1/17/79

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

003285

DATE: January 17, 1979

SUBJECT: Sergeant's Flea and Tick Collar for Cats; Sergeant's Flea and Tick Collar for Dogs. EPA Registration#778-UE, 778-UR. Caswell#586, 508

FROM: William Dykstra, Ph.D
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TO: Mr. Mautz (Team 16)
RD, TS-767

Action Type: Resubmission with Data

Recommendations:

1. The toxicology studies are acceptable as Core Minimum Data and support the registration. No additional studies are required for registration.

*No RPAR criteria were exceeded.

Review:

1. Memo of 10/31/78 from W. Dykstra to William Miller.

2. The skin sensitization Potential of Naled Technical in Guinea Pigs (Socal 1293/35:28, Nov. 15, 1978) Accession No. 236683 (EPA Reg.#239-1633).

Test Material: Naled Technical code SX820, positive control: DNCB

Two studies were performed with guinea pigs. Initially 15 guinea pigs each were treated with 0.5 ml of a 3.0% solution of Naled Technical in acetone and 10 guinea pigs each were treated with 0.5 ml of 0.03% solution of DNCB in acetone. The animals were treated 10 times over a 22 day period. The material was applied as a patch for 6 hours to the right side of the animal which had been previously clipped and lightly abraded with fine sandpaper. Skin irritation was scored after the first, sixth, and ninth applications using a modification of the scoring system of Draize. Fourteen days after the last application, the animals were challenged by applying 0.5 ml of the respective test material to the left side of each animal and wrapping the treated area as previously described.
After 24 hours the irritation reaction was scored. In the 2nd study, using the method described above, the study was repeated using 25 guinea pigs treated with Naled Technical and 20 guinea pigs treated with DNCB. During the second study the irritation was scored 24 hours after the first and just prior to the fourth, seventh and tenth applications. The animals were rechallenged on the same site six days after the first challenge. The initial and challenge test were compared statistically.

Results:

1st Study: Five of the 14 surviving animals treated with Naled Technical had challenge reactions which were more intense than their initial reaction. This difference in response was not statistically significant for the group; however, it did represent a weak positive response for a few animals. Seven of the 10 animals treated with DNCB had challenge reactions larger than their initial reaction. This difference in response was statistically significant for the group and was considered a positive reponse.

2nd Study: Only three of the 23 surviving animals treated with Naled Technical has responses from the first challenge which were noticeably larger than their initial treatment. This difference in response for the group was not statistically significant, however it represents an extremely weak positive response by three animals. Eleven of these animals had larger responses than their initial response from the second challenge. This difference in response is significantly different from the initial response, but it is not known if this latter increase represents a positive sensitization response or an increase in irritation. Due to the second application, 12 of the 18 surviving animals treated with DNCB responded to both the first and 2nd challenges. The response for DNCB in both challenges was statistically significantly larger than the initial response and was considered positive.

Conclusion: Naled Technical produced a very weak positive response in the sensitization studies.

Classification: Core-Minimum Data

3. The Evaluation of Dibrom as a potential Neurotoxic Agent following Oral Administration to Hens Protected by Atropine Sulfate (FDRL No. 5981, Nov. 14, 1978) Accession#236682 (EPA Reg.#239-1633)

Test Material: Dibrom Technical; SX820; positive control : TOCP

The test material was administered to five birds per level orally (1 ml/kg) at 0.2 log intervals between 25 and 159 mg/kg. Prophylaxis with atropine sulfate provided minimal protection to the birds. LD_{50} was calculated to be 110 mg/kg.

A second lot of twenty adult hens received the LD_{50} (117 mg/kg) in corn oil and were atropinized. Twelve positive control birds received TOCP (370 ppm) in corn oil. Twelve birds were administered corn oil (vehicle control). Observation for 22 days. Gross and histological examination.

Results: The TOCP birds displayed delayed neurotoxic signs (ataxia) and showed positive demyelination at histologic examination. Technical Dibrom treated birds showed signs of acute toxicity but no symptoms of delayed neurotoxicity. No significant differences were seen between vehicle control and Dibrom treated birds in general observations, body weight, food consumption,

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neurologic evaluation scores, gross and histological examination of spinal cords.

Conclusion: Dibrom is not a delayed neurotoxic agent.

Classification: Core-Minimum Data

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