#323EE

Shaughnessy No.:122101

Date Out of EAB: AUG 17 1984

To: Don Stubbs
Product Manager 41
Registration Division (TS-767)

From: Samuel Creeger, Chief
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached, please find the EAB review of...

Reg./File # : 84-LA-04

Chemical Name: CGA 64250

Type Product : Fungicide

Product Name : Tilt

Company Name : Ciba Geigy

Purpose : Recommend rotational restriction

ZBB Code : 3(c)(5)

Action Code(s): 510

Date Received: 2/28/84

Date Completed: 8/17/84

EAB #(s) : 4219

TAIS Code: 51

Total Reviewing Time: 1.0 days

Total Contractor Time: 38.6 days

Deferrals to:

____ Ecological Effects Branch

____ Residue Chemistry Branch

____ Toxicology Branch

1.0 INTRODUCTION

The State of Louisianna has requested a Sec. 18 exemption to use the herbicide Tilt to rice. Data supplied by Ciba-Geigy Corporation were included with the request, in accessions numbered 252646 and 252647.

Among the studies submitted for review were worker exposure and mathematical modelling studies. These studies were not reviewed as part of the Sec. 18 evaluation; they should be resubmitted as conventional Sec. 3 data.

Due to their apparently large volume, the rotational crop data were forwarded to an EPA contractor (Dynamac Corporation) for review (see § 3.0 and 4.0, below).

The existing EF data base for Tilt was recently reviewed (6/25/84) and found to be adequate to support an EUP use on Rice (and other specified crops), provided a crop destruct or rotational crop restriction appeared on the label.

EAB concurrence is apparently a moot question at this point since the Sec. 18 request was for the 1984 growing season which began on March 1.

2.0 STRUCTURE and DIRECTIONS FOR USE

See earlier reviews.

3.0 DISCUSSION OF SUBMITTED DATA

The evaluation of the submitted rotational crop data, prepared by the EPA contractor (Dynamac Corporation) is appended to this review.

Of the 67 studies submitted only 30 were actually reviewed due to the extremely disorganized nature of the rotational crop studies. Of the rotational crop studies which were reviewed, all were found to be inadequate in support any rotational interval.

4.0 EXECUTIVE SUMMARY OF SUBMITTED DATA

The following executive summary was taken from the Dynamac review, and is quoted here in its entirety.

"The half-life of CGA-64250 in an aerobically incubated Swiss silt loam soil was 60-69 days. Radiolabeled carbon in the dioxolane and triazole rings was largely evolved as $^{14}CO_2$ (42-45%) or was incorporated into bound (nonextractable) residues (26-30%) within 168 days. The [alpha]-hydroxy derivative was tentatively identified as a transient degradate. This data is considered ancillary because the study was conducted with a foreign soil.

A supplemental study identified an unknown degradate reported in a previously submitted study (Unknown U_1, Refer to EAB review, 6/17/81, Action Code 115) as 1,2,4-triazole.

Degradation in aerobic and anaerobic aquatic environments appears to be very slow. Losses may be due to strong adsorption to sediments rather than breakdown. The data submitted were not adequate to quantify the rate of aquatic degradation, to describe the mechanism(s) of loss, or to define the metabolite distribution. The ketone derivative (CGA-91304) was tentatively identified as a degradate formed by anaerobic aquatic metabolism.

Data from the rotational crop studies indicated that triazole residues accumulate in corn planted 180 days posttreatment, in cabbage planted 143 days posttreatment, and in lettuce planted 279 days posttreatment. Metabolites were not identified, and expected residue levels under specified conditions were not established.

In summary, CGA-64250 is degraded at a moderate rate in aerobically incubated soil. The dioxolane and phenyl rings are apparently mineralized, but the triazole ring is persistent. Degradation in aquatic environments (aerobic and anaerobic) appears to be very slow."

5.0 CONCLUSION

EAB cannot recommend a rotational interval based on the submitted data.

The worker exposure and mathematical modelling studies included with this Sec. 18 request were not reviewed at this time.

