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

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OCT 19 1988

MEMORANDUM:

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Lois Rossi, PM # 21
Herbicide/Fungicide Branch
Registration Division TS-767C

THRU: Quang Bui, Ph.D., Section Head Quang Bui 10/7/88
Rev. Sec. I/HFASB
Health Effects Division TS-769C

THRU: William L. Burnam, Chief
HFASB
Health Effects Division TS-769C

FROM: D. Ritter, Toxicologist DR 10-6-88
Rev. Sec. I/HFASB
Health Effects Division TS-769C

Subject: Chlorothalonil Registration Standard Data Call In; request to evaluate Acute Inhalation Study in the Rat. Chlorothalonil Product GX-198.

Registrant: Griffin Corporation, Valdosta, GA.

Caswell #: 215B.

TOX Project #: 8-1069.

Griffin Corporation is requesting our review of a Rat Acute Inhalation Toxicity study to support continued registration and re-registration of products containing Chlorothalonil. The study is identified as:

Acute Inhalation Toxicity, Rat, Study # 3159.37, dated 6/8/88.
Performing Laboratory: Springborn Life Sciences, Inc., Spencerville, OH.
Author: K. G. Michelwicz, Ph.D.

The DER is attached. The study was rated CORE Guideline with a TOX Category of II. The Registrant should provide a Confidential Statement of Formulation for this product.

Primary Reviewer: D. Ritter, Toxicologist DR 10-6-88 Caswell #: 215B
Rev. Sec. # I, HFASB
Secondary Reviewer: Quang Bui, Ph.D. Quang Bui
Section Head, Rev. Sec. # I, HFASB

006908

DATA EVALUATION RECORD

STUDY: Acute Inhalation Toxicity, Rat EPA Guideline # 81-3.

LABORATORY: Springborn Life Sciences, Inc., Spencerville, OH.

STUDY NUMBER & DATE: 3159.37 6/8/88.

ACCESSION NUMBER: 40729701

MRID: 40729701

MATERIAL TESTED: Chlorothalonil Product GX-198, Batch # 88012731, AN #80041[1]
Gray Liquid. Diluted to 70% (w/v) with distilled water.

ANIMALS: Young adult Sprague-Dawley rats obtained from Charles River Laboratories, Inc., Portage, MI. Initial weight range 212 - 307 Gm.

TITLE OF REPORT: Acute Nose Only Inhalation Toxicity of Chlorothalonil, Product GX-198 in Rats.

AUTHOR OF REPORT: Kevin G. Michelwicz, Ph.D.

CONCLUSIONS:

All levels of exposure to Test Material resulted in high mortality and a precise LC_{50} cannot be determined, but it is substantially less than 0.3 mg/L. The lowest LC_{50} for a TOX Category II rating is 0.2 mg/L. The results of this study therefore support a TOX Category of II for this product.

CORE RATING: Guideline data.

TOXICITY CATEGORY: II

METHODS:

A. STUDY DESIGN

1. Animal Assignment -

Five males and five females each were assigned to one of four groups to receive a nose-only liquid aerosol containing the Test Material or distilled water for a single exposure of 240 minutes duration.

2. Husbandry - Standard GLP.

3. Feed and Water - Available ad libitum, except during compound administration.

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1 NOTE: CSF not provided; this may be a 4 lb/gallon formulation.

2

4. Compound Administration -

Animals were immobilized in plastic tubes with only the nose exposed to the breathing zone of the apparatus, which was a 270 Liter Rochester-type inhalation chamber.

A high pressure air source piped through an atomizing nozzle was used to generate the test atmosphere. A peristaltic pump delivered the diluted test material to the nozzle. Atmosphere flow rate was monitored continuously using Dwyer meters.

Temperature, relative humidity, % O_2 content and air flow rate were recorded at ca 30 minute intervals during the exposure period.

Nominal Aerial Concentration of Test Material in mg/L was determined by dividing the amount of Test Material used in mg by the total amount of air used in Liters, and adjusting for the 70% concentration of product in the Test Material.

Gravimetric Concentration was derived by drawing a sample of test atmosphere through a pre-weighed filter and recording its weight differential in mg, then dividing this value by the amount of test atmosphere used in Liters, and adjusting for the 70% concentration of product in the Test Material.

Particle Size was determined hourly by drawing test atmosphere through an Anderson 2000 impactor, weighing the different pre-weighed filters and dividing by the volume of air used. The Mass Median Aerodynamic Diameter and geometric Standard Deviation were also determined from these data.

5. Observations -

For mortality, twice daily. For signs of overt toxicity, two or three times during the day following exposure, then thereafter for 14 days.

6. Termination -

All animals were necropsied at death or were killed on day 14 and subjected to gross necropsy. Special attention was paid to the respiratory system.

3

006908

B. RESULTS:

1. Atmospheric parameters -

TABLE I

Test Material Exposure Levels

Exp. #	Treatment	Ave. Grav. Conc. (mg/L)	Ave. Nominal Conc. (mg/l)	Mass Median Aerodynam. Diam.(u)
1	Dist. HOH	5.2	254	7.4
2	CTN	3.4	193	4.4
3	CTN	1.8	68	4.9
4	CTN	0.3	18	3.6

2. Mortality -

The mortality associated with inhalation exposure to Chlorothalonil is shown in Table II.

TABLE II

MORTALITY

Dose mg/L	Males[1]	Females	Combined
0	0/5	0/5	0/0
3.4	4/5	4/5	8/10
1.8	5/5	4/5	9/10
0.3	4/5	5/5	9/10

1 Number dead/number exposed

4

3. Cageside Observations -

Control and test animals were soiled with urine and feces and was thought to be due to the restraint system used.

Signs of toxicity in all test group animals included hypoactivity, respiratory distress, dehydration, tremors, prostration and possible hypothermia.

4. Body Weights -

Control animals exhibited weight gain during the observation phase of the study. All moribund animals suffered weight loss, while the three surviving rats showed decreased weights during days 1 through 8 but then partially recovered this loss.

5. Gross Necropsy Findings -

Treatment-related abnormalities were reported for all animals that died during the study. These included mottled, red and tan lungs, white rubbery material was found in the tracheas; there was congestion in the cerebral vessels and yellow gelatinous material in the intestines.

CONCLUSIONS:

All levels of exposure to Test Material resulted in high mortality and a precise LC_{50} cannot be determined, but it is substantially less less than 0.3 mg/L. The lowest LC_{50} for a TOX Category II rating is 0.2 mg/L. The results of this study therefore support a TOX Category of I for this product.

CORE RATING: Guideline data.

TOXICITY GATEGORY: I.

5