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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Releasable



DATE: August 22, 1977

SUBJECT: AA trex 4L - Addition of Data to Files, EPA Reg. No. 100-497
Caswell #63, Shaughnessey #080803

FROM: Toxicology Branch
Registration Division

TO: Robert Taylor
Product Manager #25

THRU: O.E. Paynter, Ph.D.
Chief, Toxicology Branch

Recommendation

no action required

Review

1. Acute Oral LD₅₀ of AA trex 4L with Ethylene Glycol - 5.0%
-(Industrial Bio-Test, IBT #A9536, 4/30/71, submitted by
Ciba-Geigy on 6/2/77)

Forty Charles River albino rats ranging in body weight from 150-224 g were divided into 4 groups of 10 animals each (5 male, 5 female) and administered 2.0, 3.0, 4.6 and 6.8 g/kg of the test material by intubation.

Following administration of the test material the rats were housed individually and observed for the succeeding 14 days for signs of toxicity and/or mortality. Initial and final bodyweights were recorded. Necropsies were performed on all animals.

Results

LD₅₀=3.8(2.9-4.8)g/kg

Toxic Signs: hypoactivity, ataxia, ruffed fur, muscular weakness

Necropsey: hemor hages in G.I. tract, pale livers, alopecia, hyperemia of lungs.

Classification: Core-Minimum Data TOX CATEGORY:III

- 1) body weight and food consumption were not measured daily.

2. Acute Dermal LD₅₀ of AA trex 4L with Ethylene Glycol -5.0%
-(Industrial Bio-Test, IBT #A9536, 4/30/71, submitted by
Ciba-Geigy on 6/2/77)

Eight New Zealand albino rabbits ranging in body weight from 2.42-3.14 kg were divided into 2 groups of 4 animals each (2 male, 2 female) and received skin applications of undiluted test material at dose levels of 6.8 and 10.2 g/kg to the unabraded skin of their shaved backs. The test material remained in contact with the skin for 24 hours under an impervious cuff.

Following the 24 hour exposure the material was washed away and the animals observed for 14 days post exposure. Necropsies were performed on all animals. Initial and final body weights were recorded.

Results

LD₅₀ > 10.2 g/kg

Toxic Signs: well defined erythema and slight edema at 24 hrs.

Necropsy: unremarkable

Classification: Core-Minimum Data TOX CATEGORY: III

- 1) although the number of dose levels employed is rather scant, the results are definitive. Also "Guidelines" does not call for testing amounts in excess of 5 g/kg.

3. Primary Eye Irritation of AA trex 4L with Ethylene Glycol -5.0%
-(Industrial Bio-Test, IBT #A9536, 4/30/71, submitted by
Ciba-Geigy on 6/2/77)

0.1 ml of undiluted test material was instilled into the conjunctival sac of the right eye of each of 5 New Zealand albino rabbits. One hour, 24 and 72 hours and 7 days following instillation, the cornea, iris and palpebral conjunctiva were examined and graded according to Draize.

Results

Corneal opacity present in 1/6 rabbits on day 1, clearing by day 3. Minimal conjunctival irritation in 6/6 rabbits clearing by day 7.

Classification: Core-Minimum Data TOX CATEGORY:II

- 1) although only 5 animals were used the results are consistent between animals thus giving credence to the results.

4. Acute Vapor Inhalation Study of AA trex 4L with Ethylene Glycol -5.0%
-(Industrial Bio-Test, IBT #N9537, 3/3/71, submitted by Ciba-Geigy on 6/2/77)

Ten Charles River albino rats (5 male, 5 female) were exposed in a 70 liter plexiglas inhalation chamber for 4 hours to a vapor concentration of 6.8 mg/L of the test material. Following exposure the animals were returned to their cages and observed for changes in behavior and/or mortality for a period of 14 days. Initial and final body weights were recorded. Necropsies were performed on all animals.

Results

LC50>6.8mg/L {no deaths occurred over a 4 hour exposure period}

Toxic Signs: decrease in body weight gain in 3 female rats

Necropsy: hyperemia of lungs

Classification: Supplementary Data TOX CATEGORY:III

- 1) an insufficient number of dose levels were employed; therefore, LC50 could not be calculated.

5. Primary Skin Irritation of AAtram 20 G
-(Industrial Bio-Test, IBT #8530-10435, 5/16/77, submitted by Ciba-Geigy on 6/2/77)

0.5 ml of the undiluted test material was applied to one abraded and one intact skin site of 6 New Zealand albino rabbits and held in contact with the skin under an impervious cuff for 24 hours. Dermal irritation was scored at 24 and 72 hours by the method of Draize.

Results

P.I.=7.2/8.0

TOX CATEGORY:I

Classification: Core-Minimum Data

- 1) readings were not made on 2 intact and 2 abraded skin sites.

6. Primary Skin Irritation of AA trex 4L

-(Industrial Bio-Test, IBT #8530-10435, 5/16/77, submitted by Ciba-Geigy on 6/2/77)

0.5 ml of the undiluted test material was applied to one abraded and one intact skin site of 6 New Zealand albino rabbits and held in contact with the skin under an impervious cuff for 24 hours. Dermal irritation was scored at 24 and 72 hours by the method of Draize.

Results

P.I.=2.1/8.0

TOX CATEGORY:III

Classification: Core-Minimum Data

- 1) readings were not made on 2 intact and 2 abraded skin sites.

At this point in time, the studies are deemed to be acceptable for registration purposes.

William Greear