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To: Walt Waldrop
Product Manager PM #74
Special Review and Reregistration Division (H7508W)

From: Emil Regelman, Supervisory Chemist
Environmental Chemistry Review Section #2
Environmental Fate & Ground Water Branch/EFED (H7507C)

Thru: Henry Jacoby, Chief
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

Reg./File # : 083601

Common Name : Triphenyltin Hydroxide

Product Name : Super Tin

Company Name : Griffin Corporation/Hoechst Celanese

Purpose : Registrant response to a 12/9/87 review of a field dissipation study.

Type Product: fungicide Action Code: 629 EFGWB #(s): 92-0027,0125,0156,0368 Review Time: 5 days

EFGWB Guideline/MRID/Status Summary Table: The review in this package contains...

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Y= Acceptable (Study satisfied the Guideline)/Concur
P= Partial (Study partially satisfied the Guideline; additional information is still needed)
S= Supplemental (Study provided useful information, but Guideline was not satisfied)
N= Unacceptable (Study was rejected)/Non-Concur

MRID 42063501

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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Triphenyltin Hydroxide- Expedited Review of a Request for
Reclassification of the Status of the Soil Field Dissipation (164-1) Data
Requirement.

FROM: Dana Spatz, Chemist 
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

TO: Walt Waldrop, PM 74
Reregistration Branch
Special Review and Reregistration Division (H7508W)

THRU: Emil Regelman, Supervisory Chemist
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C) 

MAR 16 1992

Henry Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

The registrant has, for the third time, requested that EFGWB reevaluate and reclassify the two soil field dissipation studies (40106501 and 40106502) originally reviewed by the Branch on December 9, 1987. In that review, the studies were found to be scientifically sound, but because of certain deficiencies, did not satisfy the field dissipation data requirement. Those deficiencies included: 1) only one application was made whereas the label allows for multiple applications, 2) residue characterization was incomplete, and 3) the pattern of decline of parent and formation and decline of degradates was not established. The registrant was informed on numerous occasions, (EFGWB reviews dated 6/21/88 and 3/22/91 and in meetings on 3/22/91 and 9/10/91) that they must repeat the field dissipation studies, making sure to apply the maximum amount of pesticide as specified on the product label. All major metabolites required characterization and the depth of leaching for both parent and major degradates had to be defined.

On April 12, 1991 the registrant submitted protocols for two new field dissipation studies. These protocols were found to be basically sound, with modification, by EFGWB on May 8, 1991. They initiated one of the two studies and immediately experienced difficulties in validating the analytical method and terminated the study. In this most recent request for reconsideration of these previously submitted dissipation studies and to upgrade them from supplemental to acceptable, the registrant has submitted: 1) data from the analytical laboratory which is attempting to validate the existing analytical method, documenting their troubles in obtaining satisfactory recoveries of the di- and monophenyl derivatives of TPTH from fortified soil, and 2) summaries of results of previous fate studies conducted with TPTH. The registrant has attempted to argue that existing data provide sufficient information about the fate and behavior of TPTH in soils, and at the same time argue that existing analytical methods will not allow any quantitative characterization of the degradation of TPTH in soils because TPTH and its degradates bind so tightly to soil. This argument contradicts itself. EFGWB does not believe that the fate of a pesticide can be adequately understood in the absence of residue characterization.

EFGWB has reviewed this additional information and has screened the recently submitted photodegradation on soil (421198-01) and photodegradation in water (420495-02) studies (a thorough review will be completed shortly), and concludes that the Minnesota and Georgia field dissipation studies cannot be upgraded. The registrant has not presented any new information which compels the Branch to reclassify the field dissipation data requirement as satisfied. While EFGWB understands that the registrant may be having technical difficulties in validating Battelle's analytical method, this does not obviate the need for critical information on the fate and transport of TPTH and its degradates in soil under actual use conditions. EFGWB remains concerned about the persistence of TPTH. The two photodegradation studies reaffirmed this concern by indicating that TPTH does not photodegrade in water or on soil.

