BB-1188

3/9/82

DATE

SUBJECT: EPA Registration Number 239-2458
Orthocide Vitavax 20-20 Seed Protectant

004666

FROM: Deloris F. Graham
FHB/TSS

TO: Henry Jacoby
Product Manager (21)

Applicant: Chevron Chemical Company
Ortho Agricultural Chemicals Division
940 Hensley Street
Richmond, California 94804

Active Ingredients

Captan	19%
Related Derivatives	1%
Carboxin	20%
Inert Ingredients	60%

Background: Submitted Acute Oral, Eye Irritation and Primary Dermal Irritation Studies in response to the Carborxin Registration Standard. Studies conducted by Chevron. Data under accession number 246774. Method of support not indicated.

Recommendation

(1) FHB/TSS finds the data acceptable to support the conditional registration of this product in compliance with the carboxin registration standard. However, for future submissions please note:

(a) In the Eye Irritation study, nine rabbits (six with treated unwashed eyes and three with treated washed eyes) must be used.

(b) In the Primary Dermal Study, four test sites (2 abraded and 2 intact) per animal must be used.

(2) Based on the Eye Irritation study the appropriate signal used is WARNING.

Label:

(1) Proposed labeling is acceptable.

Review:

(1) Acute Oral Toxicity Study: Chevron: Socal 1074/31:56; December 1, 1977.

Procedure: Five groups. Three of the groups consisted of 5M and 5F Sprague-Dawley rats, one consisted of 10M and 5F and one consisted of 10M and 10F. Each received one of the following doses: 3.3, 5.0, 7.5, 10, 15 g/kg. The rats weighed between 200-277 g. Observations were made daily for 14 days. Necropsy performed on all animals.

Results: At 5 g/kg, 1/10 M died; at 7.5 2/5 F died; at 10 g/kg, 7/10 M and 9/10 F died; at 15 g/kg, 5/5 M and 5/5 F died.

Toxic signs observed included diarrhea, depression, weakness, convulsions, chewing of extremities, reduce food consumption, and weight loss.

Necropsy revealed enlarged liver and spleen; reduced body fat; kidneys which appeared necrotic had small masses attached to them.

LD_{50} for males was 8.4 g/kg with confidence limits between 5.8 and 12 g/kg. LD_{50} for females was 7.3 g/kg with confidence limits between 5.0 and 11 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(2) Eye Irritation Study: Chevron; Socal 1072/30:74; October 10, 1977.

Procedure: A 0.1 ml of the test material was applied to one eye each of 6 rabbits. Observations were made at 1, 24, 48, 72 hours and 7, 10 and 14 days.

Results: At day 1, 2/6 animals had corneal opacity (1/6 = 5, 1/6 = 10); 6/6 iris irritation (6/6 = 5), redness (1/6 = 2, 5/6 = 3), chemosis (1/6 = 1, 2/6 = 2, 3/6 = 3), discharge (2/6 = 2, 4/6 = 3). Roughened cornea also observed.

At day 3, 4/6 had corneal opacity (3/6 = 5, 1/6 = 10), iris irritation (4/6 = 5); 6/6 redness (2/6 = 2, 4/6 = 3); 5/6 chemosis (2/6 = 1, 3/6 = 2), discharge (1/6 = 1, 4/6 = 2).

At day 7, 2/6 corneal opacity (1/6=5, 1/6=10); 5/6 redness (1/6=1, 4/6=2); 4/6 discharge (3/6=1, 1/6=2). Roughened cornea and pannus also observed.

At day 14, pannus present and roughened cornea; 1/6 redness (1/6 = 1).

Study Classification: Core Minimum Data. Nine rabbits (6 with treated unwashed eyes and 3 with treated washed eyes) must be used.

Toxicity Category: II - WARNING

(3) Primary Dermal Irritation Study: Chevron; Socal 1073/30:75; October 13, 1977.

Procedure: Each of six rabbits received 0.5 g of the test material at one intact and one abraded skin site under occlusive wrap for 24-hour exposure under occlusive wrap. Observations made at 24, 48, 72 hours and at 7 days.

Results: At 24 hours, slight to moderate erythema (scores 1 to 3) and slight to well defined erythema (scores 1 to 2) in all six rabbits. At 72 hours, 2/6 slight erythema (score of 1). At day 7, no irritation present. Primary irritation score was 1.8.

Study Classification: Core minimum data. Four test sites (2 abraded and 2 intact) per animal must be used.

Toxicity Category: IV - CAUTION

Carboxin science review

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Pages _____ through _____ are not included in this copy.

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___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

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X A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

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