

US EPA ARCHIVE DOCUMENT

6-3-80

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATE: June 3, 1980

SUBJECT: EPA Registration No. 1352-20
Flo-Pro V Seed Protectant

FROM: Sherell A. Sterling *led*
FHB/TSS *6-16-80*

TO: Henry Jacoby
Product Manager (21)

Applicant: Martin B. Barke
Cargill, Inc.
P.O. Box 9300
Minneapolis, MN 55440

Active Ingredient:
Carboxin 29.52%
Inert Ingredients 70.48%

Background: This amendment was submitted in order to change the signal word and precautionary statements from Toxicity Category I to Toxicity Category III, Acute Oral, Acute Dermal, Eye and Skin Irritation, and D.O.T. Corrosivity tests were submitted and are under Accession Number 242451. In lieu of an Acute Inhalation study, a sheet entitled "Inhalation Toxicity Statement" was submitted which presents justification for not requiring an Acute Inhalation study for this formulation. Per phone conversation with M. Barke the "Flo-Pro Vitavax" tested is the same as the alternate formulation of 1352-20 (submitted 3/12/80). The "alternate" method of support was chosen.

Recommendations:

1. The Acute Oral study is adequate and acceptable to support conditional registration of "Flo-Pro Vitavax."
2. The Acute Dermal study is adequate and acceptable as support for conditional registration of "Flo-Pro Vitavax." Please note the following reporting procedure for future submissions:
 - a. Response data must be reported in tabular form by sex and dose level.
3. An Acute Inhalation study was not submitted; however, justification for not submitting such data was submitted. This justification is sufficient to demonstrate that an Acute Inhalation study is not necessary at this time for "Flo-Pro Vitavax." Please note that this study may be required in the future.

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4. The Eye Irritation study is considered adequate and acceptable for conditional registration purposes for "Flo-Pro Vitavax."
5. The Skin Irritation study is considered adequate and acceptable for conditional registration purposes for "Flo-Pro Vitavax."
6. The D.O.T. Corrosivity Potential test is considered supplementary data; however, this study is not required by EPA for conditional registration. This study does not satisfy EPA testing procedures since the exposure period was only 4 hours.
7. Based on the data submitted, the appropriate signal word for the "Flo-Pro Vitavax" formulation is CAUTION.
8. FHB/TSS objects to the registration of the alternate formulation under EPA Registration No. 1352-20.

Note to the PM: In a phone conversation with Dr. Barke, he explained that the labeling with the signal word CAUTION would only be marketed on the alternate formulation; the DANGER labeling would appear on the original formulation. The applicant intends to register both formulations with different labeling under EPA Registration No. 1352-20. Please note that the data submitted are acceptable and adequate for the conditional registration of "Flo-Pro Vitavax" under a separate EPA Registration Number.

Comments:

1. FHB/TSS contacted Toxicology Branch (S. Gross) by phone on 6/3/80 to discuss the "Inhalation Toxicity Statement." Based on the information relayed over the phone, Toxicology considered this statement reasonable and acceptable in lieu of Acute Inhalation data.
2. Efficacy (Grable) has requested to review the labeling for this product.

Labeling Recommendations:

1. The subheading "Humans" must be expanded to "Hazard to Humans and Domestic Animals." Likewise, the subheading "Environmental" must be expanded to "Environmental Hazards."

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2. The statements:

"Keep product away from food or ^{ed} food products. Bags containing treated seed should be labeled 'Treated seed --do not use for feed, food or oil purposes'."

must be placed under the "Directions for Use" heading as a general restriction.

3. Please include the statement:

"Do not contaminate water by cleaning of equipment or disposal of wastes."

under the "Environmental Hazards" heading.

4. The "Inhalation Toxicity Statement" refers to use in a "closed system." FHB/TSS points out that the system described is not a closed system, but a "slurry treater." If the product is intended for use ^{only} in the slurry treater, this must be included on the labeling.

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Review:

1. Acute Oral Administration - Rats; Hill Top Research
#80-0377-21; April 22, 1980

Procedure: Groups of 5M, 5F Sprague-Dawley rats (189-265g) received oral dosages of "Flo-Pro Vitavax" at 5.0 g/kg. Rats were observed for 14 days post-treatment. Survivors were sacrificed at termination of study; all animals were subjected to necropsies.

