

US EPA ARCHIVE DOCUMENT



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

~~APR 4 1984~~

APR 5 1984

MEMORANDUM

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: 84-LA-04; Section 18 emergency exemption for the  
use of TILT in/on rice in Louisiana.  
Caswell #: 323EE

TO: Don Stubbs (PM#41)  
Registration Division (TS-767C)

and

Residue Chemistry Branch  
Hazard Evaluation Division (TS-769C)

FROM: William Dykstra, Ph.D.  
Toxicology Branch  
Hazard Evaluation Division (TS-769C)

*WAB for  
Dykstra 4-4-84*

THRU: Christine F. Chaisson, Ph.D.  
Head, Review Section No. 4  
Toxicology Branch  
Hazard Evaluation Division (TS-769C)

*CF. Chaisson 4/4/84  
WAB 4/5/84*

Requested Action:

A total assessment of the pesticide has been requested by  
Registration Division. One-liners are attached.

Recommendations:

1. The requested Section 18 is not toxicologically supported,  
since the active ingredient, CGA-64250, is a liver oncogen  
in mice. A risk assessment is required to determine  
oncogenic risk to persons exposed to CGA-64250. The risk  
assessment will be available from the contractor in about  
four weeks. No tolerances are established for CGA-64250.  
RCB residue estimates are not presently available.

Review

1. No new toxicity data were submitted.

2. Section 18 Program

It is estimated that 250,000 acres of rice will potentially need to be treated for rice sheath blight in 1984.

The time of usage will be from May 1, 1984 through September 1, 1984 with no more than 141,000 pounds active of TILT to be used.

EPA Accession No. TOX Category CORE Grade/ Doc. No.

Results: LD50, LC50, PIS, NOEL, LEL

Study/Lab/Study #/Date	Material	EPA Accession No.	Results: LD50, LC50, PIS, NOEL, LEL	TOX Category	CORE Grade/ Doc. No.
Acute oral LD50 - rat Stillmeadow #1663-80 6/23/80	Tilt 3.6E 41.8% a.i.	244271	LD50 = 1310 (1130-1520) mg/kg (both sexes)	III	Minimum 000789
Acute dermal LD50 - rabbit Stillmeadow #1664-80 5/15/80	Tilt 3.6E 41.8% a.i.	244271	No deaths LD50 > 5010 mg/kg	III	Minimum 000789
Primary eye irritation - rabbit Stillmeadow #1665-80 4/30/80	Tilt 3.6E 41.8% a.i.	244271	Corneal opacity in 6/6. Unwashed eyes reversible by day 7.	II	Minimum 000789
Primary skin irritation- rabbit Stillmeadow #1666-80 4/25/80	Tilt 3.6E 41.8% a.i.	244271	P.I.S. = 4.6; moderately irritating	III	Minimum 000789
Acute inhalation LC50 - rat Toxigenics #420-0212 6/10/80	Tilt 3.6E 41.8% a.i.	244271	LC50 > 2.45 mg/L/4 hrs.	III	Minimum 000789
Sensitization - guinea pig Stillmeadow Inc. #1667-80 6/27/80	Tilt 3.6E 41.8% a.i.	244271	Positive sensitizing effect.		Minimum 000789
Acute oral LD50 - rat CG#785244 12/7/78	CGA 64250 Tech. 88%	244272	LD50 = 1517 (958-2291) mg/kg (both sexes)	III	Minimum 000789

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LD50, LC50, PIS, NOEL, LEL

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Material

Study/Lab/Study #/Date	Material	EPA Accession No.	Results: LD50, LC50, PIS, NOEL, LEL	TOX Category	CORE Grade/ Doc. No.
Acute oral LD50 - mice CG#785243 5/7/79	CGA 64250 Tech. 88%	244272	LD50 = 1490 (1138-1875) mg/kg (both sexes)	III	Minimum 000789
Acute oral LD50 - chinese hamster CG#790146 4/20/79	CGA 64250 Tech. 88%	244272	LD50 = 3006 (2152-3943) mg/kg (both sexes)	III	Minimum 000789
Acute oral LD50 - rabbit CG#785247 11/2/78	CGA 64250 Tech. 88%	244272	LD50 = 1344 (1062-1710) mg/kg (both sexes)	III	Minimum 000789
Acute I.P. LD50 - rat CG#785246 3/13/79	CGA 64250 Tech. 88%	244272	LD50 = 508 (381-653) mg/kg (both sexes)	II	Minimum 000789
Acute dermal LD50 - rat CG#785245 1/22/79	CGA 64250 Tech. 88%	244272	LD50 > 4000 mg/kg (both sexes)	III	Minimum (abraded skin not tested) 000789
Primary eye irritation - rabbit CG#785248 10/26/78	CGA 64250 Tech. 88%	244272	Corneal opacity reversible in 72 hours. P.I.S. = 2.4/110 (unwashed eye) P.I.S. = 0.4/110 (Washed eye)	II	Minimum 000789
Primary dermal irrita- tion - rabbit CG#785249 10/29/78	CGA 64250 Tech. 88%	244272	P.I.S. = 1.4; Slight irritation 4 hours	IV	Minimum 000789
Acute inhalation LC50 - rat CG#790741 6/21/79	CGA 64250 Tech. 88%	244272	LC50 = 1264 (1075-1650) mg/m <sup>3</sup>	III	Minimum 000789

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EPA Accession No. CORE Grade/Doc. No.

Results: ID<sub>50</sub>, LC<sub>50</sub>, PIS, NOEL, LEL

TOX Category

Study/Lab/Study #/Date	Material	EPA Accession No.	Results: ID <sub>50</sub> , LC <sub>50</sub> , PIS, NOEL, LEL	TOX Category	CORE Grade/Doc. No.
Sensitization - guinea pig CG#785250 2/8/79	CGA 64250 Tech. 88%	244272	Negative		Minimum 000789
Mutagenicity - salmonella CG#7812577 1/4/79	CGA 64250 Tech. 88%	244272	Negative with and without microsomal activation. Negative mutagen		Minimum 000789
Mutagenicity - mouse dominant lethal CG#790034 10/31/79	CGA 64250 Tech. 88%	244272	Negative mutagenicity		Minimum 000789
Mutagenicity - chinese hamster nucleus anomaly CG#79-0805 9/17/79	CGA 64250 Tech. 88%	244272	Negative mutagen		Minimum 000789
Teratology - rat CG#790011 9/10/79	CGA 64250 Tech. 88%	244272	Negative at 300 mg/kg (HDT) Fetotoxic NOEL = 100 mg/kg Fetotoxic LEL = 300 mg/kg (ossification retardation)		Minimum 000789
Teratology - rabbit CG#790009 9/10/79	CGA 64250 Tech. 88%	244272	Negative at 180 mg/kg (HDT) Fetotoxic NOEL = 180 mg/kg (HDT)		Minimum 000789
90-Day feeding - rat CG#790014 8/30/79	CGA 64250 Tech. 88%	244272	NOEL = 240 ppm LEL = 1200 ppm (reduced body wt. in females)		Minimum 000789
90-Day feeding - dog CG# 8/9/79	CGA 64250 Tech. 88%	244272	NOEL = 50 ppm LEL = 250 ppm (lymphoid follicles in mucous of membrane stomach)		Minimum 000789