32322

Shaughnessy #: 122101

Due date 7/2/84

Init: 08 JUN 1984

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Registration Division (TS-767)

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JCR

Attached please find the EAB fate review of...

Reg./File No.: 100-617

Chemical: CGA - 64250

Type Product: Fungicide

Product Name: TILT

Company Name: Ciba - Geigy

Submission Purpose: Occupational Exposure Assessment/Applicator

ZBB Code: Other

ACTION CODE: 330

Date in: 4/18/84

EAB #: 4298

Date Completed 6/7/84

TAIS (levels II) 61

Days 4

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1.0 INTRODUCTION

CIBA-Geigy has submitted an evaluation of potential health risk to farm workers that could result from the the use of TILT (CGA-64250) as a fungicide on wild and domestic rice, wheat, barley, and rye.

2.0 Method

The occupational exposure of mixer/loaders, applicators, and clean-up workers was estimated using data collected from field studies while applying TILT to rice. Re-entry exposure for rice, wheat, barley, and rye fields were calculated based on scouting times, data from a dislodgeable foliar residue study (EIR-83011,submitted December 9, 1983) and estimated hourly dermal exposure values. These data are summarized in CIBA-GEIGY's environmental fate submission of March 13, 1984 (EPA Accession No. 252646).

Exposure estimates were based on a 24% dermal absorption value for an 8-hour period which was determined from a dermal penetration study in rats (EPA Accession No 072218, Shaughnessy # 122101). These estimates include differences in application techniques and protective clothing worn by farm workers that are characteristic of the specific crop that was treated. The assumption was made that an average man weighed 70 kilograms and would work 50 years out of a 70-year life span instead of 40 years. The average estimated occupational exposure for each type of worker is shown in the two tables below. The exposure was the same for agricultural personnel working with wild or domestic rice. Exposure values were similar for the wheat, rye or barley field application.

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 daily (mg/day/1.5 kg = ppb). It was also assumed that the total exposure for agricultural workers would include 12.62 ppb of TILT because of ingestion of pecans, bananas, rice, wheat barley, rye, kidney and liver.

Occupational Exposure for Applying Tilt to Rice

Worker Category	Average Daily Exposure (ug/kg/day)	Lifetime Contributions		Total** ppb
		ug/day	ppb*	
Mixer-Loader/Cleanup	0.01	0.5	0.33	12.95
Applicator	0.029	1.45	0.97	13.59
Scout	0.001	0.05	0.03	12.65
Mixer-Loader/Cleanup Applicator + Scout	0.04	2.0	1.33	13.95

Occupational Exposure for Applying Tilt to Barley

Worker Category	Average Daily Exposure (ug/kg/day)	Lifetime Contributions		Total** ppb
		ug/day	ppb*	
Mixer-Loader/Cleanup	0.01	0.5	0.33	12.95
Applicator	0.002	0.1	0.07	12.69
Scout	0.0001	0.005	0.003	12.62
Mixer-Loader/Cleanup Applicator and Scout	0.0121	0.605	0.403	13.02

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

** Worker exposure + daily ingestion

3.0 DISCUSSION

The methods used by Ciba-Geigy for estimation of occupational exposure for mixer/loaders and applicators to TILT appear 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 (~3 orders 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.

Estimated average daily exposure values submitted by Ciba-Geigy March 5, 1984 (EAB #4226) for mixer/loaders, applicators and the two combined, were 0.11, 0.23, and 0.34 ug/kg/day, respectively for a pecan occupational study. These data were reviewed by EAB (May 16, 1984) and found to be unacceptable because they were much lower than expected, and the surrogate study used for HDE estimation involved only a single replicate. This submission for rice, and barley, reported the corresponding values: 0.01, and 0.02, ug/kg/day for mixer/loader and applicator which were one-tenth the values reported above. This indicates once again that HDE values used by Ciba-Geigy in their estimation of occupational exposure of farm workers to TILT were lower than expected values.

Once the estimated overall dietary exposure of 12.62 ppb was added to the dermal exposure values for each worker category, by crop-type, no significant difference in lifetime exposure between workers, or for that matter the general population was evident. All of the values for total exposure was approximately 13 ppb. It is inconceivable that the lifetime exposure of an agricultural worker who applies Tilt for fifty years can be equal to that of a bus driver in New York City. This only appears to be true because the contribution by dermal exposure to the occupational expsoure is orders of magnitude too low. It is generally accepted that the route of greatest exposure for the farm worker is dermal via the hands.

4.0 RECOMMENDATIONS

CIBA-GEIGY should be encouraged to explain why their HDE values are so much lower than expected for a real-world agricultural scenario, inculding a reversed order for mixer/loader, applicator personnel, and lower dermal than 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 appear to be unacceptable, the resulting occupational exposure estimates are also unacceptable.

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