US EPA ARCHIVE DOCUMENT

CASWELL FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

008127

OCT 17

Oct 17 1990

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: SACB Review of Primary Eye Irritation Study with Foil® Flowable Formulation (ID No. 53633-10; Record No. 266,960; HED Project No. C-1516; Caswell No. 66).

TO: Phil Hutton/Mike Mendelsohn (RM-17)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: Roy D. Sjoblad, Ph.D., Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

THROUGH: Reto Engler, Ph.D., Chief
SACB, HED (H7509C)

Following is a Data Evaluation Report for a Primary eye irritation study in rabbits with Foil® Flowable Microbial pesticide.

RN 5815-92

Printed on Recycled Paper

11/17/90

Reviewer: Roy D. Sjoblad; SACB
Secondary Reviewer: Peto Engler, Chief, SACB

008127

DATA EVALUATION REPORT

STUDY TYPE: Primary eye irritation - rabbit

MRID: 415400-01 CASWELL NO.: 66

TEST MATERIAL: Foil™ Flowable

SYNONYMS: Bacillus thuringiensis var. kurstaki; E32424

STUDY NO.: L08239-#9

SPONSOR: Ecogen Incorporated; Langhorne, PA.

TESTING FACILITY: IIT Research Institute; Chicago, IL

TITLE OF REPORT: EPA Subdivision M Primary Eye Irritation/Infection of Foil™ Flowable Microbial Pesticide

AUTHORS: Robert L. Sherwood, Ph.D.

DATE ISSUED: March, 1990

CONCLUSION: The test material caused conjunctival discharge, reversible before 7 days after dosing; and erythema and chemosis not completely reversible at 7 days after dosing. The maximum Draize score was 10.7 for males at 2 days, and was 12.7 for females at 1 day after dosing. The maximum combined score was 11.0 at 2 and 3 days after dosing.

Classification: Acceptable. The test material can be placed in TOX Category II.

I. STUDY DESIGN: A. Test Material: Foil™ Flowable, Lot #179-36 023A0401; tan liquid suspension; B. Test animals: New Zealand albino rabbit, 2.76-3.08 kg for females and 2.45-2.53 kg for males at dosing. C. Methods: Three male and three female rabbits were dosed with undiluted test material by placing 0.1 ml into the conjunctival sac of the right eye of each rabbit. Eyelids were held closed for about 2 seconds following dosing. The left eyes were untreated, and served as controls. Prior to dosing, eyes were examined for lesions (2% fluorescein and UV light) and animals with unsuitable eyes were not used in the study. Each animal was observed daily for mortality, morbidity, and clinical signs of toxicity. Treated eyes were examined at 1 hour and at 1, 2, 4, 7, and 10 days after dosing. Ocular lesions were scored according to the system of Draize (1959). The test material was evaluated for number of spores of the active ingredient (dilution plate counting on trypticase soy agar after heating for 30 min at 65°C)

D. Results: The test material (0.1ml) contained about $1x10^9$ viable spores. No animals died as a result of treatment with the test material. No signs of corneal opacity or of irritation to the iris were observed. Conjunctival discharge (scores 1 to 2) was observed in

all test eyes at 1 day and 2 days after dosing. At 3 days after and at 4 days after dosing, 3/6 eyes showed mild discharge. No ocular discharge was observed at 7 days after dosing. Mild to moderate erythema was observed in almost all treated eyes through day 4 after dosing; one eye showed severe erythema at days 1 and 2. At 7 days, 3/6 eyes still showed mild erythema, while no erythema was observed at 10 days. Slight to moderate chemosis was also observed in all eyes at 1 hour after dosing through 4 days. 3/6 animals showed a score of 3 for chemosis from about days 1-3. One eye showed a score of 4 for chemosis at day 1. At 7 days, 3/6 eyes showed slight to moderate chemosis; and 1/6 eyes showed slight chemosis at day 10. The maximum Draize score for males was 10.7 at 2 days, and for females was 12.7 at 1 day. The maximum combined score was 11.0 at days 2 and 3 after dosing.