UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

46

DATE: October 22, 1979

SUBJECT: EPA File Symbol: 1812-ELN
Griffin Simazine 4L Flowable Herbicide;
Caswell #740

FROM: S. A. Sterling 11-22-79
FHB/TSS E 11/22/79

TO: Willa Garner, Ph.D.
Product Manager (23)

Applicant: Griffin Corporation
P.O. Box 1847
Valdosta, GA 31601

Active ingredient:
Simazine.....42.8%
Inert ingredients.....57.2%

Background

This is an application for conditional registration of a new product under the "cite-all" method of support. The data submitted include Acute Oral (ACC# 240887), Acute Dermal (ACC# 240883), Acute Inhalation (ACC# 240882), Eye Irritation (ACC# 240886) and Skin Irritation (ACC# 240885) studies. In each of these studies, the test material was Flowable Simazine 42.8%. All studies were conducted by Cannon Laboratories, Inc. of Reading, PA.

Recommendations:

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

2. The Acute Inhalation study is supplementary data and, as such, is not adequate or acceptable for the conditional registration of this product. Since the "cite-all" method of support is being used, this study need not be repeated.

3. The appropriate signal word is "CAUTION" as proposed by the applicant.

4. Based on the human and domestic animal hazard data submitted, FHB/SS would have no objection to the conditional registration of this product provided that the following labeling revisions are made.

Labeling:

1. All storage and disposal statements must be grouped under the heading "STORAGE AND DISPOSAL." This heading must be set in the same type size as required for the Child Hazard Warning. The storage and disposal section must appear under the "Directions for Use." [40 CFR 162.10(i)(2)(ix)]

2. The preferred placement of the "Keep Out of Reach of Children" statement is above the signal word.

3. A precautionary statement similar to the following must appear on the labeling:

   "In case of eye contact, flush with plenty of water. Get medical attention if irritation persists."

Review:

1. Acute Oral LD_{50} of Flowable Simazine 42.8%, Lot # 07112 in Spraque - Dawley Rats; June 29, 1979.

   Procedure: A group of 5M, 5F Spraque-Dawley rats (200-300g) received an oral dosage of 5000mg/kg. Animals were observed for 14 days, survivors were sacrificed and all were examined for gross pathological alterations.

   Results: No mortalities. Symptoms included piloerection, ptosis, ataxia, nasal discharge and shallow respiration. Necropsy revealed no gross pathological alterations.

   Study Classification: Core Guideline Data.

   Toxicity Category: IV

2. Acute Dermal LD_{50} of Flowable Simazine, 42.8%, Lot # 07112 on New Zealand Albino Rabbits; June 26, 1979.

Procedure: 5M, 5F New Zealand albino rabbits (2.43-3.36 kg) with abraded skin received an application of 1.61 ml/kg of test material. Exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days post-exposure, sacrificed, and subjected to gross pathological examination.

Results: No mortalities. 5/10 animals exhibited erythema on day 1; all animals appeared normal day 2 - day 14. 3/10 animals exhibited nasal discharge. Necropsy revealed dark red areas in lungs of all animals.

Study Classification: Core Minimum Data. Dosage was less than 2 g/kg.

Toxicity Category: III - CAUTION. The procedure submitted states that dosage is 2 g/kg; calculations show that 1.61 ml/kg is approximately 1.8 g/kg. However, since no deaths occurred at this dosage level and considering other studies submitted with this application, the data justify classification in category III.

3. 4-Hour Acute Inhalation Toxicity Study of Flowable Simazine 42.8%, Lot # 07112; July 3, 1979

Procedure: A group of 5M, 5F Sprague - Dawley rats (220-304 g) were exposed for 4 hours to the aerosolized test substance. During the exposure, nominal concentration was 5.1 mg/l and actual atmospheric concentration was 0.009 +/- 0.003 mg/l. All animals were observed for 14 days then subjected to a gross pathological examination.

Results: 1F died; necropsy of animal revealed blocked caecum; hemorrhagic areas in caecum, colon, large intestines; colon, small intestines, large intestines, stomach and abdominal cavity filled with fluid; fat deposits were drained. No other mortalities and no other gross pathological alterations observed. F body weights declined from day 2 - day 4; all body weights showed overall increase on day 14.

Study Classification: Core Supplementary Data.
Atmospheric concentration was too low to assign proper toxicity category.

4. Primary Eye Irritation Study of Flowable Simazine 42.8% on New Zealand Albino Rabbits; June 18, 1979.

Procedure: 0.1 ml of test material was applied into one eye of each of 9 (6M, 3F) New Zealand albino rabbits. Three rabbits had the treated eye flushed with lukewarm water for 1 minute, 20 seconds post-treatment; remaining 6 were unwashed. Scoring at 24, 48, 72 hours, 4 and 7 days.

Results: In unrinsed group at 24 and 48 hours, 6/6 showed conjunctival redness, 2/6 ocular discharge; 1/6 showed conjunctival redness at 72 hours; all scores were zero by day 4. In rinsed group, at 24 and 48 hours 2/3 showed conjunctival redness; 1/3 showed redness at 72 hours; all further scores were zero.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

5. A Primary Dermal Irritation Study of Flowable Simazine 42.8% on Abraded and Nonabraded Skin on New Zealand Albino Rabbits;June 13, 1979.

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

Results: At 24 hours, 4/6 rabbits showed erythema (maximum score = 1) at abraded sites; 2/6 rabbits showed erythema (maximum score = 1) at intact sites; no edema. All scores were zero by 72 hours. Primary Irritation Index is 0.17.

Study Classification: Core Guideline Data.

Toxicity Category: IV.