

US EPA ARCHIVE DOCUMENT

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 1812-266
JUDGE

FROM: William S. Woodrow USCO 12-28-89
Precautionary Review Section E 1/3/90
Registration Support Branch
Registration Division (H7505C)

TO: B. Chambliss/S. Lewis (PM 21)
Fungicides-Herbicides Branch
Registration Division (H7505C)

APPLICANT: Griffin Corp.
P.O. Box 1847
Valdosta, GA 31603-1847

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
<u>Chlorothalonil (Tetrachloroisophthalonitrile)</u>	<u>40.4</u>
_____	_____
_____	_____
<u>Inert Ingredient(s):</u>	<u>59.6</u>
	<u>Total 100.0%</u>

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BACKGROUND:

The Griffin Corp. submitted an acute inhalation study for domestically produced technical chlorothalonil in response to a data call in. This study (lab. # 3159-37 6-8-88) was reviewed by David Ritter of Toxicology Branch, and in Ritter's report was designated both Tox. Category I, and also Tox. Category II. Griffin requested clarification concerning the Toxicity Category for the study reviewed by Ritter (1), and (2) submitted a second acute inhalation study for review that was conducted using a Taiwanese produced technical chlorothalonil.

RECOMMENDATIONS:

- 1) The acute inhalation toxicity study # 3159-37 performed by Springborn Life Sciences, and reviewed by David Ritter of Toxicology Branch (domestically produced technical chlorothalonil), must be designated Toxicity Category I. (MRID-40729701)
- 2) The acute inhalation toxicity study

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performed using Taiwanese technical chlorothalonil (study # 3159-49) is acceptable to RSB/PRS, and was designated Toxicity Category I.

LABELING :

The "Judge" product label must be changed as follows to reflect a Toxicity Category I designation for acute inhalation toxicity, regarding technical chlorothalonil:

- 1) The WARNING signal word must be changed to "DANGER."
- 2) The word "Poison" must appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison".
- 3) Under Precautionary Statements, following "Harmful if swallowed", add "Fatal if inhaled. Avoid breathing spray mist. Wear a mask or pesticide respirator jointly approved by the Mining Enforcement and Safety Administration and the National Institute for Occupational Safety and Health."

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Remove contaminated clothing and wash before
re-use."

3) The "If Inhaled" Statement of Practical
Treatment is adequate.

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4

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

Product Manager: (21) Reviewer: W. Woodrow
 MRID No.: 406404-01 Report Date: 12-27-89
 Testing Laboratory: Springborn Life Sciences Report No. 3159-49
 Author(s): K. G. G. Michlewicz
 Species: Rat, Sprague Dawley
 Sex: 5M, 5F Weight: 221-260g
 Source: Charles River Labs.
 Test Material: Taiwanese Technical Chlorothalonil (white powder)
 Quality Assurance (40 CFR \$160.12): adequate

Summary:

- LC₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LC₅₀ is < 0.15 mg/L
- Mean Concentration: _____
- Tox. Category: I. Classification: Guidelines

Procedure (Deviations From S81-21: 5M, 5F rats were exposed for 4 hours in a 270 L Rockstar-type inhalation chamber. A Model FD-100 (Unifab Corp.) particle generator and a high pressure oilseed air source used to generate test atmosphere.

Results:

Exposure Concentration (mg/L)	Reported Mortality (NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
0.15 mg/L	5/5	5/5	10/10
all animals dead within 3 days			

Symptomology & Gross Necropsy Findings:

The nominal concentration was determined (mg into apparatus ÷ total L air through chamber) = Geometric concentration measured by passing collected chamber samples through pre-weighed glass fiber filters (wt. gain ÷ L of air sampled) @ 30 minute intervals

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5

2.

A particle size analysis was conducted 12 hours during exposure using an Andersen 2000 cascade impactor (Model 20-900). Stages 1-8 & final filter fitted with pre-weighed glass fiber filters. Samples pulled through sampler, MMAD & GSD both determined. Animals observed daily to day 15. Body weights days 1 & termination. Gross necropsies on all animals.

Results:

Aerosol concentration

The average gravimetric concentration was 0.15 mg/L, the nominal concentration was determined to be 1.6 mg/L. The MMAD was 3.2 μ & geometric standard deviation was 1.8.

Particle size distribution (from cascade impactor)

particle diameter (μ)	% particles in size range (partial)
3.3-4.7	17.36%
2.1-3.3	46.53
1.1-2.1	11.81

Animals All animals dead by day 3. Prior to death, decreased activity, dark moistened nasal eyes, nose, mouth respiratory distress, tachycardia, piloerection, lacrimation. Necropsy shows mottled lungs, sloughing of epithelial tracheal lining, hemorrhage/engorged blood vessels.

Conclusion: Tracheal challenge LC₅₀ < 0.15 mg/L

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Page _____ is not included in this copy.

Pages 7 through 8 are not included.

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 quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
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