011542

GUIDELINE 81-5

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DATA EVALUATION REPORT III

STUDY TYPE: Primary Dermal Irritation in Rabbits

PC CODE: 014503 TRID NO.: 400242-01

TEST MATERIAL: Aquatreat DN-30

SYNONYMS: Nabam (approximately 30%, in aqueous solution)

STUDY NUMBER: 86-5349A

SPONSOR: Alco Chemical
909 Mueller Drive
Chattanooga, Tennessee 37406

TESTING FACILITY: Biosearch Inc.
P.O. Box 8598
Philadelphia, PA 19101

TITLE OF REPORT: Primary Skin Irritation - Rabbits

AUTHOR: Costello, B.

REPORT DATED: October 31, 1986

EXECUTIVE SUMMARY: There was no dermal irritation (all scores 0 for erythema/eschar and for edema) at 4, 24, 48 and 72 hour readings following 4-hour occluded exposure to 0.5 ml of the test material. The PDIS (average of 24 and 72-hr scores) was equal to 0.00.

TOXICITY CATEGORY: IV

CLASSIFICATION: Acceptable. The study adequately defines a toxicity category IV classification (signal word: CAUTION) for technical Nabam (Aquatreat DN-30, 30% Nabam in aqueous solution) in terms of its primary dermal irritation potential. This study can be used as supporting data (Guideline 81-5) for the registration and/or reregistration of products consisting of or containing technical Nabam (Aquatreat DN-30, 30% Nabam in aqueous solution) as an active ingredient.

PRIMARY DERMAL IRRITATION IN RABBITS

III-2

A. MATERIALS:

1. Test Material: (from p. 2) Aquatreat DN-30
   Description: Yellow liquid
   Lot number: 48180
   Purity: not reported
   Stability: not reported
   Contaminants: not reported
   Other information: The test article was received 10/15/86 and the study was initiated 10/28/86.

2. Test animals: Species: rabbit; Strain: New Zealand white; obtained from Buckshire Corp., Perkasie, PA.

B. STUDY DESIGN:

1. Animal assignment and preparation:

   From p. 5: "A group of six rabbits was clipped over a wide area on their backs approximately 24 hours prior to the application. Animals with healthy intact skin were used."

2. Dosage:

   "A 0.5 ml portion of the Test Article was applied to the test site. Adjacent areas of untreated skin served as a control for the test. Gauze patches were placed over the treated and control areas, which were then held in place with non-irritating tape. A suitable semi-occlusive dressing was wrapped around the trunks of the animals to hold the patches in place."

   "The wrapping was removed at the end of the four hour skin contact period and the test sites were washed with deionized water."

3. Compliance:

   On page 3 there is a signed and dated Good Laboratory Practice Compliance Statement.

C. METHODS AND RESULTS:

1. Observations:

The treated areas were examined and scored for edema and erythema. using the scoring method of Draize. within 30 to 60 minutes of patch removal and also after 24, 48 and 72 hours.

Results: Refer to appended page 1 for the Primary Skin Irritation scores. The PDIS (average of 24 and 72-hour scores) = 0.00.

D. DISCUSSION:

There was no indication of any irritation (all scores =0). The PDIS (average of 24 and 72-hr scores) was 0.00. The study adequately defines a toxicity category IV classification (signal word: CAUTION) for technical Nabam (Aquatreat DN-30, 30% Nabam in aqueous solution) in terms of its primary dermal irritation potential. This study can be used as supporting data (Guideline 81-5) for the registration and/or reregistration of products consisting of or containing technical Nabam (Aquatreat DN-30, 30% Nabam in aqueous solution) as an active ingredient.

Nathan Revised

Page 4 is not included in this copy.

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_____ Identity of the source of product ingredients.

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