

SHAUGHNESSEY NO.

EEB BRANCH REVIEW

DATE: IN 1-10-84 OUT 1-16-84

FILE OR REG. NO. 45167-R

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 10-5-83

DATE RECEIVED BY HED 1-6-84

RD REQUESTED COMPLETION DATE 3-1-84

EEB ESTIMATED COMPLETION DATE 2/6/84

RD ACTION CODE/TYPE OF REVIEW 161/Old Chemical

TYPE PRODUCT(S): I, D, H, F, N, R, S Biological

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. T. Gardner (17)

PRODUCT NAME(S) Margosan-O

COMPANY NAME Vikwood Ltd.

SUBMISSION PURPOSE Proposed full registration of lettuce, corn, potato,
tomato, cabbage, spinach, and chrysanthemum uses

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
	Azadirachtin	.3%

1-16-84 REVIEW

EEB REVIEW

PESTICIDE NAME

Azadirachtin

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

Proposed full registration of lettuce, corn, potato, tomato, cabbage, spinach, and chrysanthemum uses.

100.2 Formulation Information

(from label submitted under Acc. No. 252097 Sect. V)

Active ingredients:

Azadirachtin.....	.3%
Inert ingredient	99.7%
Total	100.0%

100.3 Application Methods, Directions, Rates

(from label submitted under Acc. No. 252097 Section V)

"DIRECTIONS FOR USE

Dilute Margosan-O with 150 parts clean water to get .2% concentration.

Consult the Technical Bulletin attached for modifications to this percentage.

Use only clear well-washed sprayer and store unused mixture in a cool dark place. Spray plant or tree leaves to a "wet" condition weekly or as indicated in the Technical Bulletin."

"PESTS: The following pests have shown great vulnerability to Margosan-O: Gypsy moth larvae, Leafminer (*Liriomyza trifolii*), Beet armyworm, Cabbage looper, Corn earworm, Fall armyworm, Colorado potato beetle, Bertha armyworm, Diamond back moth, Desert locust and Alfalfa looper.

100.4 Target Organisms

(see labeling under 100.3)

100.5 Precautionary Labeling

The label did not bear an Environmental Hazard block. However, "Precautionary Statements:" and "Cautionary Word: "contained statements of protecting nontarget species.

"PRECAUTIONARY STATEMENTS"

—"Margosan-O diluted to a stronger concentration than .2% (150 x water) may have some harmful effect on birds or fish."

CAUTIONARY WORD: Some plants may exhibit phytotoxicity when Margosan-O is applied topically therefore, various strength solutions should be used as root irrigant for a systemic uptake in these instances."

101 Hazard Assessment

101.1 Discussion

Azadirachtin is a chemical obtained through from the seeds of a tree. The company, Vikwood Ltd., provided the following historical background:

"The Neem seed of the Indian tree named Azadirachta indica, an indigenous species of India and other tropical regions of that area, as well as Africa, yields a natural product whose essence repels insects by smell or taste, and also acts as a growth modifier by inducing hormonal change in various insects in their larval stages.

For centuries people in India have stored their food grains in the home in complete freedom from pest infestation by the simple addition of either whole or chopped Neem seed which results in a repellancy factor to most insects. Since it is either impractical or impossible to remove all the Neem seeds from the grains, they are cooked along with the food and no toxic effects have ever been noted.

For over sixteen years the Neem seed has been under study in various areas of the world resulting in the first annual Neem Conference held in Germany in 1981. In the U.S.A. the work of the USDA group in Beltsville, Maryland has been going on for seven years, and the efforts of that group were presented at the Neem Conference by Martin Jacobson, biochemist, in 1981 as well as in 1983. He presented his own work along with the contributions of Doctors Warthen and Uebel of USDA Beltsville. He also mentioned the current state of testing Margosan-O since Vikwood Ltd. has been in active collaboration with the USDA for over two years.

