

4-8-81

113501
SHAUGHNESSEY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 2/4/81 OUT 4/8/81

FILE OR REG. NO. 100-607

PETITION OR (EXP. PERMIT NO.) _____

DATE OF SUBMISSION 1/12/81

DATE RECEIVED BY HED 1/30/81

RD REQUESTED COMPLETION DATE 4/15/81

EEB ESTIMATED COMPLETION DATE 4/15/81

RD ACTION CODE/TYPE OF REVIEW 315/Amendment: Nonfood Use

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

DATA ACCESSION NO(S). 244183

PRODUCT MGR. NO. H. Jacoby (21)

PRODUCT NAME(S) Ridomil 2E Fungicide

COMPANY NAME CIBA-GEIGY Corporation

SUBMISSION PURPOSE Submission of data in response to previous EEB review

SHAUGHNESSEY NO.

CHEMICAL & FORMULATION

% A.I.

113501

Ridomil 2E

25.11%

①
X

Pesticide Name: Metalaxyl

100 Pesticide Label Information

100.1 Pesticide Use

Ridomil 2E is proposed to be used for the control of certain diseases in tobacco and non-bearing citrus.

100.2 Formulation Information

Active Ingredient:

Metalaxyl: N - (2,6-dimethylphenyl) -N-

(methoxyacetyl) alanine methyl

ester.....25.11%

Inert Ingredients..... 74.89%
100.0 %

Aquatic toxicology tests have shown that the formulated product is more toxic than the technical material to those organisms tested (see section 103 of this review and section 103 of 1/21/80 EEB Review). The cause of this is apparently the "inerts", either alone or in combination with the active ingredient. A 5/7/79 memo from the Residue ^{Chemistry} Branch (on file at the Toxicology Branch) provides the following analysis of the Ridomil 2E formulation:

% by wt.

Active ingredient: CGA-48988 Technical
(90% a.i.)

27.9

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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100.0

INERT INGREDIENT INFORMATION IS NOT INCLUDED

The above formulation is referred to as Ridomil 2 EG in a 6/15/78 memo from the Toxicology Branch on file at TB. A formulation containing [REDACTED] described in 11/27/78 memo from TB (on file at TB), is no longer proposed for use, according to TB.

100.3 Application Methods, Directions, Rates

Application information from the proposed label submitted by CIBA-GEIGY (dated February 17, 1981 and revised March 17, 1981) is attached.

The proposed rates convert to pounds of formulated product per acre as follows (formulated product is used in this conversion since it is more toxic than active ingredient alone):

A. Tobacco

1) plant beds

a) soil application

-all states except PA: 1 qt. FP/acre=

2lb. FP/acre

PA: 2 qts. FP/acre = 4lb. FP/acre

b) foliar application

1pt. FP/acre = 1lb FP/acre

-applied 70 days after soil treatment; 1 or 2 applications no closer than 14 days apart.

2) field - planted tobacco

a) Blue mold control: 1-2 qts. FP/acre =
2-4 lb FP/acre, soil
applied and incorporated.

b) Black Shank Control:

2-6 qts. FP/acre = 4-12 lbs FP/acre, soil
applied and incorporated. Amount applied
depends on tobacco type, location, and
disease level (see label). One (1)
application only.

B. Nonbearing Citrus

1. nurseries

a) soil drench:

4-6 fl. oz. FP/100 gals. water over row at
100-250 gals/1000' row.

The maximum application rate thus equals 15 fl.
oz. (0.94 lb)/1000' row. According to Dr. Joseph
Knapp of the University of Florida Agricultural
Extension Experimental Station at Lake Alfred,
Florida (personal communication, 3/27/81), a
typical row width in a citrus nursery is two (2)
feet with the fungicide applied in a 12" band of
soil (6" to both sides of the plant). With 24"
rows (center of one row to center of next row),
there would be approximately 21,705 feet of row
per acre. At 0.94 lb. FP/100' row, this would be
approximately 20.4 lb. FP/acre at the maximum
application rate.

b) soil surface spray: 2 gals. FP/acre = 16 lb
FP/acre, followed by a 1/2 inch irrigation.

The first application of Ridomil in citrus nurseries is to be made at the time
of planting with repeat applications at three - month intervals during the
period when trees are actively growing.