Two new studies must be conducted to fulfill the 164-1 data requirement. The fate of TPTH and its degradates, especially after multiple applications, is not yet well understood. The field dissipation studies conducted to date have not addressed the potential for accumulation of TPTH from multiple applications, but have strongly suggested that TPTH may be persistent in the field under certain environmental conditions (half-life up to 260 days in Minnesota). The registrant must conduct the two field studies as agreed to in the March 22, 1991 meeting and as stipulated in EFGWB's review (May 8, 1991) of the submitted protocols for "Ground Application to Pecans with Super-Tin 4L" and "Ground Application to Sugar Beets with Super-Tin 4L." These studies are important for an understanding of the fate of TPTH, not so much from a ground water perspective (TPTH is not expected to leach), but a worker exposure/non-target organism perspective. The Occupational and Residential Exposure Branch has expressed a concern about the persistence of TPTH and a need for data on the fate of TPTH in the field as applied according to the maximum use rate. The studies must not only define the pattern of TPTH decline under actual use conditions, but also the

patterns of formation and decline of its degradates, DPT and MPT. As indicated in the TPTH Registration Standard (1984), there is a concern about the intermediary degradation products, in that they may be the cause of some of the observed toxic effects of TPTH. Accordingly, the Registration Standard required that the tolerances for TPTH be revised to include the intermediary degradation products, DPT and MPT.

BACKGROUND

Triphenyltin hydroxide is a nonsystemic, protectant, foliar fungicide registered for use on pecans, carrots, potatoes, and sugar beets. Of the total domestic usage, 85% is applied to pecans. On December 17, 1984 TPTH was placed into Special Review with the issuance of a PD 1. The trigger for initiation of a Special Review was data indicating that TPTH produces teratogenic effects in laboratory animals. TPTH is a Restricted Use Pesticide.

The first request from the registrant for a reevaluation of the two studies was received by the Agency on April 20, 1988 and was reviewed by the Branch on June 21, 1988. In the April 20, 1988 submission, the registrant argued that since the protocols for the two soil field dissipation studies were approved by the Branch, the studies should be acceptable. In the June 21 response EFGWB outlined the deficiencies with the two studies. Those deficiencies included: not making the maximum number of allowable applications, incomplete residue characterization (only residues on Day 14 of the Minnesota site were identified, residues were not characterized from the Georgia site), patterns of parent decline and degradate formation were not established, incomplete meteorological data and no control plot data. Also in that review it was stated that the soil field dissipation studies would have to be repeated, making sure to apply the maximum amount of pesticide as specified on the product label, to characterize all major metabolites, and to define the depth of leaching.

In the second request, the registrant made the argument that the results of the two soil field dissipation studies, which indicate somewhat rapid dissipation of TPTH ($t_{1/2}$: 7-30 days) and low mobility, taken together with the results of the aerobic soil metabolism study, which demonstrate that TPTH is degraded, mainly to CO_2 , in silty clay and silt loam soils with half-lives of ≈ 8 and 16 days, respectively, clearly define the fate of TPTH in soil and preclude the need for conducting additional soil field dissipation studies. In fact, both soil field dissipation studies did not indicate rapid dissipation of TPTH. The half-life calculated by the registrant for the Minnesota study was 260 days. The registrant also indicated that the maximum label rate on the test crops had been lowered from 4.75 oz ai per acre, which was the test rates, to the present maximum label rate of 4 oz ai per acre.

With respect to the maximum label rate, the label for Super Tin 4L (Griffin Corporation) indicates that the maximum application rate for pecans, the major use crop, is 12 fluid ounces of product per acre (0.375 lbs ai/A) with a maximum of 10 applications (2-4 week intervals) during a single growing season (3.75 lbs ai/A). The soil field dissipation studies tested only a single application. This was not appropriate considering that all uses listed on the label involve multiple applications. The soil field dissipation studies did not address the potential for accumulation of TPTH from the multiple applications.