108801
+
080808

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

F800

DATE: January 14, 1980

SUBJECT: EPA File Symbol: 100-ANU
Milocep; Caswell #_____, 705A

FROM: Sherell A. Sterling SAS 1-23-80 E 1/24/80
FHB/TSS

TO: Willa Garner
Product Manager (23)

Applicant: Ciba-Geigy Corporation
Agricultural Division
P.O. Box 11422
Greensboro, NC 27409

Active Ingredients:

108801 — Metolachlor. 36.3%
080808 — Propazine. 18.7%

Inert Ingredients 45.0%

Background: This submission is in support of the conditional registration of Milocep. The data are in Accession No. 235980 and include Acute Oral, Acute Dermal, Acute Inhalation, Eye and Skin Irritation studies. A method of support has not yet been chosen. These studies were conducted at the International Research and Development Corporation (IR&D). The test substance was Milocep 5L.

Recommendations:

1. The Acute Oral, Acute Dermal, Eye and Skin Irritation studies are adequate and acceptable to support the conditional registration of this product.

2. The Acute Inhalation study is Core Supplementary Data. The summary (page 3) argues, however, that inhalation exposure will not be likely and that higher atmospheric concentrations were not obtainable. The data show that the product is no worse than toxicity category II. For these reasons, further Acute Inhalation studies will not be required at this time.

3. As proposed by the applicant, the appropriate signal word is DANGER based on the Eye Irritation study.

4. FHB/TSS has no objection to the conditional registration of this product, based on the hazards to humans and domestic animals, provided that the labeling revisions noted below are made.

Labeling:

1. The statement:
   "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
   must appear on the labeling under the heading "Directions for Use."

Review:

1. Acute Oral Toxicity (LD50) Study in Rats; IR&D #382-043; October 17, 1978

   Procedure: Groups of 5M, 5F Sprague-Dawley strain rats (231-300 g) received oral dosages at levels of 1574, 2314, 3401, 5000, 7350 and 10805 mg/kg of the test substance. Animals were observed for 14 days. At termination of study, survivors were sacrificed; all animals were subjected to necropsies.

   Results: At 1574 mg/kg there were no mortalities. At 2314 mg/kg, 1/5F died. At 3401 mg/kg, 1/5M and 4/5F died. At 5000 mg/kg, 2/5M and 4/5F died. At 7350 and 10805 mg/kg, all animals died. LD50 for males is 4811 mg/kg with a 95% confidence range of 3771-6139 mg/kg. LD50 for females is 2944 mg/kg with a 95% confidence range of 2185-3965 mg/kg. The body weights of all survivors increased. Symptoms observed include salivation, diarrhea, hyperactivity, ataxia, tremors, lacrimation, ~~hypo~~hyper sensitivity to touch and prostration. Pathological alterations observed were: stomach - distended, contains light brown oily material, glanular mucosa with hyperemia, non-glandular mucosa with brown foci, glandular mucosa with red foci, contains creamy colored material, contains red fluid; intestines - small with creamy colored fluid, duodenum with mucosa and hyperemia, small with red fluid, enlarged with yellow fluid; lungs - congestion, consolidated with several green nodules containing a light green purulent material; thoracic cavity - hydrothorax; thymus - congestion; kidneys - hydronephrosis, ulceration, pale coloration; spleen - dark coloration.

   Study Classification: Core Guideline Data.

   Toxicity Category: III-CAUTION

2. Acute Dermal Toxicity Study in the Albino Rabbit; IR&D #382-044; October 17, 1978

Procedure: 8M, 8F New Zealand white rabbits (2300-2757 g) were used in this study; 4M and 4F were used as controls; 2M and 2F with intact skin, 2M and 2F with abraded skin received an application of 5000 mg/kg of Milocep. Exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days. At termination of study, survivors were sacrificed and all animals were subjected to necropsies.

Results: No mortalities. 2F lost weight. Symptoms include erythema, edema, atonia, desquamation, coriaceousness, fissuring and blanching. Necropsy revealed lungs dark with few yellow foci, few dark red foci and slight congestion.

