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CAMPBELL FILES

Reviewed by: Susan L. Makris, M.S. *Susan L. Makris 11/19/91*  
Section III, Toxicology Branch II (H7509C)  
Secondary reviewer: James N. Rowe, Ph.D. *James N. Rowe 11/20/91*  
Supervisor, Section III, Toxicology Branch II (H7509C)

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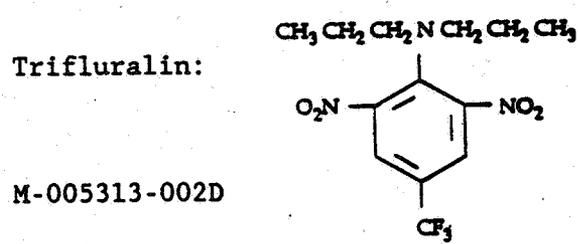
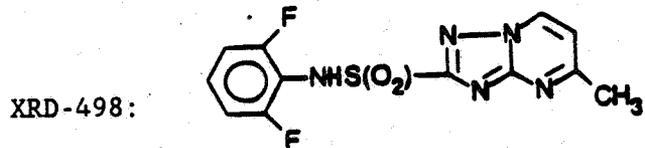
DATA EVALUATION REPORT

STUDY TYPE: Acute Dermal Toxicity in Rabbits (Guideline 81-2)

EPA IDENTIFICATION NOS.: MRID NO.: 419938-06  
HED PROJECT NO.: 1-2384  
CASWELL NO.: 889

TEST MATERIAL: XRM-5313

SYNONYMS: Formulation containing: 2.6% XRD-498 [N-(2,6-difluorophenyl)-5-methyl(1,2,4)triazolo(1,5a)pyrimidine-2-sulfonamide] and 35.8% Trifluralin (Treflan;  $\alpha,\alpha,\alpha$ -trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine)



STUDY NUMBER: M-005313-002D

SPONSOR: DowElanco  
9002 Purdue Road  
Indianapolis, Indiana 44268-1189

TESTING FACILITY: The Toxicology Research Laboratory  
Health and Environmental Sciences  
The Dow Chemical Company  
Midland, Michigan 48674

TITLE OF REPORT: XRM-5313: Acute Dermal Toxicity Study in New Zealand White Rabbits

AUTHORS: N.M. Berdasco  
L.G. Lomax

DATE REPORT ISSUED: May 23, 1991

CONCLUSION:  
Toxicity Category: At least III (from 2,000 through 5,000 mg/kg).

Median Lethal Dose: The LD<sub>50</sub> is greater than 2000 mg/kg in male and female New Zealand White rabbits.



confirmed at necropsy, but no other macroscopic abnormalities were observed in rabbits at study termination. The investigators stated that "the observed erythema, fissuring, scaling, and crusting were consistent with the skin effects noted in the Material Safety Data Sheet for the solvent used in preparation of the formulation, [REDACTED]

Body weight data:

Mean body weight data are presented in Table 1. All rabbits gained or maintained body weight over the course of the study.

Table 1. Mean body weight data - grams

Sex		Day -1	Day 1	Day 2	Day 8	Day 15
Males	Mean	3315	3139	3148	3094	3176
	S.D.	102	50	127	88	104
	N	5	5	5	5	5
Females	Mean	3070	2914	2902	2878	2954
	S.D.	41	65	62	46	60
	N	5	5	5	5	5

Note: Data were extracted from report No. M-005313-002D, pages 15 and 16.

STUDY DEVIATION:

The following information was not presented in the report: the approximate amount of test material applied per unit of skin exposed (calculated in mg per square cm of skin), as recommended in Guideline 81-2 (h)(3)(ix).

COMPLIANCE:

The following signed and dated statements were included:

- Statement of No Data Confidentiality
- GLP Compliance Statement
- Flagging Statement (negative)
- Quality Assurance Statement

DISCUSSION:

1. In view of the fact that FIFRA guideline 81-2 defines 2000 mg/kg as the limit dose for dermal acute studies, and since there was no mortality in rabbits dosed at that level, the dermal LD<sub>50</sub> of XRM-5313 is greater than 2000 mg/kg. Further acute dermal toxicity testing is not required.
2. Based upon the criteria presented in 40 CFR Part 156.10 and the results of this study, the test material, XRM-5313, is classified as at least Toxicity Category III (from 2,000 through 5,000 mg/kg).

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED