

US EPA ARCHIVE DOCUMENT

8-10-84

File Copy



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

001019

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Triphenyltin Hydroxide Registration Standard.
Applicator "Risk Assessment" for Use on Pecan
Trees.
TOX Chem. No. 896E

TO: Tom Johnston
Project Manager for Triphenyltin Hydroxide
Fungicide-Herbicide Branch
Registration Division (TS-767)

FROM: Edwin R. Budd, Section Head
Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: William L. Burnam, Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

Background

At the June 21, 1984 OPP Policy Group Meeting on the triphenyltin hydroxide (TPTH) Registration Standard (RS), it was decided to recommend that TPTH be placed in Special Review on the basis of teratogenicity. Other toxic effects of TPTH (immunotoxicity, reproductive effects and the lack of a NOEL for "endometrial hyperplasia" in the mouse study) were considered to be insufficient grounds, at this time, for placing TPTH in Special Review, although it was agreed among the participants that EPA should list these toxic effects as additional concerns in the RS and Special Review. As more data on these effects are generated and reviewed, they may possibly be added to the PD 2/3 if warranted by the results. (See draft minutes of this meeting.)

It was also decided at the same meeting that an applicator "risk assessment" for the air blast application of TPTH to pecan trees should be prepared for inclusion in the RS. It was believed that this particular use presented the greatest potential applicator exposure to TPTH.

Accordingly, Exposure Assessment Branch (EAB) has now calculated daily exposure estimates for workers for this use. (See memorandum from Joseph C. Reinert to Edwin R. Budd, dated August 2, 1984.) Total daily exposures for mixers/loaders/applicators (assumed to be the same individual) were calculated to be the following.

lyz

001012

Typical value	0.74 mg/kg/day
Lowest value	0.68 mg/kg/day
Highest value	0.88 mg/kg/day

Present Action

Toxicology Branch (TB) has divided the No Observed Effect Levels (NOELs) and/or Lowest Observed Effect Levels (LOELs) for the several toxic effects of TPTH by the daily exposure estimates provided by EAB. These quotients are presented in the table below. Note that the quotients for LOELs are not "margins of safety." Rather, they are the ratio between an effects level and an exposure. Quotients for NOELs, on the other hand are "margins of safety" for the particular toxic effects.

	<u>Worker Exposure (mg/kg/day)</u>		
	<u>Typical</u> (0.74)	<u>Lowest</u> (0.68)	<u>Highest</u> (0.88)
<u>Teratogenicity*</u>			
NOEL - None	-	-	-
LOEL = 1.0 mg/kg/day	$\frac{1.0}{0.74} = 1.35$	$\frac{1.0}{0.68} = 1.47$	$\frac{1.0}{0.88} = 1.14$
<u>Immunotoxicity</u>			
NOEL - None	-	-	-
LOEL = 0.1 mg/kg/day	$\frac{0.1}{0.74} = 0.14$	$\frac{0.1}{0.68} = 0.15$	$\frac{0.1}{0.88} = 0.11$
<u>Reproductive Effects*</u>			
NOEL = 0.025 mg/kg/day	$\frac{0.025}{0.74} = 0.03$	$\frac{0.025}{0.68} = 0.04$	$\frac{0.025}{0.88} = 0.03$
LOEL = 0.05 mg/kg/day	$\frac{0.05}{0.74} = 0.07$	$\frac{0.05}{0.68} = 0.07$	$\frac{0.05}{0.88} = 0.06$
<u>Endometrial Hyperplasia*</u> (mouse study)			
NOEL - None	-	-	-
LOEL = 1.05 mg/kg/day	$\frac{1.05}{0.74} = 1.42$	$\frac{1.05}{0.68} = 1.54$	$\frac{1.05}{0.88} = 1.19$

* See the TB Chapter of the RS for TPTH for additional information and comments on these toxic effects (John D. Doherty to Tom Johnston, dated March 27, 1984).

2

001013

3

It is clear from the data presented above that worker exposure for the air blast application to pecan trees is in the same dosage range as that in which toxic effects were observed in experimental animals.

Attachments:

cc: Joseph Reinert
Judy Heckman
Anne Barton
Amy Rispin
John Jordan

OPP:HED:TOX:E.BUDD:sb 8/10/84 X77395 Rm. 820D

#2-D20

3