April 24, 1981

Trimec Bermuda and Bentgrass Broadleaf Lawn Herbicide
EPA Registration No. 2217-597

Sherell A. Sterling
FHB/TSS

Richard Mountfort
Product Manager (23)

Registrant: PSI/Gordon Corporation
300 South Third Street
Kansas City, KS 66118

Active Ingredient
2,4-D, dimethylamine salt ...................... 6.25%
MCPP, dimethylamine salt .................... 10.83%
Dicamba, dimethylamine salt .................. 1.20%

Background: These eye irritation studies were submitted in response to an earlier review (see Sterling, 1/21/80). The intent of the studies was to substantiate the labeling comment "... washing of eyes has shown to be of doubtful value ....". The method of support was not indicated.

The studies submitted on February 22, 1980 were conducted on several formulations. Testing was done by Midwest Research Institute of Kansas City, Missouri and Stillmeadow, Inc. of Houston, TX.

Recommendations:

1. The studies submitted were adequate and acceptable for the formulations tested. However, the "Trimec Bermuda and Bentgrass Broadleaf Lawn Herbicide" (EPA Reg. No. 2217-597) formulation was not tested. The formulations tested are not substantially similar to EPA Reg. No. 2217-597. FHB/TSS has therefore determined that adequate "eyewash" data have not been submitted on this product. We hasten to add that data available are adequate for conditional registration purposes.

2. FHB/TSS is of the opinion that eyewash data on the formulation or a substantially similar formulation are lacking; therefore, the statement that the eyewash is of "doubtful value" has not been substantiated.

3. FHB/TSS recommends that the entire "Note" section under the "Statement of Practical Treatment" be deleted. In addition, it is the opinion of FHB/TSS that since the eyewash has not been proven more harmful for this product, the eyewash is appropriate for practical treatment. The "Note" is inappropriate as it detracts from the basic reason for the "Practical Treatment" statement-- to provide emergency treatment information to be used by non-medical people until medical personnel can be reached.

4. FHB/TSS notes that data for "2,4-D (Iso-octyl ester)" was not submitted under MRI Project #4823-B(1) as the title of the study indicates.
Labeling Recommendations:

1. The signal word "DANGER" is appropriate, as proposed.

2. The "Environmental Hazard" section must be revised as follows:

   Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

3. The statement "Do not apply when weather conditions favor drift from target areas" must be relocated under the "Directions for Use" section.

4. The statement "Keep from freezing" should be located under the "Storage" direction in the "Storage and Disposal" section.

Review:

1. Rabbit Eye Irritation; Stillmeadow #1344-79; October 17, 1979; Acc. No. 244753

   Procedure: 9 New Zealand white rabbits each received 0.1 ml of "EH 600" in one eye. The test substance "EH 600" is composed of the following active ingredients:

   - 2,4-D, DEA salt .................. 23.54%
   - MCPP, DEA salt .................. 15.69%
   - Banvel, DEA salt .................. 3.92%

   Three eyes were rinsed 30 seconds after treatment with room temperature tap water for one minute. Eyes scored through day 21.

Result: Upon instillation, 3/6 in unwashed group vocalized. All eyes showed red blister in conjunctival sac at 1 hour. At 24 hours, the unwashed eyes exhibited corneal opacity in 1/6=5, 2/6=20, 1/6=30; iris irritation is 6/6=10; conjunctival redness in 6/6=2; chemosis in 2/6=3, 4/6=4; discharge in 4/6=2, 2/6=3; also noted were necrosis (6/6) and corneal stippling (5/6). One animal found dead on day 7. Day 21, unwashed eyes exhibited corneal opacity in 1/5=10, 1/5=20, 1/5=30 1/5=40; iris irritation in 2/5=5, 3/5=10; redness in 2/5=1, 3/5=2; chemosis in 2/5=2, 2/5=3, 1/5=4; discharge in 2/5=1, 3/5=2; also cornea invaded by blood vessels (5/5), corneal swelling (2/5); ptosis around eye (1/5).

Upon instillation 1/3 animals with washed eyes vocalized; red blisters seen in conjunctival sac of 3/3 rabbits. After 24 hours, washed eyes showed corneal opacity in 1/3=30, 2/3=40; iris irritation in 3/3=10; redness in 3/3=2; chemosis in 1/3=3, 2/3=4; discharge in 3/3=2; necrosis and corneal stippling in all rabbits. At 7 days, corneal opacity in 3/3=10, cornea invaded by blood vessels; iris irritation in 3/3=10; redness in 3/3=2; chemosis in 2/3=3, 1/3=4; discharge in 1/3=1, 1/3=2, 1/3=3; necrosis and stippling in 3/3. By day 21, corneal opacity in 1/3=5, 1/3=40; also invasions of cornea by blood vessels, swollen cornea; iris irritation in 1/3=10; redness in 3/3=1, chemosis in 1/3=1, 2/3=2; discharge in 1/3=2.
Study Classification: Core Guideline Data.

