UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

TCX

CASWELL FILE

DATE: November 25, 1980

SUBJECT: Flo Pro C Seed Protectant
EPA Registration No. 1352-18

159

FROM: Sherell A. Sterling 12-3-80
FHB/TSS

TO: Henry Jacoby
Product Manager (21)

Applicant: Cargill, Inc.
Cargill Building
Minneapolis, MN 55402

Active Ingredient:

Captan	28.37%
Related derivatives	1.63%
Inert Ingredients	70.0%

Background: The applicant proposes a change in signal word from CAUTION to DANGER based on recent Eye Irritation studies. Acute Oral, Acute Dermal, Eye and Skin Irritation and D.O.T. Corrosivity studies were submitted on the Flo Pro C Seed Protectant formulation. In addition, Eye Irritation studies were conducted on Flo Pro C-R Captan, Gustafson 30DD 30% Captan, Stauffer 4F 39% Captan and Ortho 4F 37.2% Captan. All studies were conducted by Hill Top Research, Inc. of Miamiville, Ohio. The "alternate" method of support was chosen.

Recommendations:

1. The Acute Oral study is adequate and acceptable for conditional registration purposes.

2. The Acute Dermal study is adequate and acceptable for conditional registration purposes.

3. An Acute Inhalation study was not submitted; however, a statement was submitted and reviewed previously (see Sterling 7/9/80). This study is not required at this time.

4. The Eye Irritation studies are adequate and acceptable for conditional registration purposes. It should be noted that only data on the exact formulation can be used in support of an application under the "alternate" method of support.

5. The Primary Dermal Irritation study is adequate and accepatable for conditional registration purposes.

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6. The D.O.T. Corrosivity test is not necessary for conditional registration; however, it is acceptable as supplementary data.

7. FHB/TSS has no objection to the change in signal word from CAUTION to DANGER for both "Flo Pro C Seed Protectant" and "Flo Pro C-R Seed Protectant."

8. Precautionary labeling is acceptable as submitted at this time.

Comments:

1. Please note that the labeling directions are different for the two formulations. Since the "Flo Pro C" does not contain a dye, the directions must include a statement concerning the addition of dye; "Flo Pro C-R which contains a dye does not require these directions. The definition of alternate formulation [40 CFR 162.6 (b)(3)] states that a change in composition must not require a change in labeling directions.

2. Please note the Gustafson, Stauffer and Ortho products tested retain the signal word CAUTION; data submitted by Cargill shows that signal word should be DANGER based on the eye irritation studies. the

3. The degree of disparity between "caution" and "danger" signal words between competitors' products needs further assessment within FHB.

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12-17-80

Review:

1. Acute Oral Administration - Rats; Hill Top Ref. # 80-667-21; July 31, 1980; Acc. No. 243564.

   Procedure: A group of 5M (232-253 g), 5F (171-189g) Sprague - Dawley rats received a dosage of 5g/kg of the test substance. The test substance was Flo Pro C 30% Captan and it was administered by oral intubation. The rats were observed for 14 days. At the termination of the study, survivors were sacrificed; all animals were subjected to gross necropsies.

   Results: No mortalities reported. All animals appeared normal for duration of study; all animals gained weight. No gross pathological alterations observed at necropsy. $LD_{50} > 5g/kg$.

   Study Classification: Core Guideline Data.

   Toxicity Category: IV - CAUTION

2. Acute Dermal Toxicity - Rabbits; Hill Top Ref. # 80-667-21; July 31, 1980; Acc. No. 243564.

   Procedure: One group of 5M, 5F New Zealand white rabbits (2308 - 2902 g), all with abraded sites received an exposure to 2g/kg oz. Flo Pro C 30% Captan. Exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days. Animals which survived study were sacrificed at termination of study; all animals received gross necropsies.

   Results: No mortalities reported. Approximately 1/2 of the animals incompletely absorbed the material. Symptoms included: erythema, edema, atonia, desquamation, necrosis, coriaceousness, fissuring, scar tissue, nasal discharge, open sores, slight depression, emaciation, inability to use hind legs. Necrospies revealed pitted kidneys; lack of body fat in 1 rabbit. LD_{50} 2 g/kg.

   Study Classification: Core Guidelines Data.

   Toxicity Category: III - CAUTION.

3. Acute Eye Application - Rabbits; Hill Top Ref. # 80-667-21; July 31, 1980; Acc. No. 243564.

   Procedure: A total of 9 New Zealand white rabbits received 0.1 ml of Flo Pro C 30% Captan in one eye each. Three of these rabbits' treated eyes were irrigated with 200 ml. of lukewarm tap water for 60 seconds, 30 seconds post-instillation. Scoring according to Draize's method of 24, 48, 72 hours and 7, 10, 13, 16, 19, 21 days.

Results: At 24 hours, unirrigated eyes showed corneal opacity in 2/6=5, 2/6=15, 1/6=20, 1/6=30; iris irritation in 6/6=5; conjunctival redness in 1/6=2, 5/6=3; chemosis in 2/6=2, 4/6=4; discharge in 6/6=2. At 7 days unirrigated eyes still showed opacity in 2/6=5, 2/6=20 with continuing irritation noted in iris and conjunctivae. By day 21, corneal opacity in 2/6=20; iris irritation in 1/6=5. Non-irrigated eyes appeared vascularized in 2/6; 3/6 animals with blisters.

In the irrigated eyes at 24 hours, corneal opacity in 1/3=10, 1/3=15, 1/3=20; iris irritation in 3/3=5; conjunctival redness in 3/3=3; chemosis in 1/3=3, 2/3=4; discharge in 3/3=2. All opacity gone by day 7 with only redness in 2/3=1. At 21 days, only redness in 1/3=1 observed. All irrigated eyes exhibited blisters under lids.

Study Classification: Core Guideline Data.

Toxicity Category: I - DANGER.

4. Acute Eye Irritation Potentials of Flo Pro C 30% Captan, Gustafson 30DD 30% Captan, Flo Pro C-R 30% Captan, Stauffer 4F 39% Captan, and Ortho 4F 37.2% Captan; Hill Top Ref. # 80-667-21; July 31, 1980 (not accessioned)

Procedure: Five groups of 9 New Zealand white rabbits received a 0.1 ml dosage of one of five test substances in one eye of each animal. Test substances were Flo Pro C 30% Captan, Gustafson 30DD 30% Captan, Flo Pro C-R 30% Captan, Stauffer 4F 39% Captan and Ortho 4F 37.2% Captan. Three of the treated eyes in each of the five groups were irrigated with 200 ml of lukewarm tap water for 60 seconds, 30 seconds post-treatment. Scoring according to Draize's method at 24, 48, 72 hours and 4, 7 days.

Results: For Flo Pro C 30% Captan, unirrigated eyes at 24 hours showed corneal opacity in all eyes (2/6=5, 2/6=15, 1/6=20, 1/6=30); also all eyes exhibited iris and conjunctival irritation. By day 7, unirrigated eyes showed opacity only in 2/6=5, 2/6=20 with iris and conjunctival irritation persisting. Irrigated eyes for this substance at 24 hours showed corneal opacity in 1/3=10, 1/3=15, 1/3=20; iris irritation and conjunctival irritation in all eyes. Corneal opacity, iris irritation cleared by day 7; only redness exhbited in 2/3=1. Both irrigated and non-irrigated eyes exhibited blisters under the eyelid and vascularization.

Gustafson 30DD 30% in unirrigated eyes at 24 hours exhibited corneal opacity (2/6=30, 2/6=40, 1/6=60, 1/6=80); iris irritation was noted in 3/6, other 3 not able to score due to severe corneal opacity; conjunctival irritation in all animals. By day 7, unirrigated eyes still showed opacity (1/6=10, 1/6=20, 1/6=30, 1/6=40, 1/6=80); 2 eyes remained impossible to score for iris irritation due to severe opacity; conjunctival irritation persisted. Irrigated eyes at 24 hours showed corneal opacity (2/3=10, 1/3=15) at 24 hours; iris and conjunctival irritation in all eyes. At 7 days corneal opacity in 1/3=80, 2/3=5; 1/3 eyes impossible to score due to opacity, 2/3=5; conjunctival irritation persisted in all eyes.

For Flo Pro C-R 30% Captan, non-irrigated eyes at 24 hours showed opacity in 1/6=5, 5/6 with opacity and swelling too severe to score; iris irritation in 5/6 too swollen and opacity too severe to score; conjunctival irritation in all animals. Irrigated eyes at 24 hours exhibited opacity in 2/3=20, 1/3 too severe to score; iris irritation not scored in 1/3 due to extreme swelling and corneal opacity, 1/3=1, 1/3=2; conjunctival irritation in all eyes. At 7 days, only opacity in 1/3=80 with inability to score iris in 1/3; conjunctival irritation persisting. Blisters formed under eyelids of irrigated group.

