7-28-93

FINAL

DATA EVALUATION REPORT

Fortress

Study Type: Acute Dermal Toxicity

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
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Principal Reviewer — Pia Lindström, DPH — Date 7/26/93

Independent Reviewer — William McLellan, Ph.D. — Date July 27, 1993

QA/QC Manager — Sharon Segal, Ph.D. — Date 7/27/93

Contract Number: 68D10075
Work Assignment Number: 2-097
Clement Number: 261
Project Officer: Caroline Gordon

EPA Reviewer and
Section Head: Marion Copley, D.V.M.
Review Section IV, Toxicology Branch I/HED

Signature: Marion Copley
Date: 8/2/93

DATA EVALUATION REPORT

STUDY TYPE: Acute Dermal Toxicity (Rabbit); Guideline 81-2

EPA IDENTIFICATION NUMBERS

CAS No.: 54593-83-8

MRID No.: 425592-07

PC Code: 129006

Tox. Chem. No.: 663P

TEST MATERIAL: Fortress® 5G (Granule)

SYNONYM: DPX-43898-26; IN 43898-26; Phosphorothioic acid, 0,0-diethyl 0-(1,2,2,2-tetrachloroethyl) ester

SPONSOR: Du Pont Agricultural Products, Wilmington, DE

STUDY NUMBER: HLR 236-92

TESTING FACILITY: E.I. du Pont de Nemours and Company, Haskell Laboratory for Toxicology and Industrial Medicine, Newark, DE

TITLE OF REPORT: Acute Dermal Toxicity Study with DPX-43898-26 in Rabbits

AUTHOR: J.W. Sarver

STUDY COMPLETED: August 26, 1992

CONCLUSIONS: Limit test--Estimated acute dermal LD_{50} in males: >2000 mg/kg
Estimated acute dermal LD_{50} in females: >2000 mg/kg

TOXICITY CATEGORY: III

CORE CLASSIFICATION: Core Guideline. This study meets the requirements set forth under EPA guideline series 81-2 for an acute dermal toxicity study.

A. MATERIALS

Test Compound

Test material:	DPX-43898-26 (5G Formulation)
Identification number:	17469
Physical description:	Brown solid granule
Purity:	5.3%
Storage condition:	Not reported
Stability:	Not reported

Dose Level: 2000 mg/kg test material moistened with deionized water (limit test)

Controls: None were used

Test Animals

Species:	Rabbit
Strain:	New Zealand White
Source:	Hare Marland, Hewitt, NJ
Sex:	Male and female
Age:	Young adult
Weight:	Males--3.34-3.56 kg; Females--2.95-3.48
No. animals/dose:	5/sex

B. TEST PERFORMANCE

Environmental Conditions:	Temperature 20° ± 2°C Humidity 50% ± 10% No. air changes per hour not reported A 12/12 hour light/dark cycle was maintained
Skin Preparation:	24 hours prior to dermal application, the back of each animal was shaved.
Application:	The test compound was applied to a gauze pad approximately 190 cm^2 in size which was then applied to the shaved back of the animals (10% of total body surface). The test site was then wrapped with plastic film, stretch gauze bandage, and an elastic adhesive bandage. After 24 hours, the bandages were removed and the test site was washed with warm water and dried with a paper towel.
Exposure Time:	24 hrs
Observation Period:	14 days
Observation Frequency:	5 hours after treatment; daily thereafter
Body Weight Intervals:	Days 0, 1, 7, and 14
Gross Pathology:	NO
Histopathology:	NO

C. RESULTS

Mortality: No mortality was observed. Animals were sacrificed on day 14.

Clinical Observations: No clinical signs were observed.

Dermal Observations: Slight erythema was evident in one male and one female 24 hours after exposure. By 48 hours, no dermal effects could be observed.

Body Weights: Slight decreases in body weights were observed 24 hours after treatment in all animals. Overall, the decreases were 4% and 3% lower than on day 0 in males and females, respectively. All animals were gaining weight by day 7. Mean body weights were as follows:

Group	Day 0	Day 1	Day 7	Day 14
Males	3425 g	3296 g	3668 g	3564 g
Females	3140 g	3050 g	3332 g	3407 g

D. REVIEWER'S COMMENTS

This study was well designed, conducted, and reported. The reviewers agree with the study authors conclusions.

E. QUALITY ASSURANCE MEASURES

Was the test performed under GLPs? YES

A quality Assurance Statement, signed and dated August 25, 1992, was submitted and included dates when findings were reported. (The findings were not stated.)