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DATA EVALUATION REPORT

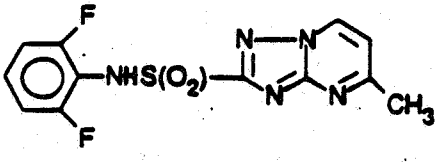
STUDY TYPE: Primary Eye Irritation in Rabbits (Guideline 81-4)

EPA IDENTIFICATION NOS.:
MRID NO.: 419938-07
HED PROJECT NO.: 1-2384
CASWELL NO.: 889

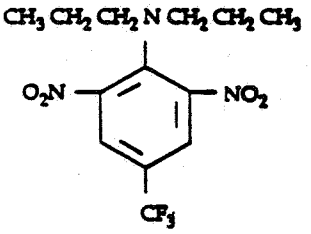
TEST MATERIAL: XRM-5313

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-005313-002C

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 Eye Irritation Study in New Zealand White Rabbits

AUTHORS: N.M. Berdasco

DATE REPORT ISSUED: May 17, 1991

CONCLUSION:

Toxicity Category: I; corneal opacity was not reversible within 21 days.

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.
   Denver, Pennsylvania
   Age: Adult
   Weight: 2.9-3.4 kg

METHODS:

Six young adult rabbits, three of each sex, confirmed to be free of ocular defects/irritation, received a 0.1 ml single dose of the undiluted test material in the conjunctival sac of the right eye. The left eye was left untreated and served as the control. Due to moderate discomfort noted in the first rabbit dosed, both eyes of each subsequently dosed rabbit were anesthetized with Ophthaine® ocular anesthetic prior to test substance installation. The treated eyes of all rabbits remained unwashed.

The behavior of each rabbit was observed immediately following treatment for indications of pain or discomfort. The eyes were examined 1, 24, 48, and 72 hours after test material application, and at Days 7, 14, and 21. Lesions in the cornea, iris, or conjunctiva were graded numerically according to the EPA FIFRA Guideline 81-4 recommendations. The study was terminated 21 days post-treatment.

RESULTS:

Individual animal ocular irritation scores are presented in Table 1. At the one-hour observation interval, slight redness of the conjunctivae and/or iris was noted in all rabbits. By 24 hours postdose, the conjunctival redness had progressed to a moderate grade and was accompanied by slight conjunctival chemosis, slight to marked conjunctival discharge, and slight corneal opacity. The conjunctival discharge noted was reversed in all but one rabbit by 48 hours postdose, and the conjunctival chemosis was no longer observed in any animal at 14 days postdose. At study termination (21 days postdose), slight corneal opacity and slight conjunctival redness were observed in three animals and one animal, respectively.

STUDY DEVIATIONS: None noted.

COMPLIANCE:

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

Table 1. Individual Ocular Irritation Gradings

| Observation Time | Conjunctivae | | | Cornea. Opacity | |
|---|---|---|---|---|---|
| | Redness | Chemosis | Discharge | | |
| One hour | 1 1 1 1 1 1 | 0 0 0 0 0 0 | 0 0 0 0 0 0 | 0 0 0 0 0 0 | 0 0 0 1 0 0 |
| 24 hours | 2 2 2 2 2 2 | 1 1 1 1 1 0 | 2 1 2 3 2 2 | 0 1 1 1 1 1 | 0 0 1 1 0 0 |
| 48 hours | 2 2 1 2 1 1 | 1 1 0 1 0 0 | 0 0 0 2 0 0 | 0 1 1 1 1 1 | 0 0 1 0 0 0 |
| 72 hours | 1 2 1 2 1 1 | 1 1 1 1 1 0 | 0 0 0 0 1 0 | 0 1 1 1 1 1 | 0 0 0 0 0 0 |
| 7 days | 0 1 1 1 0 0 | 0 1 1 1 0 0 | 0 0 0 0 0 0 | 0 1 1 1 0 0 | 0 0 0 0 0 0 |
| 14 days | 0 1 0 1 0 0 | 0 0 0 0 0 0 | 0 0 0 0 0 0 | 0 1 1 1 0 0 | 0 0 0 0 0 0 |
| 21 days | 0 0 0 1 0 0 | 0 0 0 0 0 0 | 0 0 0 0 0 0 | 0 1 1 1 0 0 | 0 0 0 0 0 0 |

DISCUSSION:

According to 40 CFR Part 156.10, observations noted on this study, specifically corneal opacity which was not reversible within 21 days, would place the test material into Toxicity Category I.