

12/13/1999

DATA EVALUATION RECORD

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

Study Type: §81-2, Acute Dermal Toxicity

Work Assignment No. 2-01-52F (MRID 44373515)

Prepared for
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Disclaimer

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

12/13/99

B. STUDY DESIGN and METHODS:

1. In-life dates: September 1995
2. Animal assignment and treatment: Fur from the dorso-lumbar areas (approximately 10% of the total body surface area)¹ of five young adult Alpk:AP,SD rats/sex was clipped 16-32 hours prior to dermal administration of a 480 g/L SC formulation of ZA1296 at 2,000 mg/kg (limit dose). The undiluted test substance was evenly applied to the clipped site. Each site was covered with a 4-ply 7-cm x 7-cm gauze patch which was kept in contact with the skin using an occlusive dressing and covered with plastic secured with PVC tape. After 24 hours, the coverings were removed, and each application site was gently washed with warm water. The rats were observed for signs of systemic toxicity/gross abnormalities between 1 and 4 hours following treatment, and once daily thereafter for up to 14 days. Dermal irritation was also observed once daily following patch removal. Body weights were recorded at 0 (prior to dosing), 2, 5, 7, and 14 days. At 14 days, the surviving animals were sacrificed, necropsied, and examined for gross pathological changes.
3. Statistics: Not applicable to this study.

II. RESULTS AND DISCUSSION:

- A. Mortality: All animals survived the 14-day observation period.

Dermal LD₅₀ Males = >2,000 mg/kg (observed)
Females = >2,000 mg/kg (observed)

- B. Clinical observations: Signs of urinary incontinence were observed in 4/10 animals on day 1. No other clinical effects were observed.

In all animals, yellow and/or brown staining of the treated area was observed throughout the study. Slight erythema was noted at 6/10 treatment sites up through day 4. In addition, small scattered scabs were observed at 2/10 sites on day 5.

- C. Body Weight: The majority of animals showed a slight weight loss between days 0 to 2, but gained weight by the end of the study. Males exhibited an overall (0-14 days) mean increase in body weight of 16%. Although all females generally gained weight after day 2, increases were slight, and averaged only 5.8% overall.

¹Percent body surface area calculated by reviewer using (BW)^{2/3} conversion.

2
4
7/72

- D. Necropsy: Gross necropsy of animals sacrificed after 14 days revealed yellow staining of the hair in 8/10 rats. In addition, red spots on the lungs was observed in one animal.
- E. Deficiencies: There were no deficiencies that affected the validity of the study results.