KAP-1347
TXR-000037

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: July 21, 1980

000038

SUBJECT: EPA File Symbol 4581-GUR
Decco Salt No. 22: Caswell # 311, 375A

FROM: Deloris F. Graham DGB 7/25/80
FHB/TSS E 8/7/80

TO: Henry Jacoby
Product Manager (21)

BEST AVAILABLE COPY

Applicant: Pennwalt Corporation
Decco-Tiltbelt Division
1713 South Carolina Avenue
P.O. Box 120
Monrovia, California 91016

Background: An Acute Oral, Acute Dermal and Eye Irritation Study was submitted in support of the conditional registration of this product. These studies were conducted by Pharmacology Research Inc. The method of support used is alternate. These data are under accession number 242341. The "alternate" method of support was chosen.

Recommendation:

1. The Acute Oral, ~~and~~ Acute Dermal, and eye irritation studies submitted are Core Supplementary and are not acceptable to support the conditional registration of this product.

   a. In the Acute Oral Study male and female animals must be used. $LD_{50}$ and 95% confidence limits for male and females must be reported separately. Individual symptomology and necropsy reports must be submitted. Suspension must be defined. Animals must be fasted prior to initiation of study.

   b. In the Acute Dermal Study, $LD_{50}$ and 95% confidence limits for males and females must be reported separately. Four test sites (2 intact and 2 abraded) per animal must be used. Only a paste can be used, a 50% of W/V solution is not acceptable.

   c. In the Eye Irritation Study, nine rabbits (six with treated unwashed eyes and three with treated washed eyes) must be used. Observations must be made at 24, 48 and 72 hours after dosing and four and seven days.

2. The referenced data (Accession No. 126549) cannot be used in support of this registration since it is not identical to the "Decco Salt No. 22" formulation. Under the "Alternate" method of support, data must be on an identical formulation.

Active Ingredients:
2,6-dichloro-4-nitroaniline . . . . . 48.8%
Thiophanate-methyl (dimethyl [(1,2 - phenylene) bis (iminocarbonothioyl)] bis [carbamate]) . . . . 24.4%
Inert Ingredients . . . . . 26.8%

EPA FORM 3206 REV 3-76

1 of 4

3. FHB/TSS objects to the conditional registration of this product until acceptable acute toxicity data is submitted. Please see the enclosed "Proposed Guidelines" for acceptable testing and reporting procedures, sections 163.81-1 thru 5.

Label:

1. Reserve labeling comments until acceptable acute toxicity data is submitted.

Review:

1. Acute Oral Toxicity Study: Pharmacology Research, Inc.

   Procedure: Seven groups, consisting of five male rats each, were administered one of the following doses: 1.6, 2.0, 2.5, 3.2, 4.0, 5.0 and 6.4 g/kg of an aqueous suspension of the test material.

   Results: At 1.6 g/kg no mortalities; at 2.0 g/kg, 1/5 died; at 2.5 g/kg, 3/5 died; at 3.2 g/kg, 1/5 died; at 4.0 g/kg, 3/5 died; at 5.0 g/kg, 3/5 died; 6.4 g/kg, 5/5 died. Symptoms observed included anorexia, hypersensitivity, hypertonicity, induced tremor, and induced muscular spasms. Majority of surviving animals showed significant and prolonged losses in body weight. They recovered five to ten days after dosage. $LD_{50}$ is 3.4 g/kg.

   Study Classification: Core Supplementary Data. Must use male and female animals. $LD_{50}$ and 95% confidence limits for male and females must be reported separately. Individual symptomology and necropsy reports must be submitted. Animals must be fasted prior to initiation of study. Suspension must be defined.

2. Acute Dermal Toxicity Study: Pharmacology Research, Inc.

   Procedure: Six white rabbits were administered a 2.0 g/kg dose of a 50% W/V aqueous suspension of the test material under occlusive wrap for 24 hours. Observation were made for two weeks.

   Results: No mortalities or toxicity reactions. All animals showed significant losses in body weight but were recovered four to ten days after treatment. $LD_{50}$ was greater than 2.0 g/kg.

   Study Classification: Core Supplementary Data. $LD_{50}$ and 95% confidence limits for males and females must be reported separately. Four test sites (two intact and two abraded) per animal must be used. Only a paste can be used, a 50% W/V solution is not acceptable.

3. Eye Irritation Study: Pharmacology Research, Inc.

   Procedure: 0.1 g of a dry sample was placed in the conjunctival sac of one eye of six white rabbits. Observations were made at 10 minutes, and 1, 2, 3, 4 and 24 hours.

2

Results: At 24 hours no corneal opacity, iris irritation or chemosis. Very slight redness between 10 minutes and 4 hours, but had cleared at 24 hours.

Study Classification: Core Supplementary Data. Nine rabbits (six with treated unwashed eyes and three with treated washed eyes) must be used. Observation must be made at 24, 48 and 72 hours and four to seven days after dosing.