as received cannot be reviewed. The Procedure section is confusing to a degree that it is not possible to determine how the cells are assembled, how the test material is applied and how samples of the saline solution were obtained.

The Procedure section must be rewritten specifying how the cells were assembled, charged with saline and the skin applied. How the compound was weighed and when it was applied to each skin. How and when saline samples were withdrawn and was the volume replaced at each withdrawal.

All samples for analysis must be identified. Was the skin wash analyzed?

Date Evaluation Report

004573

Compound Triphenyltin Hydroxide

Citation

Triphenyltin Hydroxide (TPTH) Skin diffusion tests,  
I. Blank, Biosearch Laboratories Ltd. April 1985

Reviewed by

  
Robert P. Zendzian PhD  
Pharmacologist

7/17/88

Core classification Unacceptable

Conclusion

The report as received cannot be reviewed. The Procedure section is confusing to a degree that it is not possible to determine how the cells are assembled, how the test material is applied and how samples of the saline solution were obtained.

The Procedure section must be rewritten specifying how the cells were assembled, charged with saline and the skin applied. How the compound was weighed and when it was applied to each skin. How and when saline samples were withdrawn and was the volume replaced at each withdrawal.

All samples for analysis must be identified. Was the skin wash analyzed?