6-13-84

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

003852

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Baygon (Propoxur); Dermal Sensitization in Guinea Pigs

TO: Jay Ellenberger (PM-12
Registration Division (TS-767)

FROM: Robert P. Zendzian Ph. D. 6/13/84
Toxicology Branch
HED (TS-769)

THROUGH: William Butler, Head William H. Butler 6-14-84
Review Section III

William Burnam, Chief
Toxicology Branch

Compound Baygon (propoxur)

Registration #3125-174

Tox Chem #508

Registrant Mobay

Action Requested

The registrant has submitted a dermal sensitization study of propoxur in the guinea pig for review.

Toxocology Branch Response

The study is not acceptable and has been classified invalid. The methodology appears unique to the laboratory as it is not referenced to any source and therefore cannot be validated for specificity and sensitivity. In order to have such a protocol accepted a positive control MUST be included.

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Data Evaluation Report

Compound Propoxur (Baygon®) 003852

Citation

Propoxur (The Active Ingredient of Baygon® and Unden®) Study of Sensitization Effect on Guinea Pigs. K.G. Heimann, Bayer AG, Institut fuer Toxicologie, Study No T 8011718 Oct 15, 1982

Reviewed by [signature] 6/8/84
Robert P. Zendian PhD
Pharmacologist

Core Classification Invalid

Tox Catagory cannot be determined

Conclusion

The methodology appears unique to the laboratory as it is not referenced to any source and therefore cannot be validated for specificity and sensitivity. In order to have such a protocol accepted a positive control MUST be included.

Materials

Propoxur, 2-(1-Methylethoxy)pherol methylcarbamate BOQ 5812315; Batch No. 234; Purity 98.8%

Male guinea pigs, Pirbright White W 58 form Winkelmann

Methods

Animals were assigned randomly to a control and a treatment group of 15 animals each. The dermal area was clipped and remaining hair removed with a diplatory cream. After 24 hours each animal received 6 intradermal injections in pairs down the line of the back. Test animals were dosed as follows;

1st Injection Pair (head)
Freund's complete adjuvant, 1:1 in water.

2nd Injection pair (middle)
1% propoxur formulated with polyethylene glycol 400

3rd Injection pair (tail)
1% propoxur formulated with equal parts polyethylene glycol 400 and Freund's complete adjuvant, 1:1 in water.

The control group was dosed identically except that sites 2 and 3 did not receive propoxur.

Six days later the application sites were depilated and the site massaged with 10% sodium laural sulfate in vaseline. Twenty-four hours later filter paper saturated with either 2.5%

propoxur formulated with polyethylene glycol 400 (test group) or the vehicle (control group) was applied to the injection sites for 24 hours, secured by an elastic adhesive bandage.

Three weeks after the intradermal injection all animals were challenged for 24 hours with a filter paper saturated with 1.2% propoxur formulation applied to the left site sites and a vehicle saturated filter paper applied to the right hand sites.

Twenty-four and 48 hours after removal of the challenge material the sites were examined and scored for reaction.

Results

No reactions were observed in the test group and one reaction in the control group.