

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

OCT 08 1980

MEMORANDUM

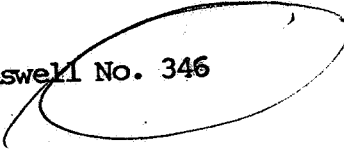
DATE: June 9, 1980

SUBJECT: Zone-3 Way Lotion (AI-1002-2) EPA File Symbol 43659-R Caswell No. 346

FROM: Carlos A. Rodriguez
Toxicology Branch/HED (TS-769)

Carlos A. Rodriguez
6/10/80.

Q 7/15/80
WLB



TO: Franklyn D.R. Gee PM 17
RD (TS-767)

Registrant: Avant, Inc.

Laboratory: Biosearch, Inc.
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Toxicology Data Review

1. Acute Oral Toxicity in Rats using Zone-3 Way Lotion (AI-1002-2),
(Project No. 80-1885A, Biosearch, Inc. submitted by Avant, Inc,
Study completed 2/7/80).

10 Albino rats (5 male and 5 female) of the Sherman Wistar Strain weighing between 200 and 300 gms. were used per dosage level of 5.0 gm/kg of the test material administered into the stomach by means of a syringe and dosing needle. The animals were observed following dosing and over a subsequent fourteen day observation period for signs of toxicity and mortalities.

Results: LD50 = >5.0 gm/kg

Toxic signs: non-toxic, no deaths

Toxicity Category: IV

Classification: Core-Minimum Study

2. Primary Skin Irritation Study (Rabbits) using Zone-3 Way Lotion (AI-1001-2), (Project No. 80-1885 A, Biosearch, Inc. Labs. submitted by Avant, Inc, Study Completed: 1/25/80).

0.5 gm of the test material was applied to the intact and abraded skin of 6 albino rabbits. Gauze patches were then placed over the treated areas and an impervious material was wrapped around the trunks of the animals to hold the patches in place. After 24 hours the wrapping was removed and the treated areas were examined for signs of irritation. Readings were also made after 72 hours. The Draize Method of Scoring was employed.

Results

Primary Irritation Index = 0.59. The sample is not a primary skin irritant.

Toxicity Category: IV

Classification: Core-Minimum Study

3. Primary Eye Irritation Study (Rabbits) with Zone-3 Way Lotion (AI-1002-2), (Project No. 80-1885 A, Biosearch, Inc. Labs., submitted by Avant, Inc, Study Completed: 2/5/80).

0.1 gm of the test material was instilled into the conjunctival sac of the right eye of each of 9 New Zealand White Rabbits weighing between 2.3 and 3.0 kg. The first 6 rabbits did not have their eyes washed subsequent to instillation. The remaining 3 rabbits had their treated eyes washed after 30 seconds with 300 ml of water. Observation of ocular lesions were made on the rabbits eyes at one, two, three, five, seven and fourteen days. Draize technique for scoring ocular lesions was used.

Results: Unwashed eyes

Corneal Opacity

- Grade (1) in 1/6 animals at 24 hours.
- Grade (1) in 3/6 animals at 48 hours.
- Grade (1) in 3/6 animals at 72 hours.
- Grade (1) in 3/6 animals at 7 days.
- Grade (2) in 1/6 animals at 7 days.
- Grade (1) in 1/6 animals at 14 days.

Iris Readings

Grade (1) in 1/6 animals at 24 hours and 48 hours.
Grade (1) in 3/6 animals at 72 hours.
Grade (1) in 4/6 animals at 7 days.
Grade (1) in 1/6 animals at 14 days.

Conjunctival Readings

Conjunctival irritation persisted in 2/6 animals at 14 days. The irritation was diminished.

Toxicity Category: I

Classification: Core-Minimum Study

Washed Eyes:

No corneal or iris irritation developed during the study. Conjunctival irritation persisted in 2/3 animals (Grade 1) at 72 hours. No irritation was seen in any of the animals by day five observation period.

Toxicity Category: III

Classification: Core-Minimum Study

4. Acute Dermal Toxicity (Rabbits) using Zone-3 Way Lotion (AT-1002-2), Project No. 80-1885 A, Biosearch, Inc. Lab., submitted by Avant, Inc. Study completed 2/7/80).