On learning of the efficacy of the Neem seed extract, and as a result of regular trading with people in India, Vikwood Ltd. Began to exchange data on pest studies and exchange formulations finally resulting in Margosan-O being offered at no charge to designated research stations of the USDA around the country on various insects."

The Margosan-O label (see Appendix I) did not provide sufficient information to estimate the concentration on animal food items, soil, or water. Rather than give directions in weight limits of product or active ingredient, per area such as, lbs/A, it provided the following instruction:

"Spray plant or tree leaves to a 'wet' condition weekly or as indicated in the Technical Bulletin.":

The Technical Bulletin was not provided. Also, the weight of product in a 1 pint container was not included, and the "ENVIRONMENTAL HAZARDS" section was not on the label.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Exposure of wild animals to azadirachtin is impossible to calculate with the available information. As reported in the above section, the label did not provide:

1. Weight of product or active ingredient to apply to crop per area
2. Technical Bulletin
3. Weight of product per volume..
4. "ENVIRONMENTAL HAZARDS" section

In addition to those items the Confidential Statement of Formula failed to give the specific gravity or pounds per gallons. Also, Accession No. 252097, received 1-4-84 indicates in the Table of Contents, Section I Chemical, A. Chemical and physical properties. This subsection A did not contain Molecular Weight, Solubility in water, DMSO, acetone, etc., Octanol/Water Partition Coefficient, Soil Adsorption Coefficient Kd, Vapor Pressure, Soil Half-life. Half-life in water, uptake by plants, or bioaccumulation in animals. The only document in this subsection was a Margosan-O label which does not bear the same statements as label under Section V Label.

Since the submitted birds studies are only sufficient up to certain levels, an EEC is necessary to complete an aquatic evaluation. The hazard assessment can not be completed at this time.

101.3 Endangered Species Consideration

Deferred until the product chemistry, environmental fate, labeling, and Technical Bulletin information is available.

101.4 Adequacy of Toxicity Data

As per Douglas Urban memo of Feb. 8, 1983, concerning the aquatic data, ".... a statement from the registrant concerning the percentage active ingredient in the technical grade of the active ingredient."....is needed to support the "Core" status or ability for these studies to meet the guideline requirements.

101.5 Adequacy of Labeling

The labeling did not include the following items:

1. Weight of product or active ingredient to apply to crop per area.
2. Weight of active ingredient per volume, in this case, 1 pint.
3. ENVIRONMENTAL HAZARDS section.

This preliminary review indicates at a minimum the following statements should be included in the ENVIRONMENTAL HAZARDS section:

1. "This pesticide (or product) is toxic to aquatic invertebrates."
2. "Do not contaminate water by cleaning of equipment or disposal of wastes."
3. "Do not apply directly to water or wetlands."

In light of the information requested in the previous section additional statements may be required, though, this is not anticipated at this time.

102 Classification

Deferred until requested information is available.

103 Conclusions

EEB has reviewed the proposed registration of azadirachtin for use on lettuce corn, potatoes, tomatoes, cabbage, spinach and chrysanthemums. EEB is unable to complete a full risk assessment (3(c)(5) finding) for this use because pertinent environmental chemistry and labeling information are lacking. In order to complete this assessment, EEB requires the following data:

1. Molecular Weight
2. Solubility and Temperature in water, DMSO, acetone, propylene glycol, etc.
3. Octanol/Water Partition Coefficient
4. Soil Adsorption Coefficient, Kd.
5. Vapor Pressure
6. Half-life in Soil and Water
7. Uptake by plants
8. Bioaccumulation in animals
9. Weight of product or active ingredient to apply to crop per area.
10. Weight of product or active per volume, in this case, 1 pint
11. A statement clarifying the percentage of active ingredient for the technical grade product.

Note to RM: It is EEB understanding that a Shaughnessey No. (S#) has not been assigned for azadirachtin. Please, notify EEB when a S# is available.

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Date: 1-17-84

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