



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 1 1993

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PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: REVIEW OF REENTRY DATA SUBMISSION TO SUPPORT THE
REREGISTRATION OF TRIPHENYLTIN HYDROXIDE (TPTH)

FROM: Jeff Evans, Biologist *JE*
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THRU: *Al Nielsen*
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Please find the OREB review of

DP Barcode: D185217

Pesticide Chemical Code: 083601

EPA Reg. No.: N/A

EPA MRID No.: 425078-01

Review Time: 3 days

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I. INTRODUCTION:

OREB has reviewed the TPTH reentry exposure assessment submitted by Jellinek, Schwartz, & Connolly, Inc. on behalf of the registrants; Hoechst Celanese Corporation, Griffin Corporation, and Elf Atochem North America, Inc. TPTH is a fungicide registered for use on potatoes, sugar beets, and pecans. This fungicide is a group B2 carcinogen with a q of $2.8 \text{ (mg/kg/day)}^{-1}$ and has been determined to be a developmental toxicant with a no observed effect level (NOEL) of 0.1 mg/kg (maternal toxicity). Although TPTH is currently in Special Review, the data being addressed in this memorandum pertain to the registrants' response to a reregistration data call-in (DCI) issued on September 28, 1990.

In the registrants' current exposure assessment, they address issues raised in previous EPA reviews of their reentry data and requests for waiver. These reviews are 1) Review of a Request for Waiver of Worker Exposure Data Requirements To Support the Reregistration of Triphenyltin Hydroxide, from Jeff Evans/OREB to Lois Rossi/SRRD, November 21, 1991, and 2) Reevaluation of a Previously Submitted Waiver Request (Pecans) to Support the Reregistration of Triphenyltin Hydroxide, June 25, 1992, from Jeff Evans/OREB to Eric Feris/SRRD.

In the first submission, the registrants presented two dissipation studies [accession # 261749] previously accepted by EPA (September 1986). The studies consisted of foliar and soil dissipation data following applications of TPTH to potatoes and peanuts. Although the registrants are not supporting the reregistration of peanuts, OREB determined that the potato data support the reregistration of TPTH on sugar beets largely due to the similar application rates and cultural techniques. However, in that submission, the registrants only addressed reentry intervals based on acute dermal and inhalation concerns. Subsequently, EPA requested that the registrants address reentry based on maternal toxicity and chronic concerns. In the same submission, EPA denied the registrants' request for waiver regarding reentry data for pecans.

In the second submission, the registrants presented a model designed to predict pecan harvester reentry exposure in lieu of conducting the reentry study on pecans. EPA again denied the waiver and requested that the registrants conduct the pecan reentry study.

In the third and current submission, the registrants addressed the developmental toxicity concerns regarding reentry and proposed restricted entry intervals (REI) for potato and sugar beet postapplication activities. The registrants also proposed fulfilling the pecan reentry data requirement via the Subdivision K nondetectable residue method. In doing so, the registrants

presented the peanut soil dissipation data accepted by EPA in 1986, contending there would be no detectable residues at the time of pecan harvest (28 days after the last TPTH application). Please note that although TPTH dissipated in the soil at the Donalsonville, Georgia site, TPTH did not appear to dissipate in the soil at the Hollandale, Minnesota site.

II. DETAILED CONSIDERATIONS:

PECANS

TPTH may be applied to pecans 10 times, at a maximum rate of 0.375 lb, active ingredient (ai) until shuck split. The interval between treatments ranges from 14 to 28 days. Pecan harvesting may begin as early as 21 days after shuck split, although harvesting is more likely to occur 28 days or more after shuck split.

The data submitted by the registrants establishes that TPTH, dissipates to less than non detectable residue levels between 21 and 28 days after application. The study was conducted on peanuts grown in Georgia which is also a typical pecan producing area. TPTH is labeled for application to pecans grown in the southeastern United States. However, in the peanut study, TPTH was applied once, at a rate of 0.24 lb, ai/ acre. Thus, the submission does not consider the highest rate and multiple applications, nor does it consider the foliar residue dissipation component. OREB believes the foliar dislodgeable residues will also contribute to postapplication exposure in addition to the soil dislodgeable residues.

POTATO AND SUGAR BEET RESTRICTED ENTRY INTERVALS (REI)

The REI's proposed by the registrant for potatoes and sugar beets address postapplication exposure to treated soil at harvest (hand-harvesting potatoes) and treated foliage during crop maintenance activities (moving hand-set irrigation pipes).