Toxicity Category: I-DANGER

2. Rabbit Eye Irritation; Stillmeadow #1340-79; Oct. 15, 1979; Acc. No. 244753

Procedure: 9 New Zealand white rabbits each received 0.1 ml of "EH 599" in one eye. The test substance "EH 599" is composed of the following active ingredients:

- 2,4-D, DMA salt .............. 20.71%
- MCPP, DMA salt .............. 20.76%
- Banvel, DMA salt ............. 3.52%

Three eyes were rinsed 30 seconds after treatment with room temperature tap water for one minute. Eyes scored through day 21.

Results: Red blister developed in conjunctival sac of 6/6 rabbits at 1 hour. At 24 hours in unwashed eyes, no corneal opacity; iris irritation seen in 6/6=10; redness in 2/6=2, 4/6=3; chemosis in 6/6=34; discharge in 4/6=2, 2/6=3; stippling and necrosis also observed. At day 21, unwashed eyes exhibited corneal opacity in 2/6=15, 1/6=20, 2/6=30, 1/6=40; iris irritation in 6/6=10; redness in 4/6=1, 2/6=2; chemosis in 6/6=3; discharge in 1/6=1, 5/6=2; also, invasion of blood vessels into cornea and corneal swelling.

Washed eyes exhibited red blisters in conjunctival sac at 1 hour. At day 21 corneal opacity in 1/3=20, 1/3=40; iris irritation in 2/3=10; redness in 1/3=1, 1/3=2; chemosis in 1/3=3, 1/3=4; discharge in 1/3=1, 1/3=2; necrosis in 1/3.

Study Classification: Core Guideline Data.

Toxicity Category: I-DANGER


Procedure: 9 New Zealand rabbits each received 0.1 ml of "EH 595" in one eye. Three eyes were rinsed 30 seconds after treatment with room temperature tap water for one minute. Eyes scored at 24, 48, 72 hours; 4, 7, 8, 9, 11, 14 days.

Results: At 24 hours the unwashed eyes exhibited corneal opacity in 5/6=20; redness in 5/6=2; chemosis in 2/6=2, 3/6=3; discharge in 1/6=2, 4/6=3. At day 7, the unwashed eyes showed redness in 1/6=1; chemosis in 3/6=2, discharge in 1/6=1. By day 14, only irritation was chemosis in 3/6=1.

Redness in 3/3=1/3 2Chm

The washed eyes at 24 hours exhibited corneal opacity in 2/3=20; 3/3=2; discharge in 1/3=1, 1/3=2, 1/3=3. By day 14, only irritation noted was chemosis in 1/3=1.
Study Classification: Core Minimum Data. Study should be continued until all scores are 0, or 21 days.

Toxicity Category: II-WARNING


Procedure: 9 New Zealand white rabbits each received 0.1 ml of "EH 601" in one eye. Three eyes were rinsed 30 seconds after treatment with room temperature tap water for one minute. Eyes scored at 24, 48, 72 hours; 4, 7, 8, 9, 11, 14, 15, 17 and 21 days.

Results: The unwashed eyes at 24 hours exhibited corneal opacity in 6/6=20; iris irritation in 2/6=5, 1/6=10; conjunctival redness in 4/6=2, 2/6=3; chemosis in 4/6=2, 2/6=3; discharge in 3/6=2, 3/6=3. Only 3 animals scored through day 21; other animals' irritation had cleared. At 21 days, corneal opacity observed in 3/3=20; iris irritation in 3/3=5; redness in 3/3=2; chemosis in 3/3=2; discharge in 2/3=2, 1/3=3.

At 24 hours, the rinsed eyes showed corneal opacity in 3/3=20; redness in 2/3=1, 1/3=2; chemosis in 2/3=2, 1/3=3; discharge in 1/3=1, 1/3=2, 1/3=3. By day 7, corneal opacity seen in 1/3=20; redness in 2/3=1, 1/3=2; chemosis in 2/3=2, 1/3=3; discharge in 1/3=1, 1/3=2, 1/3=3. At day 14 (the last scores recorded) only irritation noted was chemosis in 1/3=1.

Study Classification: Core Minimum Data.

Toxicity Category: I-DANGER

5. Primary Eye Irritation Studies in Rabbits Using PBI/Gordon Corporation Test Materials 881 (Dimethylamine), 2,4-D (Dimethylamine), and 2,4-D (Iso-Octyl ester); MRI #4823-B(1); Nov. 12, 1979; Acc. No. 244753

Procedure: 9 New Zealand white rabbits each received 0.1 ml of "881 (Iso-octyl ester)" in one eye. Three eyes were rinsed 30 seconds after treatment with room temperature tap water for one minute. Eyes scored at 24, 48, 72 hours; 7, 10, 13, 14, 17, 21 days.

