

DATA EVALUATION RECORD

7/19/2000

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

Study Type: §81-5, Primary Dermal Irritation Study

Work Assignment No. 2-01-52L (MRID 44373521)

Prepared for
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U.S. Environmental Protection Agency
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Disclaimer

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MESOTRIONE (ZA1296)

Primary Dermal Irritation Study (§81-5)

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Registration Action Branch 1/HED (7509C)

David Nixon 7/11/2000

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Marion Copley 7/19/2000

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit
OPPTS Number: 870.2500

OPP Guideline Number: §81-5

DP BARCODE: D259369
P.C. CODE: 122990

SUBMISSION CODE: S541375
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: skin irritation to the rabbit of a 480 g/L SC formulation. Zeneca Central Toxicology Laboratory, Macclesfield, Cheshire, UK. Laboratory Report No. CTL/P/4803, Study No. EB4421. November 29, 1995. MRID 44373521. Unpublished.

SPONSOR: Zeneca AG Products, Wilmington, DE.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44373521), six young adult New Zealand White female rabbits were dermally exposed to a 480 g/L SC Formulation of ZA1296 [40.5% (w:w) ai] for 4 hours; the undiluted test substance was applied to a single intact 6.25-cm² site/animal. Animals were observed for dermal irritation and mortality for up to 3 days following patch removal; irritation was scored by the Draize scale.

Very slight erythema and edema were observed at up to 5/6 and 4/6 application sites, respectively, between 30-60 minutes and 1 day following patch removal. All irritation subsided by 2 days.

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

This study is classified **acceptable (§81-5)** and satisfies guideline requirements for a primary dermal irritation study in the rabbit.

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

I. MATERIALS AND METHODS

A. MATERIALS:

- 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
- Vehicle: None
- Test animals: Species: Rabbit
Strain: New Zealand White
Age: Young adult
Weight: 2456-3718 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:

- In-life dates: September 1995
- Animal assignment and treatment: Fur from the dorsal trunk areas of six young adult New Zealand White female rabbits was clipped 1 day prior to dermal administration of a 480 g/L SC Formulation of ZA1296. The undiluted formulation was applied to a single intact site per animal using a polypropylene syringe, and covered with a 2.5- x 2.5-cm surgical gauze patch. The gauze was secured with tape and the trunk of each animal was wrapped with impermeable rubber sheeting, which was then secured with polyethylene tape. Following a 4-hour exposure period, the coverings were removed, and the test sites

were gently washed with warm water. The rabbits were observed for dermal irritation at approximately 30-60 minutes and 1, 2, and 3 days following patch removal. Erythema and edema were scored separately using the Draize scale. Body weights were recorded at the start of the study.

II. RESULTS AND DISCUSSION:

- A. Clinical observations: Very slight erythema (score of 1) was observed at 5/6 application sites at the 30-60 minute observation period and at 2/6 sites at the 24-hour observation. Very slight edema (score of 1) was observed at 4/6 sites at the 30-60 minute observation period and at 2/6 sites at the 24-hour observation. All occurrences of erythema and edema subsided by day 2. In this study, the 480 g/L SC Formulation of ZA1296 is a slight dermal irritant.
- B. Deficiencies: There were no deficiencies that affected the validity of the study results.