

Internal Correspondence

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ACN: 22452, T-4101

To D. R. Ricker - Industrial Chemical Products - 236-1B-10
From R. G. Perkins - Medical, Toxicology Services - 220-2E-02
Subject Summary of Acute Toxicity Study Report for T-4101
Date March 4, 1988

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Attached are copies of the acute oral toxicity study in rats, acute dermal toxicity study in rabbits, primary dermal irritation/corrosion study in rabbits and primary eye irritation/corrosion study in rabbits conducted by Hazleton Laboratories America, Inc. for T-4101, FC-109 FLUORAD Brand Fluorochemical Surfactant, lot 2, 41-2601-0414-0.

The following studies were conducted according to the Organization for Economic Cooperation and Development's Guidelines for Testing Chemicals.

ACUTE ORAL TOXICITY (RATS): SLIGHTLY TOXIC. Ten albino rats (Sprague-Dawley strain, 5 males, 5 females) each weighing between 200 and 298 grams each received an oral dose of T-4101 of either 0.5 grams or 5.0 grams per kilogram of body weight. For the 0.5 gram/kg dose level no clinical signs were observed. No deaths occurred and weight gains were noted. At necropsy no visible lesions were observed. For the 5.0 gm/kg dose level clinical signs included hypoactivity, ataxia, red-stained face, absence of pain reflex, miosis, prostration, tremors, diarrhea, cyanosis and yellow-stained genital region. Nine of the 10 dosed animals died between 1 day and 6 days post dose administration. At necropsy lesions included tan stains of perianal area, red and crusty ocular discharge, granular mucosa of stomach diffusely red with brown linear areas, material in the stomach, and gastrointestinal tract severely autolyzed in some animals. The acute oral LD50 in the rat of T-4101 is between 0.5 and 5.0 grams per kilogram of body weight. T-4101 is considered slightly toxic orally.

ACUTE DERMAL TOXICITY (RABBIT): PRACTICALLY NONTOXIC. Ten albino rabbits (New Zealand White strain, 5 males, 5 females) weighing between 2041 and 2343 grams each received a dermal application of T-4101 equivalent to 2.0 grams per kilogram of body weight. The area of application was occluded and 24 hours later the wrap and sample was removed. Clinical signs observed included few feces, hypoactivity, loss of appetite and thin

appearance among the female animals only. Dermal irritation consisted of slight-to-moderate erythema and edema and slight atonia and desquamation. No mortalities occurred. An increase in average body weight was observed for the male animals, but a decrease in average body weight was observed for the female animals at the day 7 observation. An increase in average body weight was observed at day 14. One female animal showed decreased body weight during the study, while 2 female animals showed decreased body weight at day 7 but had increased body weight by day 14; the remaining 2 females showed increases in body weight during the study.

At necropsy no visible lesions were observed in 2 of 5 males and in 3 of 5 females. In one male diffusely dark red auxiliary lymph nodes were observed. Dermal irritation effects were observed in 2 male and 2 female animals. Additionally, one of the latter females was observed to have a thin appearance, red areas and green fluid were noted in the gastrointestinal tract and green perianal stains were observed.

Under the conditions of this study T-4101 has a dermal LD50 in the rabbit of greater than 2.0 grams per kilogram of body weight. T-4101 is considered practically nontoxic dermally.

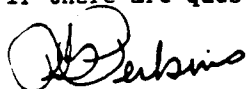
PRIMARY DERMAL IRRITATION: MINIMALLY IRRITATING. Three albino rabbits (New Zealand White strain) each received 0.5 milliliter applications of T-4101 to intact skin test sites. The sites were covered with a semi-occlusive wrap and contact was maintained for 4 hours. Thirty minutes after removal of the wrap and sample, and 24, 48, and 72 hours after application of the sample, the sites were evaluated for irritation. Very slight erythema only was observed at one test site at the 24 and 48 hour evaluation. No irritation was observed at the site at the 72 hour evaluation. No irritation was observed in the other 2 animals at any of the 4 evaluation periods. Under the conditions of this study, T-4101 is considered minimally irritating to the skin. After 24 hour occluded contact, both erythema and/or edema were observed and irritation persisted to day 14 in some animals.

PRIMARY OCULAR IRRITATION: MINIMALLY IRRITATING. Three albino rabbits (New Zealand White strain) each received 0.1 milliliters of T-4101 into the conjunctival sac of one eye. The contralateral eyes served as untreated controls. The eyes were evaluated for irritation at 1, 24, 48 and 72 hours after treatment and a sodium fluorescein examination performed at the 72 hour evaluation. At the one hour evaluation, irritation in 2 eyes consisted only of conjunctival irritation including redness, chemosis and/or discharge; iridal effects and conjunctival irritation occurred in the remaining test eye. At the 24 hour evaluation irritation in 2 test eyes now consisted of

D. R. Ricker
Page 3
March 4, 1988

corneal involvement (corneal epithelial peeling) and conjunctival irritation; only conjunctival redness was observed in the remaining test eye. At the 48 hour evaluation only conjunctival redness was observed in 1 test eye; the 2 remaining test eyes were clear. All test eyes were clear at the 72 hour evaluation and the sodium fluorescein examination was negative. A maximum primary irritation score of 6.3 of a possible 110.0 was assigned for the 1 hour evaluation. T-4101 is considered minimally irritating to the eyes under the conditions of this study.

If there are questions, please contact me.



RGP:bh (TS113 2.30)

Attachments:

- 1) Acute Oral Toxicity Study in Rats for T-4101
- 2) Acute Dermal Toxicity Study in Rabbits for T-4101
- 3) Primary Dermal Irritation/Corrosion Study in Rabbit's Foot T-4101
- 4) Primary Eye Irritation/Corrosion Study in Rabbits for T-4101