

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

MEMORANDUM

JUN 30 1983

TO: Mr. Willie Nelson (17)
Registration Division (TS-767)

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA Reg.#45167-R. Margosine-0 (Neem Extract), application
for registration as an anti-feedant extract.
CASWELL#594A

Registrant: Vikwood Ltd.
1221A Superior Ave.
Sheboygan, WI 53801

Action Requested:

Mr. Robert Larson of Vikwood Ltd., requests registration for MARGOSINE-0, an extract prepared from Indian Neem tree nuts, reported to act as an anti-feedant to control Lepidopetrous insects.

Recommendations: (No toxicity data accompanied the present application.)

1) At a February 19, 1982 meeting between Mr. Robert Larson (Vikwood Ltd., President) and EPA personnel, Mr. Larson was informed regarding toxicity test requirements for MARGOSINE-0, considered as a biorational biochemical. A list of the tox. test requirements for the Neem extract is reiterated below:

A. Studies required prior to registration

- An acute oral study
- An acute dermal study
- An acute inhalation study
- An eye irritation study
- A dermal irritation study
- A cellular immune response study

B. Studies required on a conditional basis

- A hypersensitivity study
- A genotoxicity study (Ames test)

NUMBER 11

2) In addition to a lack of toxicity data, a number of deficiencies in the product application are apparent:

- a. If food crop use is intended specific food tolerances will be required, or a request for an exemption from the requirement for tolerances must be made.
- b. The Confidential Statement of Formula should be corrected to include the active ingredient(s), as well as inert ingredients.
- c. The registrant should define to the extent possible the chemical and physical properties and the molecular structure of the active ingredient(s), if this information can be developed.
- d. The product label at present states "MARGOSINE-0 a non-toxic anti-feedant extract". The registrant should be more specific regarding pest control intent; if the product target pests are Lepidopterous insects, the label should so state.
- e. A final decision on the choice of label signal word and precautionary statements will be made following receipt and evaluation of the requested toxicity data.

3) Further consideration of MARGOSINE-0 used as a pesticide anti-feedant extract will be given upon receipt of the toxicity data and information cited above.

William S. Woodrow J.M. for *WDE*
William S. Woodrow, Ph.D.
Toxicology Branch/HED (TS-769) *6/27/83*
W. S. Woodrow
6/30/83