The Stauffer 4F 39% Captan at 24 hours in non-irrigated eyes showed opacity in 1/6=10, 1/6=60 and 4/6 with swelling and chemosis too severe to score; iris irritation in 1/6=10 and 4/6 impossible to score due to swelling, opacity; conjunctival irritation in all other eyes. At 7 days, corneal opacity in 2/6=20, 1/6=60, 2/6=80; iris irritation unable to be scored in 3/6, 2/6=5; conjunctival irritation persists. Irrigated eyes at 24 hours shows corneal opacity in 1/3=45, 2/3=60; swelling and chemosis too severe to score iris irritation in 2/3, 1/3=2; all eyes show conjunctival irritation. By 7 days, corneal opacity in 3/3=60; 1/3 still unable to be scored for iris irritation, 1/3=5, 1/3=10; conjunctival irritation persists.

Ortho 4F 37.2% Captan in non-irrigated eyes at 24 hours, opacity in 2/6=20 and 2/6 with swelling too severe to score; iris irritation in 4/6=1 and 2/6 opacity too severe to score; conjunctival irritation in all eyes. By day 7, opacity in 4/6=20, 1/6=60, 1/6=80; other irritation persists. Irrigated eyes at 24 hours showed 1/3=5, 1/3=20, 1/3=30; iris irritation in 3/3=5; redness in 3/3=3; swelling in 1/3=2, 1/3=3, 1/3=4 and discharge in 3/3=3. At day 7, corneal opacity in 1/3=5, 1/3=20; irritation persists. Both irrigated and non-irrigated eyes appeared vascularized. Blisters observed under eyelid in non-irrigated eyes.

Study Classification: Core Guideline Data.

Toxicity Category:

Flo Pro C 30% Captan - I/DANGER
Gustafson 30 DD 30% Captan - I/DANGER
Flo Pro C-R 30% Captan - I/DANGER
Stauffer 4F 39% Captan - I/DANGER
Ortho 4F 37.2% Captan - I/DANGER

5. Primary Dermal Irritation; Hill Top Ref. # 80-667-21; July 31, 1980; Acc. No. 243564.

Procedure: Six New Zealand white rabbits each received an application of 0.5 ml of Flo Pro C 30% Captan at each of 4 sites. Two sites on each animal were abraded, 24 hours under occlusive wrap. Scoring at 24, 72 hours and 7 days.

2 remained intact. Exposure was for 8hrs 12-3-80

Results: At 24 hours, the intact sites exhibited erythema in 12/12=3 and edema in 3/12=2, 5/12=3, 4/12=4; abraded sites showed erythema in 12/12=3 and edema in 2/12 =1, 5/12=2, 2/12=3, 3/12=4. By 72 hours, intact sites showed erythema in 2/12=1, 2/12=2, 6/12=3, 2/12=4 and edema at 4/12=1, 1/12=2, 1/12=3 and 4/12=4; abraded sites had erythema in 10/12=3, 2/12=2 with edema in 4/12=1, 2/12=2, 4/12=3 and 2/12=4. Irritation persisted through day 7 at most sites. Primary Irritation Index is 5.37.

Study Classification: Core Guideline Data.

Toxicity Category: II - WARNING.

6. D.O.T. Corrosivity; Hill Top Ref. #80-667-21; July 31, 1980; Acc. No. 243564.

Procedure: The substance Flo Pro C 30% Captan was applied to each of 6 New Zealand white rabbits at a rate of 0.5 ml to intact sites. Exposure was for 4 hours under occlusive wrap. Scoring a 4, 24 and 48 hours post-application.

Results: At 4 hours, very slight to severe erythema; very slight to slight edema observed. At 24 hours, very slight to well-defined erythema; very slight to moderate ~~erythema; very slight edema.~~ edema. By 48 hours, very slight to moderate erythema; very slight edema

Study Classification: Core Supplementary Data. This study is not necessary for EPA registration of pesticide products.

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STORAGE AND DISPOSAL

PROHIBITIONS
Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL
Pesticide, spray mixture or rinsate that cannot be used or chemical reprocessed should be disposed of in a landfill approved for pesticides or buried in a safe place away from water supplies.

CONTAINER DISPOSAL
Triple rinse (or equivalent) and dispose in an incinerator or landfill approved for pesticide containers, or bury in a safe place.

GENERAL
Consult federal, state or local disposal authorities for approved alternative procedures such as limited open burning.

NOTICE:
Our recommendations for use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made as to the effects of such or the results to be obtained if not used in accordance with directions or established safe practice. The buyer must assume all responsibility, including injury or damage, resulting from its misuse as such, or in combination with other materials.

