

US EPA ARCHIVE DOCUMENT



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

APR 6 1982

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DATE: April 5, 1982

SUBJECT: Tilt; 100-EUP-A0; 100-EUP-TN; Tilt in/on rice and
pecans; crop destruct CASWELL #323EE

FROM: William Dykstra, Toxicologist
Toxicology Branch/HED (TS-769)

TO: Henry Jacoby (21)
Registration Division (TS-767)

WHD *JDC*
df oep *4/5/82*
4/6/82

Recommendation:

The EUP crop destruct programs can be toxicologically supported provided RCB does not require a tolerance in/on rice.

Review:

1. The rice EUP label allows application only on rice grown for seed.
2. EUP program for rice.

STATES INVOLVED, QUANTITY OF PRODUCT
TO BE USED AND ACREAGE TO BE TREATED

<u>State</u>	1982 Season			1983 Season		
	<u>Approx. Acres</u>	<u>Gals. Tilt</u>	<u>Lbs. ai</u>	<u>Approx. Acres</u>	<u>Gals. Tilt</u>	<u>Lbs. ai</u>
Arkansas	400	63	226.8	900	141	507.6
California	100	16	57.8	500	79	284.4
Louisiana	300	47	169.2	600	94	338.4
Mississippi	150	24	86.4	300	47	169.2
Texas	200	32	115.2	600	94	338.4
Total	<u>1150</u>	<u>182</u>	<u>655.2</u>	<u>2900</u>	<u>455</u>	<u>1638.0</u>

TOTAL FOR BOTH YEARS: 4050 Acres
637 Gals. Tilt
2293.2 Lbs. Active Ingredient

States to which product may be shipped for further distribution:

Tennessee

3. The pecan EUP label bears this statement, "All pecans harvested from pecan trees treated with Tilt under the EUP must be destroyed or used for research purpose only."

4. EUP program for pecans

STATES INVOLVED, QUANTITY OF PRODUCT
TO BE USED AND ACREAGE TO BE TREATED

State	1982 Season			1983 Season		
	Approx. Acres	Gals. Tilt	Lbs. ai	Approx. Acres	Gals. Tilt	Lbs. ai
Alabama	5	5	18	50	50	180
Arizona	-	-	-	30	30	108
Arkansas	-	-	-	30	30	108
Florida	-	-	-	30	30	108
Georgia	5	5	18	70	70	252
Louisiana	10	10	36	50	50	180
Mississippi	20	20	72	50	50	180
Missouri	-	-	-	30	30	108
New Mexico	-	-	-	30	30	108
Oklahoma	5	5	18	50	50	180
South Carolina	5	5	18	30	30	108
Texas	10	10	36	70	70	252
Total	<u>60</u>	<u>60</u>	<u>216</u>	<u>520</u>	<u>520</u>	<u>1872</u>

Totals for both seasons:

580 acres
 580 gals. Tilt
 2088 lbs. active ingredient

States to which product may be shipped for further distribution:

Tennessee

Previously Submitted Toxicology Studies:

a. Memo of 4/30/81 from W. Dykstra to Henry Jacoby

1. Studies with Tilt 3.6 E

- ° Acute rat oral LD₅₀ = 1310 (1130-1520) mg/kg (both sexes)
- ° Acute rabbit dermal LD₅₀ = > 5010 mg/kg (no deaths)
- ° Primary eye irritation - Rabbit: TOX II
- ° Primary skin irritation - Rabbit: TOX III
- ° Acute rat inhalation LC₅₀: > 2.45 mg/L/4 hours
- ° Skin sensitization - Guinea Pig: positive

2. Studies with CGA-64220 Technical

- ° Acute rat oral LD₅₀ = 1517 (958-2291) mg/kg (both sexes)
- ° Acute mouse oral LD₅₀ = 1490 (1138-1875) mg/kg (both sexes)
- ° Acute chinese hamster oral LD₅₀ = 3006 (2152-3943) mg/kg (both sexes)
- ° Acute rabbit oral LD₅₀ = 1344 (1062-1710) mg/kg (both sexes)
- ° Acute I.P. LD₅₀ - Rat: 508 (381-653) mg/kg (both sexes)
- ° Acute dermal LD₅₀ - Rat: >4000 mg/kg (both sexes)
- ° Primary eye irritation - Rabbit: TOX II
- ° Primary skin irritation - Rabbit: TOX IV
- ° Acute inhalation LC₅₀ - Rat = 1263 (1075-1650) mg/m³
- ° Skin sensitization - Guinea Pig: negative
- ° Salmonella/microsomal assay: negative
- ° Mouse dominant lethal: negative
- ° Chinese hamster nucleus anomaly: negative
- ° Rat teratology: negative at 300 mg/kg; fetotoxic
NOEL = 100 mg/kg
- ° Rabbit teratology: negative at 180 mg/kg; fetotoxic
NOEL = 180 mg/kg
- ° 90-day rat feeding study: NOEL is 240 ppm
- ° 90-day dog feeding study: NOEL is 50 ppm

2. Toxicity Data Submitted with previous Petition

a. Brief summary interim reports of the chronic/oncogenic rat feeding study and mouse oncogenicity study were submitted with little data.

Of particular interest is the summary of the number of mice dying with liver masses during the period of 52-84 weeks as shown below:

NUMBER OF MICE DYING WEEKS 52 to 84

	1o Control	2o 100 ppm	3o 500 ppm	4o 2500 ppm
Interim Kill (53)	11 (0)	11 (0)	11 (2)	9 (4)
53-56	2 (1)	2 (1)	1 (0)	0
57-60	2 (1)	3 (2)	0	1 (1)
61-64	3 (0)	2 (1)	5 (2)	1 (1)
65-68	0	1 (0)	0	2 (1)
69-72	3 (1)	1 (1)	1 (0)	7 (7)
73-76	1 (1)	2 (1)	1 (0)	1 (1)
77-80	0	1 (1)	2 (1)	5 (3)
81-84	4 (1)	4 (1)	0	2 (1)
Total minus interim kill	17 (5)	22 (8)	16 (3)	19 (15)

Total plus interim kill 28 (5) 22 (8) 27 (5) 38 (19)

In parentheses - number of mice dying with liver masses during the period.

Statistical Analysis of the above data demonstrates that liver masses in mice occurred at a statistically significant increased level at the high dosage of 2500 ppm (statistics attached).

Conclusions and Recommendations:

The EUP crop destruct programs can be toxicologically supported.

ppm # RESP total % +/-2(s.d.) One tail P Statistic
 Fisher's

0.000	5	26	17.86+/- (15.7)	0.367
100.000	8	33	24.24+/- (16.14)	0.611
500.000	5	27	18.52+/- (16.50)	0.007
2500.000	10	38	30.00+/- (17.21)	

Test for Linear trend in proportions $P = 0.001$