5-12-83

005457

Date: May 11, 1983

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

From: Debora J Graham
EHE/SRB — 5/12/83

To: Henry Jacoby
Product Manager (21)

Applicant: Source Technology Ecological, 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. Stu conducted by Hill Top Research, Inc. Data und accession number 249826. Method of support not indicated.



Recommendations:
(1) EHB/SRB finds these data acceptable to support conditional registration of this product.

(2) An Acute Inhalation Study was not submitte and one must be submitted and/or data or justification as to why the study is not necessary.

(3) The appropriate signal word is DANGER

Label:
(1) The "If swallowed" statement must be revised to include "If swallowed, drink large quantity 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.



Results: At 3.2 g/kg, 4/5 F died; at 5.0 g/kg, 2/5 F died; At 8.0 g/kg, 5/5 F died. No mortalities among males. Clinical signs observed included piloerection, diarrhea, red-colored urine, anal staining, central nervous system depression, stains on paws, ocular stains, hunched back posture, ~~squinted eyes and emaciation~~. Necropsy revealed ~~white~~ discolorations in a few animals; ~~liver darkened~~ stomach - sample colored, sample like material, gas filled; intestines - sample colored, sample like

?

material, gas filled, thickened, irritated; kidneys congested; lungs - mottled; uterus - fluid; ~~enlarged~~ urinary bladder - small blood clots; lungs pleural cavity: yellow nodules adjoining lung lobes; green-yellow caseous material; intestinal serosa cannibalization, yellow/green renal stains, renal stains. LD50 for females was 4.5 g/Kg (3.4 - 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 #83-1408-21; January 10, 1983.

Procedure: Five male and five female New Zealand rabbits received 2.0g/Kg at abraded skin site under occlusive wrap for 23¾ 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 mesentary of one male and an enlarged uterus which was connected to the gall bladder in one female. LD50 greater than 2.0g/Kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(3) Primary Irritation Study: Hill Top Research, Inc. Project No. 82-1408-21; January 10, 1983.

Procedure: Six New Zealand rabbits received 0.5 gm of the test material at two abraded and two intact skin sites per animal under occlusive dressings for 24 hours. Observations made at 24 and 72 hours after treatment and at 7 days.

Results: At 24 hours, 3/6 had slight erythema and 4/6 could not be scored due to sample staining and blanching. 6/6 had slight to moderate edema (scores of 1 to 3). At 72 hours, 6/6 were limited to moderate erythema (1/6 = 2, 5/6 = 3) and slight edema (3/6 = 1, 4/6 = 2). The Primary Irritation Index = 4.0. Blanching, darkened sites, coriaceousness, atonicity (necrosis), fissuring, scale slough, scar tissue.

Study Classification: See Guideline Data.

Toxicity Category: I - DANGER

(4) Eye Irritation Study: Hill Top Research, Inc.; Project #82-1408-21; January 10, 1983.

Procedure: Nine New Zealand rabbits received 0.1 gm of the test material in one eye each. The treated eyes of three of the rabbits were washed 30 seconds after treatment with lukewarm tap water. Observations were made at 24, 48 and 68 hours and 4 and 7 days after treatment. Animals with potentially reversible damage were observed up to three additional days thereafter for a total of 21 days.

Results: At 24 hours, 6/6 animals of the unwashed group and 3/3 of the washed group had moderate to severe opacity (6/6 = 2)(3/3 = 2); 4/6 & 1/3 had iritis (6/6 = 2)(1/3 = 1).

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

At 7 days, 5/6 + 3/3 corneal opacity (1/6 = 5, 1/6 = 10, 1/6 = 40, 1/6 = 80) (3/3 = 5, 1/3 = 60); 1/6 + 1/3 iris vascularization (1/6 = 10) (1/3 = 5, 1/3 = 10); 4/6 erythema (4/6 = 1, 1/6 = 2, 1/6 = 3); 3/6 + 3/3 swelling (1/6 = 1, 2/6 = 2) (1/3 = 1, 1/3 = 2); 3/6 + 1/3 discharge (1/6 = 1, 2/6 = 3) (1/3 = 1).

At 13 days, 2/6 + 2/3 had corneal opacity (1/6 = 20, 1/6 = 40 (1/3 = 5, 1/3 = 60); 1/6 + 1/3 iris vascularization (1/6 = 10) (1/3 = 10); 3/6 erythema (3/6 = 1); 3/6 + 1/3 swelling (3/6 = 1) (1/3 = 1); 3/6 + 1/3 discharge (3/6 = 1) (1/3 = 1).

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

Vascularization, hair loss around eye, pannus & conjunctiva and blood-like discharge also observed.

Study Classification: Acute Irritation Rabbit.

Toxicity Category: I - DANGER.

Color

Page_____ is not included in this copy.

Pages 6 through 7 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.

X 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) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.