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Date Out EFB: 26 NOV 1984

TO: Hank Jacoby
Product Manager 21
Registration Division
TS-767

FROM: Samuel M. Creeger, Chief
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division

Attached please find the environmental fate review of:

Reg./File No.: 100-617

Chemical: CGA-64250

Type Product: Fungicide

Product Name: Tilt®

Company Name: CIBA-Geigy

Submission Purpose: Add new use on rice to label

Date in: 8/23/84

Date Completed: 11/26/84

ACTION CODE: 330

EFB # 4539

TAIS (level II)	Days
63	2

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1.0 INTRODUCTION

The Ciba-Geigy Company has submitted an application for registration of Tilt® (CGA-64250, as a. i.), EPA Reg. No. 100-617, for use on rice.

In review dated 6/25/84, EAB considered an experimental use permit for testing Tilt® on rice, wheat, barley, and rye. In review dated 6/20/84, EAB considered an emergency exemption (Section 18) for use of Tilt® on wild rice by the State of Minnesota.

1.1 Chemical

See review dated 6/25/84 for chemical information.

2.0 DIRECTIONS FOR USE

The complete label is appended to this review. Briefly, aerially apply 6 fl. oz (0.17 lb a. i) per acre at time of first internode elongation (panicle differentiation) and repeat at time of booting before the boot splits and head emerges, or

8-10 fl. oz. (0.22-0.28 lb a. i.) per acre at time of internode elongation; If disease reappears, use another registered fungicide for the second application.

Note: To avoid possible illegal residues 1) do not apply to stubble or ratoon rice; (2) Do not use water drained from treated fields to irrigate other crops; 3) Do not use in California.

3.0 DISCUSSION

3.1 No additional environmental fate data were included in the submission.

3.2 Data previously submitted have been found adequate to satisfy the following data requirements:

3.2.1 Hydrolysis. CGA-64250 is stable to hydrolysis at pH 1 to 13.

3.2.2 Aqueous photolysis. CGA-64250 rapidly degraded in aqueous solution under natural or simulated sunlight in presence of photosensitizers with a half-life of 2.5 to 24 hours. However, degradation was less rapid without sensitizers. The half-life of CGA-64250 was approx. 53 hours in distilled water when exposed to a mercury arc lamp. Approximately 50% of the starting material remained after 12 days when CGA-64250 in distilled water was exposed tc natural sunlight.

3.2.3 Soil photolysis. CGA-64250 did not photodegrade on soil over the 24 exposure period (termination of study).

3.2.3 Aerobic/anaerobic soil metabolism. CGA-64250 degraded slowly with a half-life of about 10 weeks in (Swiss) silty loam soil maintained under aerobic conditions. Most of the ^{14}C from CGA-64250 breakdown was evolved as $^{14}CO_2$ (42-45%) or was not extracted from the soil (26-39%).

CGA-64250 did not degrade in soil maintained under anaerobic conditions or in sterile soil under aerobic conditions

3.2.4 Leaching/mobility. CGA-64250 adsorbed extensively to soils with Freundlich K values ranging from 8.5 to 59:

Soil	%Organic Matter	K	
		Adsorption	Desorption
Sandy clay loam	5.6	59.0	70.8
Loam	3.6	26.2	31.7
Sand (Collombey)	2.2	8.5	10.6
Sand (Lakeland)	1.2	11.0	16.0

In columns of the same soils, no leaching below the 4-6 cm depth was observed for CGA-64250 and only minor amounts of aged CGA-64250 residues were found to leach. The aged metabolite, 1,2,4-triazole, was found in the leachate and accounted for 2.8% and 7.5% of the applied ^{14}C in the loam and sand (Collombey) soils, respectively. Minor amounts of ^{14}C were observed throughout the columns; however, 80%-86% of the applied ^{14}C remained in the 0-6 cm depth.

