

US EPA ARCHIVE DOCUMENT

005457

Date: May 11, 1983

Subject: EPA File Symbol: 49538-R
Phyton-27 Liquid Fungicide Concentrate

From: Diloris J. Brookman
JHB/SLB : E 5/12/83

To: Henry Jacoby
Product Manager (21)

Applicant: Source Technology Biologicals, Inc.
P. O. Box 1984
St. Paul, Minnesota 55111

Active Ingredients:
Metallic Copper from copper sulfate 5.5
Inert Ingredients 94.5

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Skin Irritation Studies. Studies conducted by Hill Top Research, Inc. Data are accession number 249826. Method of support not indicated.

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Recommendations:

- (1) JHB/SLB finds these data acceptable to support conditional registration of this product.
- (2) An Acute Inhalation Study was not submitted and one must be submitted and/or cited as justification as to why this study is not necessary.
- (3) The appropriate symbol used is DANGER.

1 *[Signature]*

Label:

(1) The "If swallowed" statement must be revised to include "If swallowed, drink large quantities of water and induce vomiting by placing finger in back of throat. Get medical attention. Never give anything by mouth to an unconscious person."

Review:

(1) Acute Oral Toxicity Study: Hill Top Research, Inc., Project # 82-1408-21; January 10, 1983.

Procedure: Four groups consisting of five female Sprague-Dawley rats each received one of the following doses: 2.0, 3.2, 5.0 and 8.0 g/kg. One group consisting of five male rats received a 5.0 g/kg dose of the test material. Observations made frequently during first 5 hours following treatment, then twice daily thereafter for 14 days. Necropsy performed on all animals.

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Results: At 3.2 g/kg, 1/5 F died; at 5.0 g/kg, 2/5 F died; (At 8.0 g/kg, 2/5 F died.) No mortality in males. Clinical signs observed included pale to cyanotic discoloration, red-colored urine, anal staining, central nervous system depression, stains on feet, red ocular stains, hunched back posture, regurgitated eyes and emaciation. Necropsy revealed edema of intestines in a few animals; two dark red spots on stomach - sample colored; sample like material, partially filled; intestines - sample colored, sample bit.

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- material, gas filled, distended, irritated; kidney congested; lungs - mottled; uterus - fetid; ~~uterus~~ accessory bladder - small blood clots; lungs plural cavity; yellow nodules adjoining lung tissue; green-yellow caseous material; epithelial peeling; cannibal yaction, yellow/green anal stains, red anal stains. LD50 for females was 4.5 g/kg (3.7 - 6.0, 95% confidence limits). LD50 for males greater than 5.0 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(2) Acute Dermal Toxicity Study: Hill Top Research, Inc. Project # 82-1408-21; January 10, 1983.

Procedure: Five male and five female New Zealand rabbits received 2.0 g/kg at abraded skin site under occlusive wrap for 23 3/4 hours. Observations made hourly for first three hours after treatment, then twice daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities. Clinical signs observed included transient nasal discharge, central nervous system depression. Irritative effects included erythema, edema, atonia, desquamation, blanching, necrosis sloughing and scarring. Necropsy revealed white nodules in the mesentery of one male and an enlarged uterus which was connected to the gall bladder in one female. LD50 greater than 2.0 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

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(3) Fluorescence Irritation Study: Hill Top Research, Inc. Project # 82-1408-21; January 10, 1963.

Procedure: Six 120 g. albino rabbits were used. 0.5 ml of the test material at two adjacent and two central sites per animal under occlusive wrap for 24 hr exposure period. Observations made at 24 and 72 hours after treatment and at 7 days.

Results: At 24 hours, 3/6 had slight conjunctivitis which could not be scored due to simple staining and blurring. 4/6 had slight to moderate edema (Scoring 1 to 3). At 72 hours, 6/6 were injured to moderate conjunctivitis (6/6 = 5/6 = 3) and slight edema (3/6 = 1, 1/6 = 2). Fluorescence Irritation Index = 4.0. Blepharitis, darkened sites, corneal opacity, atony (increased), fissuring, ulcer slough, scar tissue.

Study Classification: Low Guideline Data.

Toxicity Category: I-DANGER

(4) Eye Irritation Study: Hill Top Research, Inc.; Project # 82-1408-21; January 10, 1963.

Procedure: Nine 120 g. albino rabbits received 0.5 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed 30 seconds after treatment with lukewarm tapwater. Observations were made at 24, 48 and 68 1/2 hours and 4 and 7 days after treatment. Animals with potentially reversible damage were observed every two-three days thereafter for a total of 21 days.

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Results: At 24 hours, 4/6 animals of the untreated group and 3/3 of the washed group had moderate to severe opacity (1/6 = 20, 1/3 = 30); 4/6 + 1/3 irrit. (1/6 = 2) (1/3 = 3)

$1/6 + 2/3$ erythema ($1/6 = 3$) ($2/3 = 5$), swelling
($1/6 = 2$, $2/6 = 3$, $1/6 = 4$) ($1/3 = 2$, $1/3 = 3$, $1/3 = 4$) and discharge
($1/6 = 2$, $1/6 = 3$) ($1/3 = 5$).

At 7 days, $1/6 + 3/3$ corneal opacity ($1/6 = 5$, $1/6 = 10$, $1/6 = 45$,
 $1/6 = 80$) ($2/3 = 5$, $1/3 = 60$); $1/6 + 1/3$ iris rotation ($1/6 = 10$)
($1/3 = 5$, $1/3 = 10$); $1/6$ erythema ($1/6 = 1$, $1/6 = 2$, $1/6 = 3$); $1/6 + 1/3$
swelling ($1/6 = 1$, $2/6 = 2$) ($1/3 = 1$, $1/3 = 2$); $1/6 + 1/3$ discharge
($1/6 = 1$, $2/6 = 3$) ($1/3 = 1$).

At 13 days, $1/6 + 2/3$ full corneal opacity ($1/6 = 20$, $1/6 = 7$
($1/3 = 5$, $1/3 = 60$); $1/6 + 1/3$ iris rotation ($1/6 = 10$) ($1/3 = 10$); $1/6$
erythema ($1/6 = 1$); $1/6 + 1/3$ swelling ($1/6 = 1$) ($1/3 = 1$); $1/6$
 $+ 1/3$ discharge ($1/6 = 1$) ($1/3 = 1$).

At 21 days, $1/6 + 1/3$ corneal opacity ($1/6 = 20$) ($1/3 = 20$);
 $1/3$ iris rotation ($1/3 = 5$); $1/6$ erythema ($1/6 = 1$); $1/3$
swelling ($1/3 = 1$); no discharge.

Discoloration, hair loss around eye, purrings of
cornea and blood-like discharge also observed.

Study Classification: Case Study - Rabbits.

Specific Category: I-DANGER.

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