Date: March 31, 1983

Subject: EPA File Symbol: 19713-RTA
Dielhal Haldane 96% Technical

From: Robert J. Beahan
345/ADH
E 4/1/83

To: Richard Newhart
Product Manager (23)

Applicant: Dierol Chemical Company
P.O. Box 9306
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Active Ingredient:
5-Ethylhexyl 2-hydroxy-4-methyl-1-
Carboxylate ............................... 96.0%

 inert ingredients ................................ 4.0%

Background: Submitted Acute Oral, Eye Irritation and Skin Irritation studies conducted by Pharmacia Fine Chemicals GmbH, Data under accession numbers: 247457, 247458 and 247459. Use-all method of support.

Recommendations:

(1) Data found these data acceptable to support peroral registration of this product. However, for future submissions in the eye irritation study, formal eye (with bicarbonate buffer and 30% aqueous buffer) must be used.

(2) An acute oral study was not submitted and one must be submitted and/or cited as a
Justification as to why the study is not necessary.

Table:

1) Tabling comments reserved until an Acute Oral Tolerance Study is submitted.

Results:

1) Acute Oral Toxicity Study: Methylnitroacetaldehyde - Study # 14195; December 1975-77, EPA Accession # 347457.

Procedure: 5 groups consisting of 5 male and 5 female rats weighing between 120 to 140g each received one of the following doses: 400, 504, 635, 800 and 1008 mg/kg. Necropsy performed on all animals. Observations made for 14 days after treatment.

Results:

- at 400 mg/kg, 4/5 F died; at 504 mg/kg, 3/5 M, 4/5 F died; at 625 mg/kg, 4/5 M, 4/5 F died; at 800 mg/kg, 1/5 M, 4/5 F died; at 1008 mg/kg, 4/5 M, 4/5 F died. Symptoms observed included apathy, reduced frequency of respiration and diminished response for reflexes. Necropsy revealed changes in the urothelial epithelium in the kidney cavity and hyperemia looking greater - intestinal tract. LD50 was 569 mg/kg (482 to 621 mg/kg, confidence limits).
Study Classification: Core, Guideline Data

Toxicity Category: III-CAUTION

(2) Eye Irritation Study: Pharmateq; Study # 173-258-30; August, 1980.

Procedure: Six New Zealand rabbits received 0.1g of the test material in one eye each. Observations were made at 1, 2, 4, and 8 hours after treatment, then at 24 and 72 hours.

Results: At 24 hours, 3/6 had conjunctival redness (50=1, 50=2, 50=3) and 3/6 had discharge (50=1, 50=2, 50=3). No corneal opacity or edema irritation present. At day 3, 3/6 had conjunctival redness (50=1). All irritation had cleared by day 7.

Study Classification: Core, Minimum Data. 7 animals (4 with test material; 3 with vehicle material) were used.

Toxicity Category: III-CAUTION.

(3) Corneal Irritation Study: Pharmateq; Study # 1-3-257-30; August, 1980.

Procedure: Eight New Zealand rabbits received 0.5g of the test material in one intact eye each animal under occlusive wraps for 24 hours. Observations were made at 24 and 72 hours after treatment.

Results: At 24 hours, 7/8 had edema (50=1, no edema present. At 72 hours, irritation had cleared. Mean Irritation Index was 0.31.
Study Classification: Butt Guideline Data

Topiety Category: III - CAUTION