Contents: U.S. 5 Gallons

Flo-Pro C SEED PROTECTANT

ACTIVE INGREDIENTS:

Captan*	28.37%
Related derivatives	1.63%
INERT INGREDIENTS	70.0%

*N-Trichloromethylthio-4-cyclohexene-1, 2-dicarboximide

Captan ..... 2.94 lbs./gal.

EPA EST. NO. 36628-TN-1

EPA REG NO. 1352-18

Manufactured by
Chemical Products Division
Agricultural Products Dept.
Cargill, Incorporated
P.O. Box 9300
Minneapolis, Minnesota 55440

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

Swallowed: Harmful if swallowed, get medical attention.

Inhaled: May be harmful if inhaled, get medical attention. Avoid inhalation by using a respirator.

Skin: Avoid contact with skin or clothing. Wear rubber gloves. Wash affected area thoroughly with soap and water. Wash hands and face thoroughly with soap and water after use and before eating or smoking.

Eyes: Avoid contact with eyes. Wear protective eye covering. In case of contact with eyes, flush immediately with running water for 15 minutes and get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS
This product is toxic to fish. Keep out of lakes, streams or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

Flo-Pro is a Trademark of Cargill, Inc.

Flo-Pro C Seed Protectant is for use by professional seed treaters only.

DIRECTIONS
STORE IN COOL DRY PLACE.

Primarily designed for the protection of seed from soil borne fungi causing seed, seedling and root rots.

Treated seed must not be used for human consumption or as animal feed. Bags containing treated seed should be labeled: TREATED SEED - DO NOT USE FOR FEED, FOOD OR OIL PURPOSES.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

1. Add 1 gallon of FLO-PRO Seed Protectant concentrate to 5 gallons of cool tap water and mix thoroughly for 15 minutes to prepare the FLO-PRO dilution.
2. Add 7 oz. of CARGILL Seed Protectant Liquid Dye** to each 6 gallons of the FLO-PRO dilution and mix for an additional 10 minutes.

Seed	Application Rates (Cubic Centimeters of Diluted Product Per 100 lbs. of Seed)
Corn Field	270
Sweet	570
Wheat*	270
Oats*	420
Barley*	320
Flax	530
Peas	370
Cucumber, Cantaloupe, Tomato	420
Squash, Pumpkin, Watermelon, Muskmelon	280
Cotton Acid Delinted	420
Reginned	630
Cabbage, Cauliflower, Broccoli, Brussels Sprouts, Collards, Kale, Mustard, Turnip	210
Peppers (Calif. Wonder)	420
Cowpeas	420
Rice	480
Rye*	370
Crucifers	210

*For Seed & Seedling Rots. not for Bunt Smut.

1. Add 1 gallon of FLO-PRO Seed Protectant concentrate to 3 gallons of cool tap water and mix thoroughly for 15 minutes to prepare the FLO PRO dilution.
2. Add 7 oz. of CARGILL Seed Protectant Liquid Dye** to each 4 gallons of the FLO-PRO dilution and mix for an additional 10 minutes

Seed	Application Rates (Cubic Centimeters of Diluted Product Per 100 lbs. of Seed)
Beans (except baby limas)	250
Soybeans	240
Sorghum - hulled (Kernel Smut)	420
Sugar Beets - West	570
Spinach	570

1. Add 1 gallon of FLO-PRO Seed Protectant concentrate to 2 gallons of cool tap water and mix thoroughly for 15 minutes to prepare the FLO-PRO dilution.
2. Add 7 oz. of CARGILL Seed Protectant Liquid Dye** to each 3 gallons of the FLO-PRO dilution and mix for an additional 10 minutes.

Seed	Application Rates (Cubic Centimeters of Diluted Product Per 100 lbs. of Seed)
Clover, Alfalfa, Lespedeza, Trefoil	580
Beets, Swiss Chard, Sugar Beets-	
East	850
Blue Grass, Grasses	580

1. Use Undiluted Concentrate and add 1 oz. CARGILL Seed Protectant Liquid Dye** to each gallon of the FLO-PRO Concentrate. Mix for an additional 20 minutes.

Seed	Application Rates (Cubic Centimeters of Product Per 100 lbs. of Seed)
Onions (pelleting)	560

**21CFR Chapter 1 Section 3.13 requires grain seed treated with poisonous substances in excess of recognized tolerances be suitably colored to prevent their subsequent inadvertent use as food for men or feed for animals.

CPA 121(10)