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008866

DATA EVALUATION REPORT

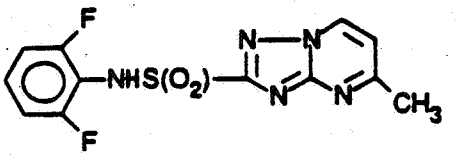
STUDY TYPE: Primary Dermal Irritation in Rabbits (Guideline 81-5)

EPA IDENTIFICATION NOS.:
MRID NO.: 419938-08
HED PROJECT NO.: 1-2384
CASWELL NO.: 889

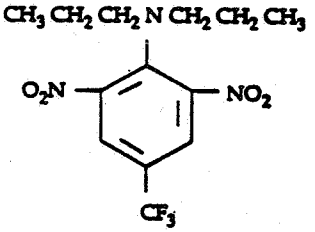
TEST MATERIAL: XRM-5313

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; α,α,α-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine)

XRD-498:



Trifluralin:



STUDY NUMBER: M-005313-002B

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: Primary Dermal Irritation Study in New Zealand White Rabbits

AUTHORS: N.M. Berdasco

DATE REPORT ISSUED: May 15, 1991

CONCLUSION:

Toxicity Category: IV (mild or slight irritation at 72 hours)

Core Classification: Guideline

MATERIALS:

1. Test compound: Description: Orange liquid
   Sample reference: AGR 291670
   Source: DowElanco, Midland, Michigan
   Active ingredients: 2.6% XRD-498 and
   35.8% Trifluralin

2. Test animals: Species: Rabbit
   Strain: New Zealand White
   Source: Hazleton Research Products, Inc.
   Kalamazoo, Michigan
   Age: Not provided
   Weight: 2.9-3.5 kg

METHODS:

Six rabbits of unspecified age and sex were clipped free of fur (over a dorsal area of approximately 15 cm^2). Approximately 24 hours later, the clipped skin was treated with a single 0.5 ml dose of undiluted test material. The test material was applied under a 4 x 4 cm gauze patch held in place with non-irritating tape, and a flannel bandage covered the area. The test material was allowed to remain in contact with the skin for 4 hours, after which time all remnants were removed from the skin with a damp disposable towel.

The skin was examined within 30 minutes, and 24, 28, and 72 hours after removal of the patches and test material. Further examinations were conducted on Days 7 and 14. Erythema, eschar formation, and edema were graded numerically according to the EPA FIFRA Guideline 81-5 recommendations. All other dermal changes were also recorded. The study was terminated 14 days post-treatment.

RESULTS:

Individual dermal irritation grades are presented in Table 1. Within 30 minutes after dosing, the animals all exhibited very slight erythema. At 24 hours postdose, the erythema had generally progressed to a slight grade, and very slight edema was observed in some animals. These signs were noted through 72 hours postdose, but by 7 days after treatment, the erythema and edema findings had nearly all reversed. Slight to marked desquamation, which failed to resolve, was also noted in all rabbits on Days 7 and 14 posttreatment.

STUDY DEVIATIONS: None noted.

Table 1. Individual Dermal Irritation Scores

Observation Timea	Erythema	Edema	Observation Timea	Erythema	Edema
Within 30 minutes	1	0	72 hours	2	0
	1	0		2	2
	1	0		2	0
	1	0		2	1
	1	0		1	0
	1	0		1	0
24 hours	1	0	7 days	0*	0
	2	1		0*	0
	2	1		1*	0
	2	1		0*	0
	2	0		0*	0
	2	1		0*	0
48 hours	2	0	14 days	0*	0
	2	2		0*	0
	2	0		0*	0
	2	1		0*	0
	1	0		0*	0
	1	0		0*	0

a Observation time is following patch removal.
* Animals exhibited slight to marked desquamation.

COMPLIANCE:

The following signed and dated statements were included:
Statement of No Data Confidentiality
GLP Compliance Statement
Flagging Statement (negative)
Quality Assurance Statement

DISCUSSION:

Based upon the criteria presented in 40 CFR Part 156.10, the Toxicity Category for skin effects following dermal administration of the test material, XRM-5313, is IV (mild or slight irritation at 72 hours).