DATA EVALUATION RECORD

MESOTRIONE (ZA1296 (480 g/L SC Formulation))

Study Type: §81-4, Primary Eye Irritation Study

Work Assignment No. 2-01-52J (MRID 44373519)

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

Prepared by
Pesticide Health Effects Group
Sciences Division
Dynamac Corporation
2275 Research Boulevard
Rockville, MD 20850-3268

Primary Reviewer:
Kimberly S. Woodard, B.S.

Signature: Kimberly S Woodard
Date: 12/13/99

Project Manager:
Mary L. Menetrez, Ph.D.

Signature: Mary L. Menetrez CEP
Date: 12-13-99

Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

1

479

EPA Reviewer: David Nixon, DVM
Registration Action Branch 1/HED (7509C)

Work Assignment Manager: Marion Copley, DVM
Registration Action Branch 1/HED (7509C)

David Nixon 7/11/2000

MCopley 7/19/2000

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit
OPPTS Number: 870.2400 OPP Guideline Number: §81-4

DP BARCODE: D259369 SUBMISSION CODE: S541375
P.C. CODE: 122990 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): 480 g/L SC Formulation of ZA1296 [40.5% (w:w) ai]

SYNONYMS: None specified

CITATION: Lees, D., and H. Connolly (1995) ZA1296: eye irritation to the rabbit of a 480 g/L SC formulation. Zeneca Central Toxicology Laboratory, Macclesfield, Cheshire, UK. Laboratory Report No. CTL/P/4804, Study No. FB5246. November 29, 1995. MRID 44373519. Unpublished.

SPONSOR: Zeneca AG Products, Wilmington, DE.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 44373519), 0.1 mL of a 480 g/L SC Formulation of ZA1296 [40.5% (w:w) ai] was instilled into the conjunctival sac of one eye of six young adult New Zealand White female rabbits. The animals were observed for up to 3 days following instillation, and eye irritation was scored by the Draize method.

No positive ocular irritation was observed during the 3-day observation period, and the slight conjunctival effects that occurred in 6/6 treated eyes completely subsided by 2 days.

In this study, the **480 g/L SC Formulation of ZA1296 is a slight ocular irritant**, and is classified as **TOXICITY CATEGORY IV** for primary eye irritation.

This study is classified **acceptable (§81-4)** and satisfies the guideline requirements for a primary eye irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

2

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: 480 g/L SC Formulation of ZA1296
   Description: Tannish brown liquid
   Lot/Batch #: WF2381; 14541-25-03
   Purity: 40.5% ZA1296 (w:w)
   CAS #: Not provided

2. Vehicle: None employed

3. Test animals: Species: Rabbit
   Strain: New Zealand White
   Age: Young adult
   Weight: 2774-3232 g (all female)
   Source: Charles River UK Ltd, Manston Road, Margate, Kent, UK
   Acclimation period: ≥6 Days
   Diet: Standard Rabbit Diet (STANDRABSQC), Special Diets Services Ltd., Witham, Essex, UK, ad libitum
   Water: Tap water, ad libitum
   Housing: One animal/cage in aluminum sheet cages
   Environmental conditions:
   Temperature: 17±2 °C
   Humidity: 55±15%
   Air changes: Approximately 25-30 changes/hour
   Photoperiod: 12-Hour light/dark

B. STUDY DESIGN and METHODS:

1. In-life dates: September 1995

2. Animal assignment and treatment: A 0.1-mL aliquot of a 480 g/L SC Formulation of ZA1296 was instilled into the conjunctival sac of the left eye of six young adult New Zealand White female rabbits. The upper and lower lids were held together briefly before releasing to prevent loss of the material. The contralateral eye served as an untreated control. Immediately following application, the initial pain reaction of each rabbit was assessed. The animals were observed for ocular irritation at 1 hour, and 1, 2, and 3 days following instillation. Eye irritation was scored by the Draize method. At the day 1-3 observations, sodium fluorescein dye procedures were used to assess any corneal damage. A modified Kay and Calandra system was used to interpret and classify the numerical scores. Body weights were recorded at day 1.

II. RESULTS AND DISCUSSION:

A. Clinical observations: No positive ocular irritation was observed during the 3-day study. Slight conjunctival redness (score of 1) was observed in 6/6 treated eyes, very slight conjunctival chemosis (score of 1) was observed in 1/6 eyes, and moderate to severe conjunctival discharge (scores of 2-3) was observed in 2/6 eyes. The conjunctival effects completely subsided from 5/6 eyes by 1 day and 6/6 eyes by 2 days. There were no corneal or irridial effects. In this study, the 480 g/L SC Formulation of ZA1296 is a slight ocular irritant.

B. Deficiencies: There were no deficiencies that affected the validity of the study results.