#323EE

Shaughnessy #: 122101

Due date 5/24/84

Init: 21 MAY 1984

TO: H. Jacoby
Product Manager #21
Registration Division (TS-767)

From: Joseph C. Reinert, Chief
Environmental Chemistry Review Section No. 2
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached please find the EAB fate review of...

Reg./File No.: 100 - EUP - 70

Chemical: CGA - 64250

Type Product: F

Product Name: TILT

Company Name: Ciba - Geigy

Submission Purpose: provide applicator exposure assessment from use on pecans

ZBB Code: Other

ACTION CODE: 716

Date in: 3/5/84

EAB #: 4226

Date Completed 5/21/84

TAIS (levels II) 61

Days 4

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1.0 INTRODUCTION

CIBA-GEIGY has submitted an analysis of occupational exposure for mixer/loaders, applicators and clean-up workers to TILT 3.6 E (CGA-64250); an experimental fungicide used for control of scab on pecan trees.

2.0 METHOD

The investigators used data collected during field applications for estimating the level of human exposure to CGA-64250. Data from the airblast spraying of pecan trees, as well as ground boom spray aplications to soybeans and grass were pooled to estimate overall occupational exposure to this chemical by agricultural workers.

All exposure estimates were based on a 24% dermal absorption for an 8-hour period. This value was determined from a dermal penetration study in rats. These data are summarized in the environmental fate section which is a part of their overall submission for pesticide registration of this chemical.

Included in these estimates are differences in the application techniques of, and protective clothing worn by, these workers during normal field operations. Assumptions were made that an average worker weighed 70 kilograms and the working period would be 50 years out of a 70-year life span.

The average estimated life exposure for three types of farm workers applying formulations of CGA-64250 to pecans is presented below:

Farm Worker Category	Estimated Average Daily Exposure (ug/kg/day)	Estimated Lifetime Contributions		Total ppb
		ug/day	ppb*	
Mixer-Loader/Clean-up Worker	0.11	5.5	3.67	5.12
Applicator	0.23	11.5	7.67	9.12
Mixer-Loader/Clean-up Worker + Applicator	0.34	17.0	11.34	12.79

* Applicator exposure calculated as if exposure occurred daily in a 1.5 kg diet at the indicated conc'n in ppb.

The lifetime contribution in ug/day was estimated by multiplying the average daily exposure by 70 kilograms.

The lifetime dietary equivalence in ppm was determined from the assumption that a 70 kg person eats a 1.5 kg diet (mg/day/1.5 kg = ppb). It was also assumed that the total exposure for agricultural workers would include 1.45 ppb of TILT because of ingestion of pecans and bananas.

3.0 DISCUSSION

At first glance, the methods used by Ciba-Geigy for calculation of the occupational exposure for mixer/loaders and applicators to TILT appeared to be consistent with accepted practices. However, their hourly dermal exposure values (HDE) for various farm worker-types for either airblast or ground boom applications are very low when compared with EPA data summaries (10^{-3} order of magnitude). As a result the average lifetime exposure values reported are much lower than expected values for a 50 year (usually 40 yr.) work period.

A Ciba-Geigy data submission reviewed by EAB on June 14, 1982 reported an HDE of only 0.0058 mg/hr. for a mixer/loader in preparing a 0.33 lb ai/acre formulation of TILT. A value of 50 mg/hr or higher would have been expected for an agricultural-use scenario of this type. The same study reported an HDE of 0.95 mg/hr for an applicator during airblast spraying of pecan trees. This suggests an exposure for the applicator that is about 160 times greater than that for the mixer/loader. It is generally accepted that the reverse is true, that is, the mixer/loader has greater exposure than the applicator if the same protective gear is worn. A later submission by Ciba-Geigy for pecan and grass (3/15/84) also confirmed greater exposure for the mixer/loader.

The June 14 submission contained data for aerial application of TILT to rice. The following numbers were reported: mixer/loader, HDE = 0.0046 mg/hr; applicator, HDE = 0.216 mg/hr. This was the same exposure data reversal that was observed with pecan above. The reported exposure to the applicator was approximately 47 times higher than that for the mixer/loader.

The June 14 exposure data for application of TILT to pecan and rice resulted from surrogate studies involving the application of Supracide^{R} 2E to alfalfa(EIR-81011), citrus(EIR-81013) and cotten(EIR-80002). The alfalfa study was used to estimate exposure for mixer/loaders during applications to both pecan and rice. The citrus study was used to estimate exposure for applicators in a pecan field ; the cotten study was used as a

surrogate to assess the exposure to an applicator spraying rice fields.

4.0 RECOMMENDATIONS

The June 14, 1982 study is not acceptable for use as a surrogate. The exposure values reported were unexplainably low and only a single experiment was conducted using a single mixer/loader, one applicator, and one flagger.

In an attempted re-registration of Chlorobenzilate, CIBA-GEIGY used two of the above studies(EIR-81011 & 80002) as surrogates for exposure assessment. The reviewer(Steve Noren 5/16/84) also found these studies to be unacceptable.

CIBA-GEIGY is invited to explain why their HDE values are so much lower than expected for a real world agricultural scenario, reversed for mixer/loader- applicator personnel, and lower than their reported inhalation exposure values. It is generally accepted that the main route of exposure is dermal via the hands. These low HDE values naturally lead to low numbers for lifetime estimates of occupational exposure to TILT. Since the surrogate studies were found to be unacceptable, the resulting occupational exposure estimates are also unacceptable.

Frank Prince 5/17/84

Frank Prince, Chemist
Review Section 2
Exposure Assessment Branch
Hazard Evaluation Division (Ts-769C)