Study Classification: Core Guideline Tox. Cat.: III - CAUTION

3. Acute Inhalation Toxicity Study in Rats; IR&D #382-047; November 3, 1978

Procedure: One group of 5M (278-296 g), 5F (208-248 g) Charles River - CD strain rats was exposed for 4 hours to an atmosphere containing an aerosol of the test substance. Gravimetric determination of atmospheric concentration was 20.8 mg/l. Analytical determination by Ciba-Geigy of atmospheric concentration showed 0.27/0.16 (Metolachlor/ Propazine) mg/l formulation at 1 hour, 0.18/0.12 mg/l formulation at 2 and 3 hours, 0.13/0.08 mg/l formulation at 4 hours.

Results: No mortalities. Symptoms observed during exposure include an increased activity and dyspnea. Weight loss in 7 rats on day 1 post-exposure. Animals appeared normal on day 1 through day 14 post-exposure.

Study Classification: Core Supplementary Data. The highest atmospheric concentration was only high enough to place substance in toxicity category II; higher dosages should be tested.

4. Primary Eye Irritation Study in the Albino Rabbit, IR&D #382-045, October 17, 1978.

Procedure: 0.1 ml of the test substance was applied into one eye of each of 9 New Zealand white rabbits. Three rabbits had the treated eye flushed with distilled water for one minute, 30 seconds post-treatment. Scoring at 1, 24, 48, 72 hours, 4, 7 and 14 days.

Results: In the "no wash" eyes at 24 hours, 5/6 exhibited very slight corneal opacity and 1/6 showed corneal dulling; 6/6 with iris irritation; 6/6 with redness (6/6 = moderate) 6/6 showed chemosis (1/6 = very slight, 1/6 = slight, 4/6 =

moderate); discharge in 6/6 (1/6 = slight, 4/6 = moderate, 1/6 = marked). By day 7, the "no wash" eyes exhibited 4/6 with corneal opacity (3/6 = very slight, 1/6 = slight) and 1/6 with corneal dulling; 3/6 with iris irritation; 6/6 with redness (3/6 = very slight, 2/6 = slight, 1/6 = moderate); 3/6 with chemosis (2/6 = very slight, 1/6 = slight); discharge in 1/6 (1/6 = slight). Symptoms include corneal epithelial peeling, pannus, vascularization of the cornea, miosis, granulation scar tissue with neovascularization, keratoconus; conjunctival blanching, purulent discharge, clear discharge, inflammation of bulbar conjunctivae resulting in occlusion of the perilimbal region of the cornea in the superior nasal and temporal quadrants.

The washed eyes exhibited no corneal opacity. At 24 hours, no iris irritation observed; 3/3 with slight redness; 2/3 with very slight chemosis. At 7 days, 1/3 exhibited very slight redness. At 14 days all eyes appeared normal. Symptoms included conjunctival blanching, purulent discharge and clear discharge.

Study Classification: Core Guideline Tox. Cat.: I-DANGER

5. Primary Skin Irritation Study in the Albino Rabbit; IR&D #382-046; October 17, 1978

Procedure: 0.5 ml of the test material was applied to each of 4 sites (2 intact and 2 abraded) on each of 6 New Zealand white rabbits. Exposure was for 24 hours under occlusive wrap. Draize scoring at 24 and 72 hours.

Results: At 24 hours, 12/12 intact sites exhibited eschar (9/12 = 1, 3/12 = 2) and 8/12 with edema (8/12 = 1). Abraded sites at 24 hours showed eschar at 12/12 sites (6/12 = 1, 5/12 = 2, 1/12 = 3) and 12/12 with edema (12/12 = 1). By 72 hours, 12/12 intact sites showed eschar (10/12 =1, 2/12 = 2) with 7/12 showing edema (7/12 = 1). At 72 hours, 12/12 abraded sites showed eschar (7/12 = 1, 5/12 = 2) and 11/12 with edema (11/12 = 1). Primary Irritation Index was 2.0.

