



CASWELL FILE

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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Triphenyltin Hydroxide - Special Review: Requirement
for a Rabbit Teratology Study

Tox Chem. No. 896E

FROM: John Doherty *John Doherty 2/3/86*
Toxicology Branch
Hazard Evaluation Division (TS-769C)

TO: Betty Shackleford
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Registration Division (TS-767C)

and

Henry Jacoby, PM 21
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Registration Division (TS-767C)

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

and

William Burnam, Deputy Branch Chief
Toxicology Branch
Hazard Evaluation Division (TS-769C)

Background:

The Toxicology Branch (TB) chapter of the Registration Standard for triphenyltin hydroxide (TPTH) indicated that a teratology study with rabbits was a data requirement for this chemical. During a meeting between EPA/OPP and representatives of both the American Hoechst and the M&T Company, the registrants

objected to this requirement on the basis that there is already teratology data in two species (the rat and hamster) and those studies have been determined to be acceptable by EPA.

TB informed the company representatives that the rabbit teratology study was being requested because this species is considered to be the most appropriate species to assess for cleft palate. The company representatives were also informed that TB is concerned with the possible development of cleft palate because the chemical tributyltin oxide (also sold by the M&T Company) was demonstrated to be associated with increased incidences of cleft palate in a rat teratology study.

In the notes on the proceedings of this meeting (refer to J. Doherty memorandum dated December 31, 1985), TB indicated that the issue of the requirement for a rabbit teratology study would be readdressed in the near future based on the comments made by the industry representatives.

TB Response

TB requests that a teratology study in rabbits be conducted and submitted.

The indications that the related chemical tributyltin oxide is associated with development of cleft palate gives probable cause to test other members of the chemical class of organotins for this lesion in the most appropriate species. Rabbits are considered to be the most appropriate species for assessing for cleft palate.