Results: No mortalities. LD₅₀ is greater than 5.0 g/kg. All animals had normal appearance, behavior was normal. All animals showed an increase in weight by termination date. No abnormalities observed at necropsy.

Study Classification: Core Guidelines Data.

Toxicity Category: IV - CAUTION

2. Acute Dermal Toxicity - Rabbits; Hill Top Research
#80-0377-21; April 22, 1980

Procedure: 5M, 5F New Zealand white rabbits (2300-3000 g) with abraded skin received an application of 2 g/kg of "Flo-Pro Vitavax". Exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days post-exposure. At termination of study, survivors were sacrificed. All animals were subjected to necropsies.

Results: No mortalities. Incomplete dermal absorption observed. Symptoms included erythema, edema, desquamation, emaciation. Necropsies revealed: kidneys--enlarged, pitted; stomach injected; irritation in stomach, intestines, abdominal cavity wall; blood-like fluid in abdominal cavity.

Study Classification: Core Minimum Data. Response data must be given by sex.

Toxicity Category: III - CAUTION

3. Acute Eye Application - Rabbits; Hill Top Research
#80-0377-21; April 22, 1980

Procedure: 0.1 ml of "Flo-Pro Vitavax" was applied into one eye of each of 9 New Zealand white rabbits. Three rabbits had the treated eye flushed with 200 ml of lukewarm tap water for 60 seconds, 30 seconds post-instillation; remaining 6 eyes were unwashed. Scoring at 24, 48, 72 hours, 4 and 7 days.

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Results: In unwashed eyes at 24 hours, erythema in 5/6 = 1 and 1/6 = 2; discharge in 3/6 = 1. All unwashed eyes were clear at day 4. All scores for washed eyes were 0.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

4. Primary Dermal Irritation - Rabbits; Hill Top Research #80-0377-21; April 22, 1980

Procedure: 0.5 ml of "Flo-Pro Vitavax" was applied to each of 4 sites (2 abraded and 2 intact) on each of 6 New Zealand white rabbits. Exposure was for 24 hours under occlusive wrap.

Results: Intact sites at 24 hours exhibited very slight erythema at 8/12 sites and well-defined erythema at 2/12 sites; 10/12 showed very slight edema. Abraded sites at 24 hours showed very slight erythema in 9/12 and 3/12 with well-defined erythema; 9/12 had very slight edema and 1/12 with slight edema. By 72 hours 3/12 had very slight erythema at intact sites; 1/12 with very slight erythema at abraded sites. All irritation was cleared by day 4. Primary Irritation Index was 1.08.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

5. D.O.T. Corrosivity Potential; Hill Top Research #80-0377-21; April 22, 1980

Procedure: 0.5 ml of "Flo-Pro Vitavax" was applied to one intact skin site on each of 6 New Zealand white rabbits. Exposure was for 4 hours under occlusive wrap. Skin sites were scored after removal of patch, at 24 and 48 hours post-application.

Results: No irritative or corrosive effects seen.

Study Classification: Core Supplementary Data. Exposure was for only 4 hours.

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Carboxin science review

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Pages _____ through _____ are not included in this copy.

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 product quality control procedures
 - Identity of the source of product ingredients
 - Sales or other commercial/financial information
 - 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
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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.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

INHALATION TOXICITY STATEMENT

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Inhalation studies for this commercial seed treatment product were not run, for the following reasons:

1. The formulation is a liquid. The active ingredient cannot be disseminated into the air from handling of the product to make the dilution for application on the seed.
2. The formulation has no volatile organic liquids, solvents.
3. The active ingredient is not volatile.
4. The active ingredient, from an inhalation standpoint, is relatively non-toxic.
5. [REDACTED]
6. The dilution is applied to the seed in a closed system. The dilution is pumped from the dilution agitation tank to the treater where it is metered onto the seed, in the seed treater. In the enclosed seed treater, the seed is tumbled and flows into an enclosed bagging bin. From the bagging bin the seed then falls into the seed bag.
7. The seed still has surface moisture at the time of bagging, all but eliminating any dust.
8. An aspirator is positioned in the bagger, exhausting any potential dust. Aspirators are also positioned at other treating points.
9. [REDACTED]
10. Free particles, as a result of the seed's surface moisture are large agglomerates.
11. All personnel wear protective face masks to eliminate potential exposure.

4/29/80
MBB:dml

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