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

AUG 16 1989

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Sodium Bromide - Acute Dermal Sensitization - Data Submitted Under MRID No. 41019601
EPA ID No. 8622-UL

TOX Chem No.: 750A
TB Project No.: 9-1043
RD Record No.: 241424

FROM: Irving Mauer, Ph.D., Geneticist
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THRU: Edwin Budd, Acting Chief 8/15/89
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

Registrant: Ameribrom, Inc.
New York City, NY

Request

Review and evaluate the following toxicology study:

Delayed Contact Hypersensitivity in the Guinea Pig with Sodium Bromide Technical Grade, performed for the registrant at the Huntingdon Research Center (HRC), Cambridgeshire (UK), HRC Report No. 881235D/DSB-30SS, issued October 20, 1988 (EPA MRID No. 41019601).

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TB Conclusions

The study is graded CORE-GUIDELINE DATA, demonstrating sodium bromide technical is not a sensitizer when assayed in the Magnusson-Kligman maximization guinea pig test.

Attachment

Reviewed By: Irving Mauer, Ph.D., Geneticist
Section I - Toxicology Branch I - IRS (H7509C)
Secondary Reviewer: Edwin Budd, Acting Chief
Toxicology Branch I - IRS (H7509C)

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DATA EVALUATION REPORT

I. SUMMARY

MRID No.: 410196-01
ID No.: 8622-UL
RD Record No.: 41424
Shaughnessy No.: 013907
Caswell No.: 750 A
Project No.: 9-1043

Study Type: (81-6) Dermal Sensitization - Guinea Pig

Chemical: Sodium Bromide

Sponsor: Ameribrom, Inc.
New York, NY

Testing Facility: Huntingdon Research Center (HRC)
Cambridgeshire (UK)

Title of Report: Delayed Contact Hypersensitivity in the Guinea Pig with Sodium Bromide Technical Grade.

Authors: S.R. Kynoch and B.I. Parcell

Study Number: HRC Report No. 881235D/DSB-30SS

Date of Issue: October 20, 1988

TB Conclusions:

Not a sensitizer when tested by the Magnusson-Kligman maximization test (30% induction followed by 5 to 10% challenge).

Classification (Core-Grade): CORE-GUIDELINE DATA

II. DETAILED REVIEW

A. Test Material - Sodium Bromide (Technical)

Description: White powder
Batch (Lot): 7320
Purity (%): 99.23
Solvent/carrier/diluent: Distilled water (DW)

B. Test Organisms - Rodent

Species: Guinea pig
Strain: Hartley/Dunkin
Age: (Not stated)
Weights - Males: (Not employed)
Females: (305 to 374 g)
Source: D. Hall, Newchurch, Staffordshire (UK)

C. Study Design (Protocol) - This study was designed to assess the sensitization potential of sodium bromide when administered dermally to guinea pigs challenged 1 week after an initial acute sensitization. The procedure was stated to conform to the Agency's Pesticide Assessment Guidelines Reference No. 81-6 (November 1982).

A signed Statement of Confidentiality Claim was provided.

A signed Statement of Compliance with EPA GLPs was provided.

A signed Quality Assurance Statement was provided.

D. Procedures/Methods of Analysis - After 5 days' acclimation and preliminary investigations of concentrations suitable for induction and challenge, one group of 20 female guinea pigs was subjected to Magnusson and Kligman's maximization test as follows:

1. Induction Phase - Test substance (75% w/w) in DW or Freund's Adjuvant was injected intradermally into the scapular region of the dorsum clipped free of hair. After 1 week, the same area was clipped and shaved, a patch of filter paper saturated with test substance (30% w/w) applied and secured under adhesive tape and elastic bandage, and left in place for 48 hours.

A group of 20 control females were induced similarly except for the omission of test substance (only DW employed).

2. Challenge Phase - Two weeks after induction, saturated paper patches of test substance (5% and 10% w/w, in DW) were affixed with adhesive tape to the shaved anterior flank (10%) and posterior flank (5%) of each animal in both groups, and left in place for 24 hours. Challenge sites were assessed for skin reactions 24, 48, and 72 hours after removal of patches, according to the following scales provided by the investigators:

"Erythema and eschar formation:

"No erythema 0
Slight erythema (barely perceptible) 1
Well-defined erythema 2
Moderate erythema 3
Severe erythema (beet redness) to slight eschar formation (injuries in depth) 4

"Oedema formation:

"No oedema 0
Slight oedema (barely perceptible) 1
Well-defined oedema (edges of area well-defined by definite raising) 2
Moderate oedema (raised approximately 1 millimetre) 3
Severe oedema (raised more than 1 millimetre and extending beyond the area of exposure) . . . 4"

E. Results - Dermal reactions elicited by the challenge application of sodium bromide were similar in both test and control groups, only 4 of 20 test animals showing slight localized erythema (Grade L1) only at the 24-hour sampling time, compared to 3 of 20 controls (Report Table 1, attached to this DER).

This was in contrast to the results of seven previous assays with formalin (a known sensitizer) in which positive reactions were recorded in the majority (85%) of challenged animals of the same strain as presented in Appendix 3 of the Final Report.

Hence, the authors concluded that technical sodium bromide did not produce evidence of delayed contact hypersensitivity in this assay.

Group body weight gain in test animals was slightly (but not significantly) less than that in controls during the 3-week test period, as calculated below from individual body weights presented as Report Appendix 2.

Group	Mean Body Weights (g)		Bwt Gain (g)
	Start	End	
Control	317.85	506.45	188.60
Test	337.50	492.35	154.85

TB Evaluation - CORE-GUIDELINE DATA

The study was performed in literal accordance with FIFRA Test Guidelines Reference No. 81-6, and we judge the results as reported to validly represent the demonstration that technical sodium bromide was not a sensitizer when assayed by the Magnusson-Kligman guinea pig maximization test.

Attachments

Sodium bromide toxicology review

Page _____ is not included in this copy.

Pages 7 through 10 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

X FIFRA registration data

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