Study Classification: Core Gudieline Data.

Toxicity Category: III-CAUTION

Milocep®

Herbicide

For weed control in sorghum (milo and sweet sorghum)

Active Ingredients:
Metolachlor:
2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl) acetamide 36.3%
Propazine:
2-chloro-4, 6-bis (isopropylamino)-s-triazine 18.7%

Inert Ingredients: 45.0%

Total: 100.0%

2½ Gallons
U.S. Standard Measure

Milocep contains 5 lbs. active ingredients per gallon.

Keep Out of Reach of Children.

Danger:
See additional precautionary statements inside booklet.

EPA Reg. No. 100-604
EPA Est. 100-LA-1

Milocep® trademark of CIBA-GEIGY
U.S. Patent No. 3,937,730 (metolachlor)

See directions for use inside booklet.

Agricultural Division
CIBA-GEIGY Corporation
Greensboro, North Carolina 27409
CGA 62L1

CIBA-GEIGY

DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

IMPORTANT: Read the entire **Directions for Use** and the **Conditions of Sale and Warranty** before using this product.

Conditions of Sale and Warranty

The **Directions for Use** of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application all of which are beyond the control of CIBA-GEIGY or the Seller. All such risks shall be assumed by the Buyer.

CIBA-GEIGY warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use** subject to the inherent risks referred to above. **CIBA-GEIGY makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall CIBA-GEIGY or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product.** CIBA-GEIGY and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty,** which may be varied only by agreement in writing signed by a duly authorized representative of CIBA-GEIGY.

Directions for Use

FAILURE TO FOLLOW ALL PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR WEED CONTROL, CROP INJURY, OR ILLEGAL RESIDUES.

Milocep is a selective herbicide for preplant incorporated or preemergence control of most annual grasses and broadleaf weeds in sorghum provided the sorghum seed has been properly treated by the seed company with Concep® at 8 oz. per 100 lbs. of seed.

Precautions: 1) If sorghum seed is not properly pretreated with Concep, Milocep will severely injure the crop. 2) Under high moisture conditions prior to sorghum emergence, some temporary stunting may occur following the use of Milocep. The crop will normally outgrow this effect.

Extremely dry weather following preemergence application of Milocep may reduce effectiveness. Cultivate if weeds develop.

Apply Milocep in water or in fluid fertilizer in a minimum of 15 gals. of spray mixture per acre.

Sprayer Equipment: Use conventional spray equipment that provides accurate and uniform application. Screens and strainers should be no finer than 50-mesh. Rinse sprayer thoroughly with clean water immediately after use.

Mixing Instructions: Shake well before using. Fill the spray tank one-half to three-fourths full with water or fluid fertilizer, add the proper amount of Milocep, then add the rest of the water or fluid fertilizer. Provide sufficient agitation during mixing and application to maintain a uniform suspension.

To determine the compatibility of Milocep with fluid fertilizer, pour 2½ teaspoons of Milocep into a pint of fluid fertilizer (assumes 5 pts. of Milocep and 25 gals. of fluid fertilizer per acre; for changes in spray volume or herbicide rate, make appropriate changes in the proportion of ingredients in the test). After thorough mixing, let stand for 5 minutes. If the combination remains mixed or can be remixed readily, the mixture is compatible and can be sprayed.

Within the rate range for a specific soil category in the rate table, use the lower rate on soil relatively coarse-textured or low in organic matter; use the higher rate on soil relatively fine-textured or high in organic matter.

