

US EPA ARCHIVE DOCUMENT

CASWELL 1159

000440

DATE: July 9, 1980

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

FROM: Sherell A. Sterling
FHB/TSS

SSS
7-22-80
E 8/4/80

TO: Henry Jacoby
Product Manager (21)

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

Active Ingredient:

Captan	28.37%
Related Derivatives	1.63%
Inert Ingredients	70.00%

Background:

An amendment was submitted for the addition of a brand name and a minor formulation change. This amendment includes a change in precautionary statements. Acute Oral, Acute Dermal, Eye and Skin Irritation studies were submitted along with an "Inhalation Toxicity Statement." The studies were conducted by Hill Top Research, Inc. of Miami, Ohio. Data are under Accession Number 242447. The method of support is "alternate."

Recommendations:

1. The Acute Oral study is considered acceptable and adequate for registration purposes.
2. The Acute Dermal study is considered acceptable and adequate for registration purposes. However, for future studies, please note that if data based on testing with at least 5 animals per sex with abraded skin are submitted showing that the LD₅₀ is greater than 2 g/kg with a 24-hour contact period, no further testing at other dose levels is necessary. In this type of study, all animals must have abraded skin; if studies at additional dosage levels are required, half of the animals must have abraded skin and the remaining animals with intact sites.

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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 C-R Seed Protectant." Please note that this study may be required in the future.
4. The Eye Irritation study is considered adequate and acceptable for registration purposes.
5. The Skin Irritation study is adequate and acceptable for registration purposes.
6. The D.O.T. Corrosivity Potential test is considered supplementary data; however, this study is not required by EPA for 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 "Flo-Pro C-R Seed Protectant" is DANGER.
8. FHB/TSS objects to this amendment if the applicant intends to register both formulations with different labeling under EPA Registration No. 1352-20. Please note that 40 CFR 162.6 only allows for amended registration if the minor formulation change "...would not require any changes in the label directions, required warning or caution statements, or the use classification...."
9. 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."

Labeling Recommendations:

1. The subheading "HUMANS" must be expanded to "Hazard to Humans and Domestic Animals." Likewise, the heading "ENVIRONMENTAL" must be changed to "Environmental Hazards."
2. Since the statement:

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

is a general restriction, it must be placed under the "Directions for Use."

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3. The following statement must be added to the "Environmental Hazards" section of the labeling:

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

4. The "Prohibitions" section under the STORAGE AND DISPOSAL heading must be revised to the following:

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

Review:

1. Acute Oral Administration - Rats; Hill Top #80-375-21;
April 22, 1980.

Procedure: A group of 5 M, 5 F Sprague-Dawley rats (183-266g) received a dosage of Flo Pro CR at 5 g/kg by esophageal intubation. Animals were observed for 14 days. At termination of study, survivors were sacrificed; all animals were subjected to necropsies.

Results: No mortalities. All body weights increased. Symptoms included purple-colored stools for first day; all other appearances were normal. No gross pathological alterations were observed at necropsy, $LD_{50} > 5$ g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

2. Acute Dermal Toxicity - Rabbits; Hill Top #80-375-21;
April 22, 1980.

Procedure: 5 M, 5 F New Zealand white rabbits (2381-3000 g), half with abraded skin, received an application of 2 g/kg of Flo Pro CR. 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. LD_{50} is greater than 2 g/kg. All animals gained weight. Symptoms included: edema, desquamation, fissuring, nasal discharge. Necropsies revealed 2/10 with injected stomach, 1/10 with mottled kidneys; no other gross pathological alterations noted.

Study Classification: Core Minimum Data. All animals should be abraded.

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Toxicity Category: III - CAUTION

3. Acute Eye Application - Rabbits; Hill Top #80-375-21;
April 22, 1980.

Procedure: 0.1 ml of Flo Pro CR 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. Draize scoring on day 1, 2, 3, 4, 7, 10, 13, 16, 19 and 21.

Results: At 24 hours in unrinsed eyes, 6/6 could not be scored for corneal opacity, iris irritation due to swelling; conjunctival redness in 6/6 = 3 with blisters under eyelids; swelling in 6/6 = 4; discharge in 6/6 = 3. At day 7, corneal opacity in 1/6 = 20, 2/6 = 30, 2/6 = 40, 1/6 = 45; iris irritation in 6/6 = 1; erythema in 3/6 = 2, 3/6 = 3 with blisters; swelling in 2/6 = 1, 1/6 = 2, 2/6 = 3, 1/6 = 4; discharge in 1/6 = 1, 3/6 = 2. At day 21, corneal opacity in 3/6 = 5, 1/6 = 30, 1/6 = 40; iris irritation in 1/6 = 1; erythema in 3/6 = 1, 3/6 = 2 with vascularization in 4/6. During study, animal showed small growth around eye; hair loss around eyes.

