EE BRANCH REVIEW

IN 11/15/79 OUT 3/17/80

FILE OR REG. NO. 100-ANT

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 10/31/79

DATE OF SUBMISSION

DATE SUBMISSION ACCEPTED

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

DATA ACCESSION NO(S).

PRODUCT MGR. NO. 21 - Jacoby

PRODUCT NAME(S) Ridomil 2E Fungicide

COMPANY NAME CIBA - GEIGY

SUBMISSION PURPOSE Conditional registration on tobacco

CHEMICAL FORMULATION Metalaxyl: N-(2,6-Dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester.....25.11%

100

Metalaxyl (Ridomil 2E)

100 Pesticide Label Information

100.1 Pesticide Use

For the control of black shank and blue mold on tobacco

100.2 Formulation Information

Metalaxyl: N-(2,6-Dimethylphenyl)- N - methoxyacetyl)alanine methyl ester	25.11%
INERTS _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	74.89%
	100%

(2 lb AI per gallon)

100.3 Application Methods, Directions, Rates

Flue-Cured Tobacco

Black Shank: Apply a broadcast application of Ridomil using the appropriate rate in the table below. Apply with a conventional ground sprayer in a minimum of 15 gals. of water per acre. Incorporate Ridomil in the top 2-4 inches of soil and form beds.

Disease	Disease Level Expected*	Rate of Ridomil per acre
Black Shank	Low to Moderate (Less than 6% Disease)	2 qts. (1 lb AI)
	High (More than 6% Disease)	4 qts.** (2 lb AI)

*Fields where black shank symptoms have occurred at the indicated levels (percent disease), based on previous field history.

**In Florida and Georgia under very high black shank levels (greater than 60% disease), use 6 qts. per ace (3 lb AI).

Blue Mold: Apply 1-2 qts. per acre (0.5-1 lb AI) broadcast and incorporate in the top 2-4 inches of soil. Under low disease pressure or for early season control, use 1 qt. per acre (0.5 lb AI). Under high disease pressure or for full season control, use 2 qts. per acre (1 lb AI).

Burley and other Tobacco

Blue Mold: Apply 2 qts. per acre (1 lb AI) broadcast and incorporate in the top 2-4 inches of soil.

Rotational Crops

If replanting is necessary, tobacco may be replanted immediately. Do not make a second application of Ridomil. Tobacco, corn, or root crops may be planted the year following treatment. Small grain cover crops may be planted during the fall following treatment provided they are plowed down and not used for food or feed. Other crops may be planted 18 months following application.

100.5 Precautionary Labeling

Environmental Hazards

Keep out of lakes, streams, or ponds. Apply only as specified on this label. Do not apply when weather conditions favor drift from treated areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

101 Physical and Chemical Properties

(See previous review by J.S. Leitzke, 1/21/80.)

102 Behavior in the Environment

(See previous review by J.S. Leitzke, 1/21/80.)

103 Toxicological Properties

(See previous review by J.S. Leitzke, 1/21/80.)

104 Hazard Assessment

104.1 Discussion

Metalaxyl is presently in for registration as a 5% wettable powder for use of ornamentals, turf and Florida non-bearing citrus (Subdue®). This submission as a 25% emulsifiable on tobacco (Ridomil®), is a substantially dissimilar use and represents an Incremental Risk to non-target organisms.

Ecological Effects Branch has proposed that an interim policy be formulated to deal with pesticides that can contaminate groundwater. This interim policy would use criteria in the following general categories to select pesticides for regulatory action: use pattern, volume of use (or potential volume), environmental chemistry and toxicity. If a pesticide triggers a number of these criteria, appropriate action is recommended.

104.2 Likelihood of Adverse Effects

(See previous review of J.S. Leitzke, 1/21/80, for more details.) Following the proposed policy, metalaxyl is of concern because of its: 1) proposed use on tobacco, a substantially disimilar use than proposed before; 2) efficacy on the fungal diseases that attack a wide spectrum of crops; 3) ability to persist and leach down to groundwater supplies; and 4) incomplete laboratory mammal chronic test requirements and differential toxicity of its different formulations.

104.3 Endangered Species Consideration

Although little acute hazard to non-target organisms is anticipated, possible chronic effects are presently unknown. Until there is more information about what levels will cause chronic effects, EEB defers comment on possible hazards of metalaxyl to Threatened and Endangered Species.

104.4 Adequacy of Toxicity Data

As noted previously by J. Tice (3/28/79), all minimum tests required for the technical material have been fulfilled. However, because aquatic tests conducted with the technical had problems and unique test conditions, these tests are not adequate to support registration of formulated products.

104.5 Additional Data Required

The following tests will be required as a condition to registraton: 1) acute aquatic tests on the formulated product, 2) an aquatic invertebrate life-cycle test on the technical, and 3) more completely quantified fate of the formulated product through field monitoring studies.

Fish embryo-larvae studies may be required in the future depending on the results of the aquatic invertebrate life-cycle test.

107 Conclusions

107.4 Data Adequacy Conclusions

As stated previously by J. Tice (3/28/79), although all minimum tests that require use of the technical material have been fulfilled, "aquatic tests of the formulated products will be necessary for the products registration."

107.5 Data Requirements

The following tests are required as a condition of registration:

1. A fish 96-hr LC_{50} on a warmwater species (preferably bluegill) and a coldwater species (preferably rainbow trout) using the formulated product, Ridomil 2E®; and

2. An aquatic invertebrate acute LC_{50} either for 48-hr on first instar daphnids or for 96-hr on early instar amphipods, stoneflies or mayflies using the formulated product, Ridomil 2E®; and

3. An aquatic invertebrate life-cycle test (preferably Daphnia magna) using technical metalaxyl.

4. Aquatic field research that will include but is not limited to:

   a. Analysis of water and sediment samples for the presence of metalaxyl (Ridomil) under conditions that would tend to maximize leaching (and runoff). This program must include samples from:

      (i) Leachate (and runoff, if possible) following application of metalaxyl;

      (ii) Tile drainage water (and include a description of the system monitored);

(iii) Receiving waters (the point at which discharged waters enter natural waters);

(iv) Surface and ground waters in or adjacent to target areas.

107.7 Recommendations

Ecological does not object to the conditional registration of Ridomil 2E® on tobacco subject to written agreement to the following conditions:

1. The Data Requirements (Sect. 107.5) will be fulfilled; and

2. It is recognized that fish embryo-larvae studies may be required in the future depending on the results of the aquatic invertebrate life-cycle test; and

3. If chronic test indicate significant impairment at levels expected to be in groundwater, then registration on this crop (and any other crop from which similar levels are found or expected) will be withdrawn or denied.

John S. Leitzke John S. Leitzke 3/17/80
Section 2
Ecological Effects Branch, HED, (TS-769)

Norm Cook Norman Cook 3/18/80
Head, Section 2
Ecological Effects Branch, HED, (TS-769)

Clayton Bushong 3/18/80
Branch Chief
Ecological Effects Branch, HED, (TS-769)