10 albino rabbits (5 male and 5 female) weighing between 2.0 and 3.0 kg each were employed in this study. All animals had their backs clipped free of hair 24 hours prior to testing. All the animals had epidermal abrasions made. All rabbits were weighed, and 2.0 gm/kg of the experimental sample was applied to the back of each animal. The treated areas were covered with large gauze patches and an impervious material was wrapped around the trunk of each animal. After 24 hours the dressings were removed and any excess of material clean and the skin reactions noted. The animals

were observed for 14 days for signs of toxicity and mortality. Gross autopsies were performed on all animals which died during the 14-day observation period and also on all survivors of the 14 day observation period.

Results:

LD50 = >2.0 g/kg.

Autopsy = revealed nothing remarkable

Toxic Signs = no unusual behavioral signs

Toxic Category: IV

Classification: Core-Minimum Study

5. Guinea Pig Contact Dermal Irritation/Sensitization using Zone-3 Way Lotion (AI-1002-2), (Project No. 80-1885 A, Biosearch, Inc. Labs., Study Completed 2/27/80).

10 albino guinea pigs weighing between 300 and 400 gms were employed in this study. A 0.5 gm of the test material was applied to the intact skin test sites. A gauze patch was placed over the treated area and an impervious material was wrapped around the trunk of the animal to hold the patch in place. After 24 hour contact period the patch was removed and the animals were allowed to rest for one day. Following the rest period another application was applied to the same skin site using a fresh sample. This sequence was repeated for a total of 10 times. After the tenth application the animals were rested for a two week period. After termination of the rest period a challenge application was put on skin sites differing from the original test sites. The challenges application remained on for 24 hours. Twenty-four hours after each induction stage application and twenty-four and forty-eight hours after challenge application, the sites were examined for signs of irritation and sensitization using the Draize method of scoring.

Results

The test material when studied in the albino guinea pig does not appear to be a primary skin irritant, fatiguing or sensitizing agent.

Classification: Core-Minimum Study.

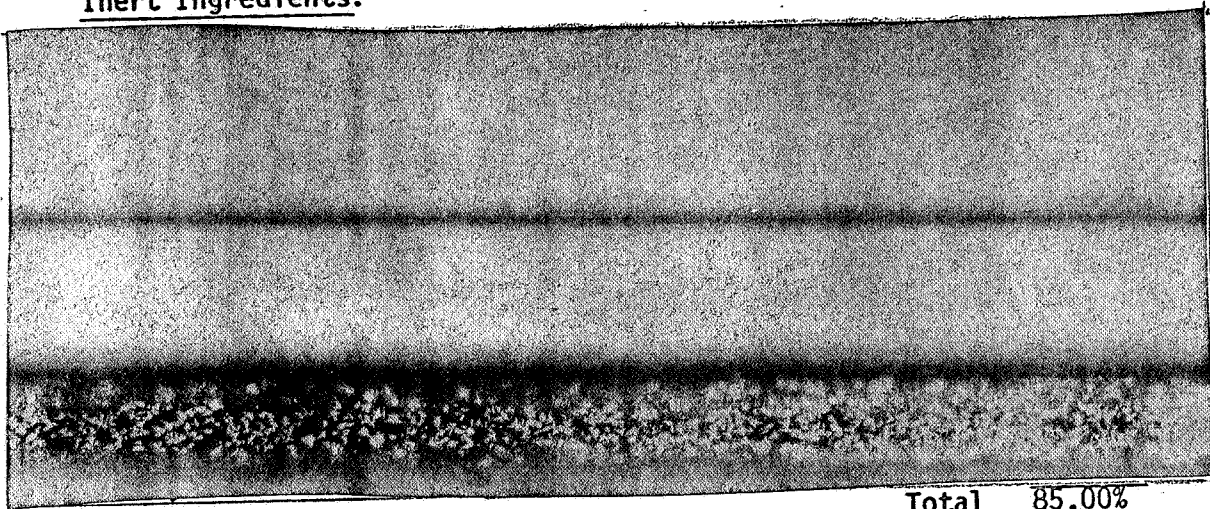
6. Compostion of Zone-3 Way Lotion

Active Ingredients:

N, N-diethyl-m-toluamide-----15.00%
and other isomers

Total 15.00%

Inert Ingredients:



Total 85.00%

7. Signal word required for this product is "Danger".

μ