The proposed hand-harvesting REI is based on the following assumptions:

hand harvesting potatoes is the worst case exposure scenario therefore the REI is also acceptable for hand harvesting sugar beets;

since TPTH did not appear to dissipate in the potato soil dislodgeable residue study (conducted in MN), a margin of exposure (MOE) was calculated instead;

the MOE is calculated by establishing an allowable exposure level (AEL) based on the NOEL for maternal toxicity (0.1 mg/kg);

if a MOE of 100 is acceptable, the AEL can not be greater than 0.001 mg/kg or 1 µg/kg;

100% dermal absorption;

the use of soil/dermal transfer coefficients (3.9 ng/ppb/hr without gloves and 1.9 ng/ppb/hr with gloves) taken from a study conducted by the Medical University of South Carolina for the Agency's Pesticide Hazard Assessment Project (Youth in Agriculture: Dermal and Respiratory Exposure Assessment of Juvenile Potato Harvesters, Aroostock County, Maine, August 1982, NTIS# PB88-194469);

the use of the highest daily mean level of 1.329 ppb TPTH from the Minnesota study at one day postapplication;

a 60 kg person working 8 hours per day.

Thus the dermal exposure was calculated as follows:

$$\begin{aligned} \text{Dermal exposure} &= \frac{5.2 \text{ } \mu\text{g/hr} \times 8 \text{ hr/day}}{60 \text{ kg}} \\ &= 0.69 \text{ } \mu\text{g/kg/day} \end{aligned}$$

Since the dermal exposure is less than 1 µg/kg/day hand harvesting potatoes using the above assumptions is below the AEL presented above.

OREB agrees with the above assumptions with the exception of the body weight. In the study used as a surrogate source for the dermal transfer coefficient, the average body weight was 42 kg. Since hand harvesting of potatoes is often conducted by juveniles, OREB contends that the 42 kg body weight should be used to calculate dermal exposure. Using the above calculations and a 42 kg body weight, the dermal exposure is 0.99 µg/kg/day yet still below the AEL giving an MOE of 100. Since the registrant assumed 100 percent dermal absorption, OREB considers this a conservative estimate.

The proposed foliar contact REI is based on the following assumptions:

the foliar residue dissipation curve $\log Y = -0.0573X - 0.498$ from the TPTH foliar dissipation study accepted by EPA in 1986 (Y = the dislodgeable foliar residue in µg/cm² and X = the number of days after the application);

a transfer coefficient of 1,800 cm²/hr;

40% dermal absorption;

a 60 kg individual working 1 and 4 hours per day;

the REI will be acceptable for potatoes sugar beets.

The AEL based on the above assumptions was presented by the registrants as follows:

NOEL = 0.1 mg/kg = 100 μ g/kg; adjust for 40% dermal absorption = 250 μ g/kg

MOE 100

AEL = 2.5 μ g/kg or 150 μ g/kg for a 60 kg individual;

The REI for 4 hours of foliar contact using the registrants' assumptions is calculated as follows:

$$\text{AEL} = \frac{150 \mu\text{g}}{4 \text{ hr/day}}$$

$$\text{AEL} = 37.5 \mu\text{g/hr}$$

AEL = acceptable dislodgeable foliar residue level
transfer
coefficient

$$\frac{37.5 \mu\text{g/hr}}{1,800 \text{ cm}^2/\text{hr}} = 0.021 \mu\text{g/cm}^2$$

$$\log 0.021 = -0.0573X - 0.498$$

$$X = 20.6 \text{ days}$$

Using the above formula and assumptions the REI for 1 hour of foliar contact is 10.2 days.

OREB agrees with the above assumptions with the exception of the use of the transfer coefficient of 1,800 cm^2/hr . This transfer coefficient was cited from a California State EPA study. OREB has not reviewed this study and therefore recommends using a transfer coefficient of 4,000 cm^2/hr from studies previously funded by EPA. Thus, the respective REI's for 4 hours and 1 hour of foliar contact is 27 and 16 days. In a previous submission, the registrants claimed workers typically are in the fields for 6 hours. The REI for this scenario is 30 days.

III. CONCLUSIONS:

The registrants have adequately addressed the reentry data requirements to support the reregistration of TPTH on potatoes and sugar beets.

The registrants have not adequately addressed the reentry data requirements to support the reregistration of pecans based on the following:

- 1) the soil data do not consider a maximum of 10 applications at 0.375 lb ai per acre since the dissipation data presented was the result of a single application at 0.25 lb ai;
- 2) the registrants did not address the contribution of foliar dislodgeable residues towards worker exposure which OREB considers significant.

OREB recommends that the registrants be directed to conduct a reentry study. OREB believes this study must be conducted for the following reasons:

- 1) this is a unique reentry scenario for which the EPA has no data;
- 2) as the registrants point out, workers are engaged in harvesting activities for approximately 30 days;
- 3) this is a very dusty working environment;
- 4) there is a high potential for worker exposure to dusts that may be contaminated with a B2 carcinogen and a strong developmental toxicant.

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Correspondence File
Chemical File (083601)
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