4-11-83

005456

Date: April 11, 1983

Subject: EPA Registration Number : 962-342
LACCO Copper Oxy Chloride Sulfate 50% Spraygate Fungicide

From: Rebecca F Graham
FHB/HSB E 4/11/83

To: Henry Jacoby
Product Manager (21)

Applicant: Los Angeles Chemical Company
4545 Ardine Street
South Gate, California 90280

Active Ingredients:
Copper expressed as metallic 50.0%
Inert Ingredients 50.0%

Background: Submitted Acute Oral, Acute Dermal Eye Irritation and Skin Irritation Studies. Studies conducted by Northwest Pacific Laboratories Inc. Data under accession number 249611. Method of support indicated as not submitted

Recommendations:
(1) FHB/HSB finds all the studies except the acute oral Study acceptable to support the conditional registration of this product. However for future submissions please note;

(a) In the Acute Dermal Study, individual necropsy reports for each animal must be submitted.

(b) In the Eye Irritation Study, Gaseous Chamber

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treated unwashed eyes and 3 with treated washed eyes must be used.

(2) The Acute Oral Study is Core Supplementary Data and thereby acceptable to support this registration because LD50 and 95% confidence limits for males and females were not submitted. Once this data is submitted this study can be upgraded to an acceptable level.

(3) An Acute Inhalation Study was not submitted and one must be submitted and/or cited or justification as to why this is unnecessary

Label:

(1) Labeling comments reserved until Acute Oral Data requested and acceptable Acute Inhalation Study is submitted.

Reviewer:

(1) Acute Oral Toxicity Study: Northwest Pacific Lab., Inc.; Report # X25016; December 7, 1982.

Procedure: 5 groups consisting of 5M and 5F Sprague-Dawley rats weighing a minimum of 180 grams each received one of the following doses orally: 1.2, 1.7, 2.0, 2.2 or 2.5g/Kg. Observations made for 14 days after treatment. Necropsy was performed on all animals that died during the test and on one animal of each sex surviving to the end of the test.

Results: At 1.2g/Kg, 1/5M died; at 2.0g/Kg, 4/5M + 4/5F died; at 2.2g/Kg, 4/5M + 4/5F died; at 2.5g/Kg, 5/5M and 5/5F died. All animals showed lethargy during the test period. Necropsy revealed pulmonary edema, abnormal livers, kidney and gastro-intestinal tract.

Study Classification: Core Supplementary data. LD50 and 95% confidence limits for males and females not given.

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(2) Acute Dermal Toxicity Study: Northwest Pacific Lab., Inc.; Report # X2J016; December 7, 1982.

Procedure: 5M and 5F New Zealand rabbits weighing between 2.0 and 3.0Kg received 5g/Kg of the test material at intact skin sites under occlusive wrap for 24 hour exposure. Observations made daily for 14 days after treatment. Necropsy performed on all animals that died during the study and on one animal per sex that survived the test period.

Results: No mortalities. No toxic signs noted. At necropsy of the one male possible slight pulmonary edema noted. LD50 greater than 5g/Kg.

Study Classification: Core Minimum Data. Individual necropsy reports for each animal must be submitted.

Toxicity Category: III - CAUTION

(3) Primary Skin Irritation Study: Northwest Pacific Lab., Inc.; Report # X2J016; December 7, 1982.

Procedure: Six New Zealand rabbits each received 0.5g of the test-material at intact skin sites under occlusive wrap for 4 hour exposure period. Observations made at 1, 24, 48 and 72 hours after treatment, then daily thereafter through 14 days.

Results: at 24 hours, 6/6 had erythema (scores of 1 to 3) and 4/6 edema (scores of 1). At 72 hours, 6/6 had erythema (scores 1 + 2) and 5/6 edema (scores of 1). At 7 days, 4/6 erythema (scores of 1) and 1/6 edema (score of 1). At day 14 all irritation had cleared.

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Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(4) Eye Irritation Study: Northwest Pacific Lab, Inc.; Report # X2J016; December 7, 1982.

Procedure: Six New Zealand rabbits received 0.1 ml of the test material in one eye each. Observations were made at 1, 24, 48 and 72 hours after treatment. If irritation present at 72 hours, observations are made at 7, 14 and 21 days after treatment or until irritation has subsided.

Results: At 24 hours, 6/6 had corneal opacity (1/6=20, 3/6=45, 2/6=60); iris irritation (4/6=5), redness (4/6=3), chemosis (1/6=1, 1/6=2, 3/6=3, 1/6=4) and discharge (4/6=1, 2/6=2).

At 72 hours, 6/6 corneal opacity (2/6=5, 3/6=15, 1/6=20); 5/6 iris irritation (3/6=5, 2/6=10); 1/6 redness (3/6=1, 3/6=2, 1/6=4); 5/6 chemosis (3/6=1, 1/6=2, 1/6=3) and 3/6 discharge (3/6=1, 1/6=2)

At day 7, 2/6 corneal opacity (2/6=5), iris irritation (1/6=5, 1/6=10), redness (1/6=1, 1/6=2), chemosis (1/6=1, 1/6=2) and 1/6 discharge (1/6=1).

At day 14, 1/6 corneal opacity (1/6=5); 2/6 iris irritation (2/6=5, 1/6=10). All irritation had cleared by day 21.

Study Classification: Core Minimum Data. 9 animals (6 with treated unwashed eyes and 3 with treated washed eyes must be used.

Toxicity Category: II - WARNING.

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