Date: March 22, 1984

Subject: EPA Registration Number: 2724-208
Gaicon RF-200 Pressurized Spray

From: Delores J. Graham
FH5/288  E  3/22/84

To: Zika Gardner
Product Manager (E&V)

Applicant: Gaicon Industries
A Division of Gaicon Corporation
12200 Preston Drive
Dallas, Texas  75234

Active Ingredients:
- Isopropyl (E,E)-11-methoxy-3,7,11
- 2,4-Dimethyl-2,4-dodecadienoate 0.03%
- Cyclohexane
- 4-tert-Butylcyclohexene, technical 1.00%
- N-Octyl bicyclohexyl decarbimide 1.00%
- Sweet Ingredient 97.77%

Background: Submitted acute oral, acute dermal, acute inhalation, eye irritation and primary dermal irritation studies. Data under EPA accession number 252259. Dermal sensitization study refused on previous submission. Study conducted by Toxicology, Inc. Method of exposure not indicated.
Recommendations:
(1) H14/28 finds these data acceptable to support conditional registration of this product. However, in the acute inhalation study, an LC50 was not submitted; it could only be determined that the toxicity category is no worse than II - WARNING.

(2) The appropriate signal word is **DANGER**.

Label:
(1) Precautionary statements must precede signal word.
(2) The precautionary statements must be revised to include "DANGER: Corrosive, causes skin burn. May be fatal if inhaled. Harmful if swallowed."
(3) The statement on practical treatment must be revised to include "If on skin, wash with plenty of soap and water and get medical attention."
(4) The storage and disposal statement must be revised similar to following: "Bottle, spray mist, or rinse water that cannot be reused according to label instruction must be disposed of according to Federal or approved State procedures under federal Resource Conservation and Recovery Act."

Received:
(1) Brite Corp. 1200 W. 5th Ave., Austin, Inc. 10/20/83  August 27, 1983.

Procedure: Five male and five female rats received 5 mg/kg of the test material orally. Observation made hourly on day of dosing, then twice daily thereafter for 14 days post-treatment.
Decopay performed on all animals

Results: No mortalities. Clinical signs reported included lethargy, loose stools, yellow/brown stained fur. Necropsy report revealed a solitary subcutaneous, rounded lesion located on the skin in the cervical region, a solitary red depression on the lung of one male. Another male had slight red irritation in the abdominal cavity and tenia ceca were clotted blood, LD50 greater than 5.1 g.

Study Classification: Carcid bidehine Data

Toxicity Category: IV (CAUTION)

(2) Acute dermal toxicity study: Topi Sciences, Inc.
Study no: 101-1024, September 15, 1985

Procedure: Five male and five female New Zealand rabbits received 5.1 kg of the test material as a painted orlin under occlusive wrap for 24 hour exposure. Observation made daily for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities. Clinical signs reported included loose stools, yellow/brown stained fur, vocalization when handled, oedema, white discharge in eyes, erythema, edema, atonia, desquamation, necrosis, oedema, edema, necrosis, white exudate at the area of pressure. Necropsy report revealed multiple, focal, red or red-brown discoloration of skin at treated sites, thickened dermis.
An analysis of specimens at test areas multiple / local, clear eyes in both / untreated of one male / 20 g greater than 5.1 gm.

Study Classification: Case Checklist Data

Toxicity Category: III - (HA1710)

(3) Acute Inhalation Toxicity Study: Airborne Inc., Study # 420-1196; July 1, 1983.

Procedure: Five male and five female rats weighing between 214 and 292 g were exposed for 4 hours to an oxygenated concentration of 0.06 mg/L (nominal concentration = 0.27 mg/L). Oxygen-moisturized median, and geometric standard deviation was 0.42 and 2.25 respectively. Temperature ranged between 70 and 75°F with relative humidity ranging between 37 and 58%. Observations made every 15 minutes during first hour 30 minutes per exposure were taken. Twenty daily for 14 days post-exposure. Necropsy performed on all 10 animals. Another group of five male and five female rats weighing between 185 and 289 g were treated in a similar fashion as the previously mentioned group except no test material was used. These animals served as controls.

Results: No mortality reported. Clinical signs reported included irregular breathing, exophthalmus, tremor in test animals. No clinical signs reported in controls. Necropsy report revealed
Lung and kidney abnormalities, subpleural multifocal inflammatory change, perivascular inflammatory involving bronchial mucosa, pulmonary interstitial edema, alveolar aggregates, pulmonary macrophages, unilateral renal hydropneumonia, pyelitis, multifocal lymphoid involvement of mononuclear cells in the gastrointestinal tract, multifocal hepatocellular necrosis, focal hepatocellular necrotive degeneration, focal multifocal necrotive degeneration of the liver, hepatic epithelium in a female rat, test animals. Similar conditions noted in necropy reports of control animals.

Study Classification: Core Protection Data, 1850

 Safety Category: IV - WARNING

(4) Eye Irritation Study - Incidence, Inc. Study 901, 1820; September 1, 1982.

Procedure: Administered to bead of eye of each test animal in one eye. The left eye of three of the rats was pre-intoxicated with lukewarm water. Observations were made at 24, 48, 72 hours, one week after treatment.

Results: At 24 hours no animals in the unexposed group had redness. At 48 hours, no cases of redness or discharge were noted in any of the animals.

Study Classification: Core Protection Data.
Toxicity Category: IV - CAUTION

(5) Primary Desmoglein irritation study. BioGenics, Inc.
Study # 410-1025; September 3, 1982.

Procedure: Six rabbits with intact skin received 0.5 g of the test material under occlusive wrap for 4 hour exposure. Observations were made at 24, 48 and 72 hours, 4, 5, 6 and 7 days after treatment.

Results: At 24 hours, 4% slight to moderate erythema (score 1, 2 and 3) and 4% slight edema (score 1). At 72 hours, 4% well defined to severe erythema (score 2, 3 and 4) and 4% slight to moderate edema (score 1, 2 and 3). Erosion formation also noted. Moderate to severe reactions persisted through day 5. By day 6 irritation had begun to resolve itself. Desquamation reported on days 6 and 7.

Study Classification: Class I Guideline Data

Toxicity Category: I - DANGER