1-20-84

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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Caseno 2070 38AAA

TO: Timothy Gardner
Product Manager, No. 17
Registration Division, TS-767C

THRU: Roger Gardner R.G. 1-20-84
Toxicology Branch
Hazard Evaluation Division TS-769C

SUBJECT: EPA Reg. No. 2724-288. Altosid; Dermal seneitization.

Registrant: Zoecon Industries, Dallas, Texas 75234

Action Requested:

Review and evaluation of dermal sensitization study with Zoecon RF-179 Methoprene Concentrate.

Conclusions and Recommendations:

Toxicology Branch can not evaluate the dermal sensitization potential of the test article without the following information:

a) Details of the experimental protocol, including the number of animals in each test group.

b) Individual animal scores (tabulated) including the preliminary dermal irritation phase of the experiment and the dermal sensitization phase.

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Data Evaluation

Dermal Sensitization

Test Substance: Methoprene Concentrate RF-175, Lot No. F-203-178-1.

Testing Laboratory: UBTL Division, University of Utah Research Institute, Salt Lake City, Utah.

Experimental Protocol:

According to the author, the protocol was based on the proposed health effects test standards for the Toxic Substance Substances Control Act (TSCA), Federal Register, Vol. 44, July 26, 1979, with modifications based on methods described by Ritz and Beuhler " Current Concepts in Cutaneous Toxicity", pp. 25-40, 1980.

Thirty-two young adult Hartley albino guinea pig males weighing 218.8 to 301.0 g were acclimated for 14 days. A strip of hair was clipped off the back on each side of the dorsal midline, about 24 hours before treatment. For the dose selection (irritation) study, four animals were treated with 0.5 ml aliquots of the concentrated material (undiluted), and dilutions 1:2, 1:4 and 1:8 in mineral oil. The material was applied in webril pads placed on the shaved area. The pads were held in place using a strip of hypoallergenic tape, a plastic barrier and elastic wrap. The wraping was removed and the skin was wiped clean after 6 hours. Twenty-four hours after the treatment, the animal skin was depilated with Neet, and after two more hours it was scored by the Draize method. Since the maximum nonirritating concentration was the 1:2 dilution, therefore, this concentration was selected to be used.

The test article or the positive control were then applied for 6 hours, once a week for three weeks on the same site for the induction phase of the experiment and on a different site for the challenge phase. The positive control was 0.3% of dinitrochlorobenzene (DNCB) in 80% ethanol. The challenge phase took place fourteen days after the last induction treatment. For the challenge phase, the designated sites were clipped free of hair 24 hours before the application of 0.5 ml of the maximal nonirritating

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concentration of the test article as previously described, and the patches were secured. The positive control was applied as 0.2% solution in acetone in the same manner. The patches were removed six hours after exposure, and 24 hours later the skin was depilated with Neet around the application site. The challenge sites were examined and scored according to Draize for erythema and edema two hours after depilation and forty-eight hours after application.

Results:

No data were provided on the skin irritation phase of this study. However, the author stated that skin irritation score of 0.0 to 0.9 was considered to be nonirritating. In addition, individual animal scoring for the dermal sensitization phase of this experiment were not reported.

10/13/83

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