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: Approval of a sample Ames test protocol to be used for mutagenicity screening evaluation of Neem Extract.
CAS. # 594A

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

Action Requested:

Vikwood Ltd. submitted an Ames test conducted by Product Safety Labs., New Brunswick, N.J., for approval by Toxicology Branch of the test protocol used to perform the Ames test.

Recommendations:

1. The sample Ames test protocol submitted for approval would be considered incomplete:

a) The tests should have been repeated.

b) Evidence that attempts were made to ensure that the highest product concentrations used induced some toxicity to the test organisms should have been included.

c) The solvent used to solubilize or dilute the test article, and a non-solvent negative control, or other indication that the test organism genetic integrity was adequate should have been employed.

2. The following list of criteria should be incorporated into each Ames study.

Replication _ All tests should be repeated at least once for reproducible determinations of response.

Number and range of dose levels - A suitable range of concentrations should be used, including at least three concentrations such that the lowest produces no effect (insignificant difference from control) and the highest induces some toxicity (if possible) to the test organisms.

For substances showing positive results, it is necessary to obtain reproducible dose-response curves in a narrow range of doses, if this is possible.

Positive control groups - Concurrent positive control substances should be selected for each test, in order to assure both the sensitivity of the indicator organisms and the function of the metabolic activation system.

Negative control groups - Concurrent negative controls should include the solvent, and, in addition, the test should include either a concurrent non-solvent negative control or a historical documentation for maintenance of genetic integrity of the indicator organisms.

3. The attached "Salmonella typhimurium Reverse Mutation Assay" (Ames test) is provided to serve as a test protocol.

William S. Woodrow for LDC 6/27/83

William S. Woodrow, Ph.D.
Toxicology Branch/HED (TS-769)

Attachment

6/30/83

TS-769:th:TOX/HED:WSWoodrow:6-22-83:card #9