



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

8/16/89

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 3125-330, 3125-331
Of tanel 1.5%, and Of tanel 5.0% (Granular)

FROM: William S. Woodrow WSW 8-16-89
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C) E 8/16/89

TO: William Miller
Insecticide - Rodenticide Branch
Registration Division (TS-767C)

APPLICANT: Mickey Chemical Corp.
Agricultural Chemicals Div.
Box 4983
Kansas City, MO. 64120

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
<u>1-Methylethyl 2-[1-ethoxy]-(1-methylethyl)amino]</u>	<u>1.5%</u>
<u>phosphino-thioyl]oxy] benzoate</u>	<u>5.0%</u>
<u>Inert Ingredient(s):</u>	<u>98.5, or 95.0</u>
Total	100.0%

✓
✓

BACKGROUND:

Mobay Chemical Corp. submitted two Oftanel Granular Insecticide acute inhalation toxicity studies; to justify an inhalation toxicity category of III for these products - a 1.5% Oftanel Granular, and 5.0% Oftanel Granular. An earlier Oftanel 5% Granular product study justified only Tox. Category II. MRID NOS. used were 406711-01, and 406711-02.

RECOMMENDATION:

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1) The acute inhalation studies submitted by [redacted] OSR/PSS. note that the toxicity category for both the 1.5% and 5.0% products is Category III.

LABELING:

Regarding the 1.5 and 5.0% Oftanel Granular Insecticide products acute inhalation statements:

- 1) The signal word, CAUTION is appropriate for both products.
- 2) For both the 1.5% and 5.0% Oftanel labels, change the Precautionary Statements as follows:

following, Harmful if swallowed, add "Harmful if inhaled. Avoid breathing dust."

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (S81-3)

Product Manager: (16)
 MRID No.: 406711-01
 Testing Laboratory: Makag Tox. Dept.
 Author(s): R.N. Shiozuka
 Species: Rat, Sprague Dawley
 Sex: 20m, 20f
 Source: Sacco Inc., Omaha
 Test Material: Optanol 5% granular (AMAZE technical) 1500 mg/kg
 Quality Assurance (40 CFR \$160.12): acceptable

Reviewer: W. Woodrow
 Report Date: 8-15-89
 Report No. 93103

Summary: 5.0% OPTANOL DUST

- LC50 (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LC50 is 2.01 mg/L
- Mean Concentration: _____
- Tox. Category: III. Classification: Guidelines

Procedure (~~Deviations From S81-2~~): Dust from 5% granular optanol generated using Pitt #3 generator (a sonic sifter). Glass beads in generator shaker & small particles carried by air stream to exposure chamber - air flow 15 LPM. Exposure Chamber - 60L

Results:

Exposure Concentration (mg/L)	Reported Mortality (NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
1.01 mg/L	0/10	0/10	0/20
Controls (air alone)	0/10	0/10	0/20

Symptomology & Gross Necropsy Findings:

cytotoxic - head exposure only. 10M & 10F exposed for 4 hrs. 10M & 10F exposed to air only for 4 hrs (controls). Particle size distribution determined & TSI Aerodynamic Particle Sizer, and a Diluter interfaced to an IBM computer. Samples collected near rat breathing zone. Results

Sampled at $\frac{1}{2}$, $1\frac{1}{2}$, 3.0 and 3.5 hours. The MMAD & GSD were calculated from values of cumulative % mass. Nominal concentration determined (wt. loss = tobacco through chamber). Gravimetric concentration of chamber aerosol - samples collected through Gelman, Metrical membrane filters (pore size 0.8 μ) - differentiated weighing. Animals observed for mortality and toxic signs frequently during exposure, 2x daily to 14 days & gross necropsy. Body weights Day 0, 3, 7 & 14.

Results

Mean gravimetric aerosol conc. = 1013 mg/m^3 , or 1.01 mg/L
 The mean MMAD = 3.9μ , geometric standard deviation =
 (mean) of 2.0.

No mortality: treated animals, or controls, all animals gained weight.

Gross pathology: Control animals - no gross lesions
 Test animals - 1 F-ventral neck ulcer, 1 M - small testes.

No toxic clinical signs.

The aerosol particles were of respirable size.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: (16)
 MRID No.: 406711-02
 Testing Laboratory: Metro Corp. - Tox. Dept.
 Author(s): R.N. Shioi Saka
 Species: 12 wt, Sprague Dawley
 Sex: 20 M, 20 F Weight: M 204-273, F 180-203g
 Source: Sasco, Inc.
 Test Material: OPTANOL 1.5% granulat
 Quality Assurance (40 CFR §160.12): acceptable

Reviewer: W. Woodrow
 Report Date: 8-15-89
 Report No. 86-041-16

Summary:

- LC₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LC₅₀ is > 0.83 mg/L
- Mean Concentration: _____
- Tox. Category: III. Classification: Guidelines

Procedure (~~Deviations from §81-3~~): Across dust generated using a Wright dust feed mechanism. Test material first ground in mortar & pestle - packed into dust feed cup @ 2615 tPa (-379) psi. Exit tube of generator inserted to top of exposure.

Results:

Reported Mortality

Exposure Concentration (mg/L)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
0.83 mg/L	0/10	0/10	0/20
Air alone (control)	0/10	0/10	0/20

~~Symptomology & Gross Necropsy Findings:~~

Chamber. Dust feed generator output mixed air = 60 liter exposure chamber. Head only exposure. Dilution of 100% of 10F exposed for 4 hrs. Similar group exposed to air only (control). Particle size distribution determined @ TSI Aerodynamic Particle Sizer & Diluter, interfaced to IBM computer.

MMD and GSD calculated from values of accumulation
of mass. Nominal concentration (wt. exposed = air [L]
passed through chamber.

Geometric concentration by collecting samples through
microsil membrane filters - pore size 0.8 μ m (samples near
breathing zone).

All control and compound exposed animals observed
for mortality and toxic symptoms @ 0.5, 1.0 & 2.5
hrs post-exposure. Animals observed 2x daily to 4 days
& weighing. Boluses @ 0, 3, 7 & 14 days.

Results

Animals: Clinical - Control, as well as treated rats
showed ocular & nasal irritation - Weight
for control rats. No mortality.
Treated or control.

Particle size distribution

- Nominal = $12.670 \text{ mg/m}^3 = 12.67 \text{ mg/L}$
- Geometric = $827.5 \text{ mg/m}^3 = 0.83 \text{ mg/L}$ (mean)
- MMD = 2.7μ (mean)
- GSD = 2.4μ (mean)

The particles were respirable