3-1-83

005143

Date: March 1, 1983

Subject: EPA File Symbol: 1471-RGI and 1471-RUN
Balan Dry Flowable

From: Deloris F. Graham
TH6/SSB F 3/1/83

To: Robert Taylor
Product Manager (25)

Applicant: Elanco Products Company
a Division of Eli Lilly and Company
740 South Alabama Street
Indianapolis, Indiana 46285

Active Ingredient:
N-butyl-N-ethyl-α,α,α-trifluoro-2,6-dinitro-p-toluidine 60%
Inert Ingredients 40%

Background: Submitted Acute Oral, Dermal and Eye Irritation studies. Studies conducted by Lilly Research Laboratories. Data under accession number 249185. Cite all and Alternate method of support.

Recommendation: 1711
(1) TH6/SSB finds these data acceptable to support conditional registration of this product. However for future ~~submissions~~ submissions please note; In the Acute Oral and Acute Dermal Studies individual necropsy reports for each animal must be submitted; in the Eye Irritation Studies animals (6 with treated

(nine washed eyes and 3 with treated washed eyes) must be used.

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(2) An Acute Inhalation Study was not submitted and one must be submitted and/or cited. I.N.A.

(3) The appropriate signal word is CAUTION.

Label:

(1) The statement "Keep out of reach of children" must precede signal word.

(2) Precautionary statements must precede "Direction for Use" and the statement "Keep out of reach of children" must be set apart from the precautionary statements as indicated in statement (1).

(3) The precautionary statements must be revised to include, "Harmful if swallowed. If swallowed drink large quantity of water and induce vomiting by placing finger in back of throat. Never give anything by mouth to unconscious person." Get medical attention".

Review:

(1) Acute Oral Toxicity Study: Lilly Research Laboratories, Study: R-O-21-82", Feb. 10, 1982.

Procedure: Five male and five female Fischer rats received 500mg/kg of the test material orally. Observations made hourly during the first 7 hours after dosing, then daily for the subsequent 14 days.

Results: No mortalities. Toxic signs included chromaturia. LD50 greater than 500mg/kg.

Study Classification: Core Minimum Data. Individual necropsy reports for each animal must be submitted.

Toxicity Category: III - CAUTION

(2) Acute Dermal Toxicity and Dermal Irritation Study: Lilly Research Lab.; Study: B-D-25-82; February 17, 1982.

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Procedure: Three male and the female rabbits received 2000 mg/kg of the test material. One-half the animals had abraded skin and the other half intact skin. Treated areas were placed under occlusive wrap for 24 hour exposure. Observations were made one hour after removal of the occlusive dressing at the end of the 24 hour exposure period, then twice daily thereafter for subsequent 14 days.

Results: No mortalities. No signs of systemic toxicity noted. LD50 greater than 2000 mg/kg.

Slight to well defined erythema (score of 2 for all) and slight edema (scores of 1 to 2) at 24 hours. At 72 hours, 4/6 had erythema (4/6 = 2) and edema (1/6 = 1, 5/6 = 2). Dermal irritation persisted through day 13 decreasing in severity and had cleared by day 14. Primary Irritation Score was 3.8. Desquamation noted at day 5 and continued to test termination.

Study Classification: Core Minimum Data. Individual necropsy report for each animal must be submitted.
Toxicity Category: III - CAUTION.

(3) Eye Irritation Study: Lilly Research Laboratory; Study: 8-E-28-82; February 9, 1982.

Procedure: Six New Zealand rabbits received 73 mg (0.1 cc) of the test material in one eye each.

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Observations were made at 1, 24, 48 and 72 hours after dosing and again after 7 days.

Results: At 1 hour, 4/6 had corneal opacity (4/6=5), iris irritation (4/6=5), 6/6 hyperemia (1/6=1, 5/6=2) and chemosis (6/6=2). No discharge reported.

At day 1, 6/6 had corneal opacity (6/6=5), iris irritation (6/6=5), hyperemia (1/6=1, 5/6=2) and chemosis (1/6=1, 5/6=2).

At day 3, 3/6 corneal opacity (3/6=5); no iris irritation; 6/6 hyperemia (6/6=1) and 5/6 chemosis (5/6=1).

At day 7, no corneal opacity or conjunctive irritation present.

Study Classification: Core Minimum Data. 9 animals (6 with treated unwashed eyes and 3 with treated washed eyes) must be used.

Toxicity Category: III - CAUTION.