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

Signature: Marion Copley
Date: 8/9/93

8/9/93

DATA EVALUATION REPORT

STUDY TYPE: Primary Dermal Irritation (Rabbit); Guideline 81-5

EPA IDENTIFICATION NUMBERS

CAS No.: 54593-83-8

MRID No.: 425592-08

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 1-92

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

TITLE OF REPORT: Primary Dermal Irritation Study with DPX-43898-26 in Rabbits

AUTHOR: J.W. Sarver

STUDY COMPLETED: March 12, 1992

CONCLUSIONS: Primary Irritation Index: 0 (non-irritant)

TOXICITY CATEGORY: IV

CORE CLASSIFICATION: Core Guideline. This study meets the requirements set forth under EPA Guideline Series 81-5 for a primary dermal irritation study.

A. MATERIALS

Test Compound

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

Dose Level: 0.5 g aliquot

Controls: None were used

Test Animals

Species:	Rabbit
Strain:	New Zealand White
Source:	Hare Marland, Hewitt, NJ
Number animals:	6
Sex:	Male
Age:	Young Adult
Weight:	2.49-2.73 kg at study initiation

B. TEST PERFORMANCE

Environmental Conditions:	Temperature 22° ± 3°C Humidity 50% ± 10% A 12/12 hour light/dark cycle was maintained
Skin Preparation:	24 hours prior to testing, the back was shaved.
Application:	Approximately 0.5 g of test material was placed on a 2 inch gauze pad and applied to the test site. The pad was secured with non-irritating tape. The animal was then wrapped with rubber sheeting secured with clips. After 4 hours, the patch was removed and residual test material was removed by gently washing with warm water and wiping dry.
Exposure Time:	4 hrs
Observation Period:	1 hr; 24 hrs; 48 hrs; and 72 hrs
Scoring System:	Skin reactions were scored using the Draize system.

C. RESULTS:

No erythema, eschar formation, or edema was observed in any animal at any observation period.

D. REVIEWERS' 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 March 5, 1992, was submitted and included dates on which findings had been reported. (The findings were not stated.)

FINAL

DATA EVALUATION REPORT

Fortress

Study Type: Primary Dermal Irritation

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
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer — Pia Lindström, DPH — Date 7/20/93

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

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

Contract Number: 68D10075
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Clement Number: 262
Project Officer: Caroline Gordon

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