6.0 SUMMARY OF DATA REQUIREMENTS

The following summary was taken from the Dynamac review, and comments concerning studies reviewed are quote in their entirety.

"Available data are insufficient to fully assess the environmental fate of CGA-64250 and the exposure of humans and non-target organisms to CGA-64250. The current submission of data to fulfill registration requirements (Subparts N and K) is summarized in the following.

Aerobic soil metabolism studies: Two studies were submitted and reviewed. Both were found to be scientifically valid. One study (Keller, Ref. 4, Acc. No. 252646) partially fulfilled data requirements by identifying a degradate isolated in a previous study. The second study (Keller, Ref. 2, Acc. No. 252646) is considered ancillary information because a foreign soil was utilized.

Anaerobic aquatic metabolism studies: One study (Kuti, Ref 1, Acc. No. 252646) was submitted and reviewed. The study was found to be scientifically invalid because it did not simulate aerobic aquatic conditions and did not have an acceptable materials balance. The study did not satisfy data requirements because the procedures and methods were not adequately described, insufficient data was submitted to verify the TLC methods, the study was not conducted at a constant temperature, and the purity of the test substance was not reported.

Aerobic aquatic metabolism studies: One study (Kuti, Ref. 1, Acc. No. 252646) was submitted and reviewed. This study was not scientifically valid because it did not have an acceptable materials balance. The study did not satisfy data requirements because the procedures and methods were not adequately described, insufficient data was submitted to verify the TLC methods, the study was not conducted at a constant temperature, and the purity of the test substance was not reported.

Terrestrial field dissipation studies: Five studies (Ref 15-19, Acc. No. 252646) were submitted and reviewed. These studies could not be evaluated because of the inadequate descriptions of experimental procedures and methodology.

Aquatic field dissipation studies: Nine studies (Ref 20-22, Acc. No. 252646 and Ref 23-29, Acc. No. 252647) were submitted and reviewed. These studies could not be evaluated because of the inadequate descriptions of experimental procedures and methodology.

Confined accumulation studies on rotational crops: One study (Madrid and Cassidy, Ref. 10, Acc. No. 252646) was submitted and reviewed. The study was scientifically invalid because the descriptions of experimental procedures was not adequate. The study did not satisfy data requirements because degradates were not fully identified, the test substance was not characterized, and immature crops were not analyzed for residues.

Field accumulation studies on rotational crops: Thirty-six studies were submitted. Nine were reviewed (Ref. 30-38, Acc. No. 252647). The studies could not be evaluated because descriptions of the experimental procedures and analytical methodology were not adequate. Twenty-five studies (Ref. 39-65, Acc. no. 252647) were not reviewed because they did not appear to contain sufficient detail to be evaluated.

Ancillary studies reviewed:

Determination of total CGA-64250 residues in crops by conversion to 2,4-dichlorobenzoic acid and analysis by gas chromatography-mass spectrometry (Balasubramanian, Gold, and Cheung, Ref. 6, Acc. No. 252646).

Gas chromatographic determination of CGA-64250 residues in crops (Balasubramanian, Ref. 13, Acc. No. 252646).

7.0 RECOMMENDATIONS

The worker exposure and mathematical modelling studies should be resubmitted as conventional Sec.3 data.

A copy of the Dynamac review (included with this review) should be forwarded to the registrant (Ciby-Geigy) for their evaluation. All issues delineated should be directly addressed.

However, due to the extremely poor organization of this submission, Ciba-Geigy may, at its sole option, choose to withdraw the package and extensively reorganize the data into a "new", more coherent package. In this case, the registrant should address the following points:

a. Great care should be exercised to include a complete discussion for every portion of every study.
b. Sampling for the same field should be grouped in the same study, rather than in multiple, disconnected studies.
c. Cited analytical methodology should be appended to the submission.
d. All chromatograms, mass spectrograms, computer printouts and the like should be visually legible and suitably labeled; marginally legible, disconnected or disorganized material will be returned unreviewed.
e. All other deficiencies addressed in the Dynamac review which are not specified above should be rectified in the final resubmission.

Emil Regelman
Chemist
EAB/HED
August 17, 1984