Results: Unwashed eyes at 24 hours exhibited redness in 6/6=1; chemosis in 5/6=2, 1/6=3; discharge in 4/6=1, 1/6=2, 1/6=3. At 3 days, corneal opacity in 2/6=20, 2/6=40; iris irritation in 3/6=1; redness in 4/6=1; chemosis in 3/6=1, 2/6=2; discharge in 3/6=1, 2/6=2. All eyes appeared clear by day 7.
Washed eyes exhibited no irritation at 24 hours. At day 2, iris irritation in 1/3=5; redness in 1/3=1; chemosis in 1/3=1; discharge in 1/3=1. All eyes were clear by day 4.

Study Classification: Core Guideline Data.

Toxicity Category: II-CAUTION

6. Primary Eye Irritation Studies in Rabbits Using
PBI/Gordon Corporation Test Materials 881 (Iso-octyl ester),
881 (Dimethylamine), 2,4-D (dimethylamine), and 2,4-D
(Iso-octyl ester); MRI #4823-B(1); Nov. 12, 1979; Acc. No.
244753

Procedure: 9 New Zealand white rabbits each received 0.1 ml
of "2,4-D (dimethylamine)" in one eye. Three eyes were
rinsed 30 seconds after treatment with room temperature tap
water for one minute. Eyes scored at 24, 48, 72 hours; 4,
7, 14 and 21 days.

Results: At 24 hours the unwashed eyes showed corneal
opacity in 5/6=20, 1/6=40; iris irritation in 6/6=5;
redness in 4/6=1, 2/6=2; chemosis in 4/6=2, 2/6=3; discharge
in 1/6=1, 4/6=2, 1/6=3. By day 21, corneal opacity in
2/6=20, 1/6=60, 1/6=5; iris irritation in 2/6=1, 2/6=2;
redness in 2/6=2, 2/6=3; chemosis in 2/6=2, 2/6=4; discharge
in 2/6=2, 2/6=3.

The washed eyes at 24 hours exhibited corneal opacity in
2/3=20; iris irritation in 2/3=5; redness in 1/3=1, 2/3=2;
chemosis in 1/3=1, 1/3=2, 1/3=4; discharge in 3/3=3.
Corneal opacity in 1/3=20; iris irritation in 1/3=20; iris
irritation in 1/3=5; redness in 1/3=2; chemosis in 1/3=2; discharge in
1/3=1 at 21 days.

Study Classification: Core Guideline Data.

Toxicity Category: I-DANGER

7. Primary Eye Irritation Studies in Rabbits Using
PBI/Gordon Corporation Test Materials 881 (Iso-octyl ester),
881 Dimethylamine), 2,4-D (Dimethylamine), and 2,4-D
(Iso-octyl ester); MRI #4823-B(1); Nov. 12, 1979; Acc. No.
244753.

Procedure: 9 New Zealand white rabbits each received 0.1 ml
of "881 Dimethylamine" in one eye. Three eyes were rinsed
30 seconds after treatment with room temperature tap water
for one minute. Eyes scored at 24, 48, 72 hours; 4, 7, 14, 21 days.

Results: At 24 hours the unwashed eyes showed corneal opacity in 1/6=10, 3/6=40, 1/6=45; iris irritation in 3/6=5, 2/6=10; redness in 3/6=1, 3/6=2; chemosis in 1/6=2, 5/6=3; discharge in 6/6=3. By 21 days, corneal opacity in 4/6=40, 1/6=80; iris irritation in 4/6=5, 1/6=10; redness in 4/6=2, 1/6=3; chemosis in 4/6=2, 1/6=4; discharge in 4/6=2, 1/6=3.

The washed eyes exhibited corneal opacity in 3/3=10; iris irritation in 1/3=5, 2/3=10; redness in 2/3=1, 1/3=3; chemosis in 1/3=2, 2/3=3; discharge in 1/3=2, 2/3=3 at 24 hours. At 21 days, corneal opacity in 1/3=20; iris irritation in 1/3=5; redness in 2/3=2; chemosis in 1/3=2; discharge in 1/3=2.

Study Classification: Core Guideline Data.

Toxicity Category: I-DANGER
Bermuda & Bentgrass

One quart covers 8,000 to 10,000 sq. ft. Do not contaminate
spray equipment with water, detergents or oil. See operator's manual for additional
instructions.

Keep out of reach of children.

Do not use or store near
values, food, or
feed areas.

Weeds in lawns
Kills 33 Troubleome
Broadleaf Lawn Herbicide
Bermuda & Bentgrass

Broadleaf & Grass


greens

escapes

green

red

green

green

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown

red

brown