In rinsed eyes at 24 hours, corneal opacity in 1/3 = 20, 1/3 = 60 and 1/3 too swollen to score; iris irritation in 2/3 = 1, 1/3 too swollen to score; erythema in 3/3 = 3 with blisters under eyelid; swelling in 3/3 = 4; discharge in 1/3 = 2, 2/3 = 3. By day 7 corneal opacity in 1/3 = 5, 1/3 = 20, 1/3 = 40; iris irritation in 1/3 = 1; erythema in 1/3 = 1, 1/3 = 2 and 1/3 = 3 with blisters; swelling in 1/3 = 4; discharge in 1/3 = 3. At day 21, corneal opacity in 1/3 = 40; erythema in 1/3 = 2 with vascularization and hair loss around eye; swelling in 1/3 = 1; 1/3 eyes misshaped from day 13-19.

Study Classification: Core Guideline Data.

Toxicity Category: I - DANGER

4. Primary Dermal Irritation - Rabbits; Hill Top #80-375-21;
April 22, 1980.-

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

Results: Erythema could not be scored at 24 hours due to sample stain. Edema visible at 24 hours in 3/12 = 1 and 9/12 = 2 at intact sites; abraded sites showed 6/12 = 1, 5/12 = 2 and 1/12 = 3. All scores were zero by 72 hours. Primary Irritation Index reported at 0.83.

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Study Classification : Core Guideline Data.

Toxicity Category : IV - CAUTION

5. D.O.T. Corrosivity Potential; Hill Top #80-375-21;
April 22, 1980.

Procedure : 0.5 ml of Flo Pro CR 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, 24 and 48 hours post-application.

Results : No erythema readings at 4, 24 hours due to stain; no erythema observed at 48 hours. No edema.

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

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FLO-PRO

CARR

SEED PROTECTANT

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

ACTIVE INGREDIENTS:

Captan (N-Trichloromethylthio-4-cyclohexene-1,2-dicarboximide) 28.37%

Related Derivatives

1.63%

INERT INGREDIENTS:

Captan 2.94 lbs./gal.

HUMANS

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

Skin: Wash affected area thoroughly with soap and water. Wash hands and face thoroughly with soap and water after use and before eating or smoking. Wear clean clothing.

Eyes: Corrosive, causes eye damage. Do not get in eyes. In case of contact with eyes, flush immediately with running water and get medical attention. Wear goggles or face shield when handling.

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

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

EPA REG NO. 1352-18
EPA EST. NO. 36628-TN-1

ENVIRONMENTAL

This product is toxic to fish. Keep out of lakes, streams or ponds.

FLO PRO is a Trademark of Cargill, Inc.

DIRECTIONS

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. FLO PRO Seed Protectant Concentrate is for use by professional seed treaters only. Observe all cautions and limitations on labeling of products used in mixtures.

STORAGE AND DISPOSAL

Prohibitions

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

Pesticide Disposal

Pesticide, spray mixture or rinseate that cannot be used or chemically 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

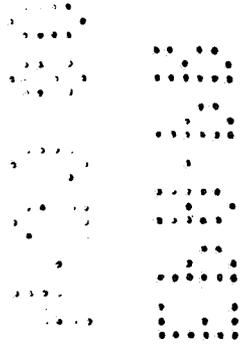
Consult federal, state or local disposal authorities for approved alternative procedures such as limited open burning.

STORAGE

Store in a cool dry place.

Contents: U.S. 5 Gallons

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DIRECTIONS

Add 1 gallon of FLO-PRO Seed Pro-tectant concentrate to 5 gallons of cool tap water and mix thoroughly for 15 minutes to prepare the FLO-PRO dilution.

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, Musk-melon	280
Cotton	420
Colton Acid Delinted	630
Reginned	630
Cabbage, Cauliflower, Broccoli, Brussels Sprouts, Collards, Kale, Mustard,	
Turnip	210
Peppers (Callf. Wonder)	420
Cowpeas	420
Rice	480
Rye*	370
Crucifers	210

*For Seed & Seedling Rot, not for Bunt Smut.

Add 1 gallon of FLO-PRO Seed Pro-tectant concentrate to 3 gallons of cool tap water and mix thoroughly for 15 minutes to prepare the FLO-PRO dilution.

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

Add 1 gallon of FLO-PRO Seed Pro-tectant concentrate to 2 gallons of cool tap water and mix thoroughly for 15 minutes to prepare the FLO-PRO dilution.

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

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

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 combinations with other materials.

