

2-1-88

EPA File Symbol 352-LAE

Primary Eye Irritation Study (MRID 40858801)

Conjunctiva redness in $\frac{3}{6}$ animals at 24 hours

Cornea opacity in $\frac{1}{6}$ animals at 1 hour.

Conjunctiva redness persisted in one animal for 48 animals

Eye in all animals cleared at 72 hours.

Toxicity Category III - Caution

Primary Dermal Irritation (MRID 40858802)

6 animals used

No ~~erythema~~ erythema or edema reported on any of the animals.

Toxicity Category IV - Caution

Dermal Sensitization Study - Guinea Pigs (MRID 40858803)

Induction phase (dermal application) conducted with 20 guinea pigs (10 males and 10 females) with 0.4 mL of test material; 5 male and 5 female guinea pigs were treated with 0.4 mL dimethyl phthalate to serve as vehicle controls.

3 males and 2 females were treated with 0.4 mL suspension of DNCB.

Two weeks after last induction treatment (3 once a week for 6 hrs); test animal received 0.4 mL of test substance, vehicle control animals received 0.4 mL of dimethyl phthalate, and positive control animals received 0.4 mL of DNCB suspension.

During induction phase slight patchy erythema noted in 2 test animals 24 hours after 1st induction treatment. No other irritation noted during induction phase in any test animals. No irritation in vehicle control animals; Positive control animals exhibited slight patchy erythema to severe erythema during the induction phase.

Other effects were necrosis and edema.

No dermal irritation in vehicle or negative control animals during challenge. Test animal exhibited slight patchy erythema by 48 hours after treatment. Positive control animals exhibited moderate to severe erythema during challenge; necrosis, blanching and edema were also observed.

Not a sensitizer.

Referenced Studies:

Acute Oral Toxicity (Rat) (Assessment No 071435)

LD₅₀ > 5000 mg/kg Toxicity Category II - Caution

* Acute Dermal Toxicity (Rabbit) (Accession Number 071435)

LD₅₀ > 2000 mg/kg

Toxicity Category III - Caution

Acute Inhalation

Category IV - Caution

Summary:

Acute Oral: Category IV

Acute Dermal: Category III

Primary Eye: Category III based on PR No. 81-3

Primary Dermal: Category IV

Acute Inhalation: Category IV

Dermal Sensitization: Not a sensitizer

Signal Word: "Caution"

Recommend PL labeling for Primary Eye & Dermal Category III

~~Data acceptable~~ acceptable; some label changes.

VKW 12/1/88 by instruction of PM to review acutes