Calculate the amount needed for band treatment by the formula:

$$\frac{\text{band width in inches}}{\text{row width in inches}} \times \text{broadcast rate per acre} = \text{amount needed per acre of field}$$

Weeds Controlled		***Weeds Partially Controlled***
barnyardgrass (watergrass)	lambsquarters	sandbur
crabgrass	morningglory	seedling johnsongrass
fall panicum	pigweed	volunteer sorghum
giant foxtail	purslane	
green foxtail		
signalgrass (Brachiaria)		
southwestern cupgrass		
yellow foxtail		
yellow nutsedge		

Application: Apply Milocep either preplant incorporated or preemergence at the appropriate rate from the following rate table. *Preplant Incorporated:* Apply to the soil within 14 days before planting and incorporate into the top 2 inches, using a finishing disk, harrow, rolling cultivator, or similar implement capable of uniform incorporation. Use a preplant incorporated application if furrow irrigation is used or when a period of dry weather after application is expected. If sorghum is to be planted on beds, apply and incorporate after bed formation. *Preemergence:* Apply to the soil surface at planting, or after planting but before weeds or sorghum emerge.

Soil texture	Broadcast rate per acre
COARSE Sand, loamy sand	DO NOT USE
sandy loam	3-3.5 pts.
MEDIUM Loam, silt, silt loam	3.5-4.5 pts.
FINE Silty clay loam, sandy clay loam, clay loam, sandy clay, silty clay, clay	4.5-5 pts.

Precaution: Application on highly alkaline soils or on eroded areas where calcareous subsoils are exposed may cause crop injury.

Rotational Crops: 1) If sorghum treated with Milocep is lost, sorghum may be replanted immediately using Concep-treated seed. Do not make a second broadcast application of Milocep. If the original application was banded and sorghum is replanted in the untreated row middles, a second band treatment of Milocep may be applied. 2) Corn, sorghum, or soybeans may be planted the following year. All other crops may be planted 18 months after application.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container. Pesticide, spray mixture, or rinsate 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. Triple rinse (or equivalent) and dispose of in incinerator or landfill approved for pesticide containers, or bury in a safe place. Consult federal, state, or local disposal authorities for approved alternative procedures such as limited open burning.

Precautionary Statements

Hazards to Humans and Domestic Animals

DANGER

Corrosive — causes eye damage. Do not get in eyes, skin, or clothing. Wear goggles or face shield when handling. May be fatal if inhaled. Do not breathe vapors or spray mists. Harmful if swallowed. May cause skin sensitization reactions in certain individuals. Wash thoroughly after handling. Avoid contamination of food.

First Aid: In case of contact with eyes, immediately flush with plenty of water for at least 15 minutes. Call a physician. If inhaled, remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth; get medical attention. In case of contact with skin, wash with soap and water. Remove and wash contaminated clothing before reuse.

Environmental Hazards

Keep out of any body of water. Do not apply where runoff is likely to occur. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply when weather conditions favor drift from areas treated.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

Agricultural Division
CIBA-GEIGY Corporation
Greensboro, North Carolina 27409

CGA 62L1

Milocep®

Herbicide

For weed control in sorghum (milo and sweet sorghum)

Active Ingredients:

Metolachlor: 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl) acetamide	36.3%
Propazine: 2-chloro-4, 6-bis (isopropylamino)-s-triazine	18.7%
Inert Ingredients:	45.0%
Total:	100.0%

Milocep contains 5 lbs. active ingredients per gallon.

See directions for use in attached booklet.

EPA Reg. No. 100-604
EPA Est. 100-LA-1

2½ Gallons
U.S. Standard Measure

Keep Out of Reach of Children.

Danger:

Precautionary Statements

Hazards to Humans and Domestic Animals

Corrosive — causes eye damage. Do not get in eyes, skin, or clothing. Wear goggles or face shield when handling. May be fatal if inhaled. Do not breathe vapors or spray mists. Harmful if swallowed. May cause skin sensitization reactions in certain individuals. Wash thoroughly after handling. Avoid contamination of food.

First Aid: In case of contact with eyes, immediately flush with plenty of water for at least 15 minutes. Call a physician. If inhaled, remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth; get medical attention. In case of contact with skin, wash with soap and water. Remove and wash contaminated clothing before reuse.

Environmental Hazards

Keep out of any body of water. Do not apply where runoff is likely to occur. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply when weather conditions favor drift from areas treated.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

Agricultural Division
CIBA-GEIGY Corporation
Greensboro, North Carolina 27409

CGA 62L1

CIBA–GEIGY