3.2.5 Fish accumulation. Bluegill sunfish had the following maximum bioaccumulation factors: whole fish-203X; edible tissue-24X and viscera-251X. The average BCF for whole fish (for the 28 day study) was 116X (range 68X to 203X). During the 14 day depuration period, 99% of the residues taken up were eliminated. Parent CGA-64250 was the primary residue extracted from muscle tissue. Other metabolites found were 1,2,4-triazole in viscera and CGA-77502 (-(2,4-dichlorophenyl)-1H-1,2,4-triazole-1 ethanol) in the carcass.

3.3 Data previously reviewed but found deficient in satisfying environmental data requirements include:

3.3.1 Aerobic and anaerobic aquatic metabolism. The submitted data suggest that degradation of CGA-64250 in aerobic and anaerobic aquatic environments is very slow (and perhaps negligible over a 12 month period). However, these conclusions

are tentative in that a number of deficiencies were noted in the studies:

The highly variable material balance from the anaerobic studies indicate that the sampling procedure or portions of the analytical methodology significantly reduced the precision and accuracy of the data;

The studies were not conducted at a constant temperature and the purity of the test substance was not reported;

The aerobic study did not simulate an aquatic metabolism study because the test system did not contain soil; suspended solids are not adequate to simulate soil underlying water;

Insufficient data are reported to evaluate the utility of the TLC analyses. Neither R_f values nor autoradiographs were included in the report. The report refers to metabolites by the company identifiers only and not all identifiers were defined;

The sampling procedures and analytical methodology were not clearly presented. The non-sterile aerobic study was reported as being sampled up to 28 days; however, reference (in the results section) is made to a 6 week sample used to quantify the material balance;

Analytical procedures used to obtain the material balance were not described. It is not clear from the report if TLC analyses were used to characterize the aqueous phase from the water-methylene chloride partition of the sediment extracts. Quantification of the ^{14}C in each case was not reported. In the methods section of the report the TLC analyses were described as consisting of single dimensional and two dimensional analyses, but footnotes in the reported results indicate that two single dimensional systems were utilized.

3.3.2 Terrestrial field dissipation. In the previous review EAB concluded that the studies were deficient. Most of the studies consisted only of data sheets. The descriptions of the experimental procedures and methodology were found inadequate. The studies should be resubmitted with a complete materials and methods narrative and a discussion of the results with the author's conclusion.

3.3.3 Aquatic field dissipation. In the previous review, EAB also concluded that the studies were deficient. Only data sheets were submitted. The studies should be resubmitted in complete reports including narratives fully describing all

experimental procedures, analytical methodology, results and the author's conclusions. Generally, data from a single study should be integrated into a single report (rather than submitting numerous interim reports).

3.3.4 Confined accumulation studies on rotational crops. In the previous review EAB conluded that the submitted study was deficient. Descriptions of the experimental procedures were not included; degradation products were not fully identified; the test substance was not characterized; and immature crops were not analyzed for residues. Storage stability data were not included.

3.3.4 Field accumulation studies on rotational crops. In the previous EAB review, EAB concluded that the studies could not be evaluated. Some studies were deficient in that descriptions of the experimental procedures and analytical methodology were not adequate. Other studies were not reviewed because they did not appear to contain sufficient detail to be evaluated.

4.0 RECOMMENDATION

4.1 EAB concludes that adequate data have not been submitted to define the environmental fate of CGA-64250 resulting from the proposed use.

4.2 Irrigated crop data are not necessary at this time since the label bears a restriction against using treated water for irrigation purposes.

4.3 The following data requirements have not been satisfied:

Aerobic aquatic
Anaerobic aquatic
Field dissipation [soil (sediment) and water]
Rotational crop

The registrant should be informed that the above deficiencies must be satisfied in order to adequately define the environmental fate of fluvalinate resulting from the proposed use.

Clinton Fletcher
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division

TILT CGA-64250 Reviews

The next 9 page(s) is/are not included in this copy of the TILT reviews.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commerical/financial information

✓ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

___ Detailed methods and results of a registrant submission.

___ Duplicate pages.

The information not included generally is considered confidential by product registrants. If you wish to obtain the information deleted, please contact the individual who prepared this response to your request.