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2. citrus resets or new plantings
water ring drench:

- a) ↓ 4-6 fl. oz FP/100 gallons of water;
apply 5 gals. of mix around each tree.
According to Dr. Joseph Knapp (personal
communication, 3/30/81, see above),
there could be 50-150 trees per acre
with a typical number of 77
trees/acre. With the trees treated at
the maximum rate of 6 fl. oz. FP/100
gals. water (at 5 gals./tree), each
tree would receive 0.3 fl. oz. FP and
the typical acre (77 trees) would thus
receive 23.1 fl. oz. (1.44 lb) FP.
- b) soil surface spray: 1-2 gallons
FP/acre = 8-16 lb FP/acre.

For all citrus resets or new plantings, the first Ridomil application is to be made at the time of transplanting with up to three (3) repeat applications, at three - month intervals to coincide with root growth flushes during the growing season.

100.4 Target Organisms

A) Tobacco

- black shank (Phytophthora parasitica, var. Nicotianae)
- blue mold (Peronospora tabacina)
- Pythium spp.

B) Non-bearing citrus

- citrus foot rot and root rot caused by Phytophthora spp.

100.5 Precautionary Hazards Proposed

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."

See the label for additional hazards to humans and domestic animals.

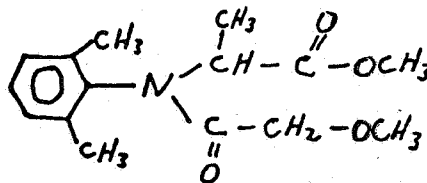
101 Physical and Chemical Properties

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101.1 Chemical name

Metalaxyl: N-(2,6-dimethylphenyl)-N-(Methoxyacetyl) alanine methyl ester

101.2 Structural Formula



101.3 Common Name

Metalaxyl

101.4 Trade Name

Ridomil 2E Fungicide

101.5 Molecular Weight

279.34

101.6 Physical State

Technical: Odorless tan powder or brown solid material
Formulation (Ridomil 2E): brown liquid

101.7 Solubility

(from 1/21/80 EEB Review)

solvent

water	0.7% (700 ppm)
methanol	65 %
benzene	55 %
hexane	0.9%
isopropanol	27 %
methylene chloride	75 %

102 Behavior in the Environment

See 1/21/80 EEB review for description of the environmental chemistry of the technical material. Research to determine soil and ground water residue levels following field applications of Ridomil 2E is presently underway. The Environmental Fate Branch is monitoring the progress and reviewing the results of this research. EFB's most recent review, dated 3/11/81, describes the results of analyses at two sites:

1) Tobacco Experimental Farm, Maryland

Ridomil dosage: 2 lbs a.i./acre (8 lbs FP/acre)
application dates: 5/29/80, 7/29/80
soil characteristics: NA
cumulative rainfall: 20.12"; and

2) Florida tobacco farm, ^WSwanee County

Ridomil dosage : 2 lbs a.i./acre (8 lbs
FP/acre)

Application date : 4/10/80
Soil: fine sand
Cumulative rainfall: 33.3" (1.7"rain fell two
days after applic.).

At the Maryland site, most Ridomil residues remained in the top 6" soil layer in amounts varying from 0.0025 - 6.03 ppm initially and through the 135-day sampling period. The highest residue in well samples was 0.236 ppm in well #3 15 days after treatment.

At the Florida site, the highest residue level detected in the soil, except for initial residues, was 0.242 ppm in the 18-24" layer 26 days after treatment. Initial residues were 0.66-1.25 ppm in the upper 6" of soil. Residues were below the detectable limit of 0.001 ppm in all 40 well samples.

Weaknesses EFB found in the above studies include the low application rate relative to present registrations, below average rainfall at the Maryland site, no analysis for the acid degradate of Metalaxyl at the Maryland site, and reporting deficient in the following: use pattern, distance of wells from treated area, soil characteristics, and recharge rate.

An EFB review of 1/12/81 indicates that the ^WSwanee County study site will be replaced by a study site in the Indian River area of Florida. The latter reportedly provides a "worst-case" situation.

103 Toxicological Properties

See section 103 of the 1/21/80 EEB review for a summary of toxicity data submitted as of that date. Additionally, the following studies have been evaluated as part of the present review.

103.2.3 Fish Acute LC50

<u>Species</u>	<u>Material</u>	<u>LC50 (96-hr.)</u>	<u>Category</u>	<u>Reviewer</u>
Bluegill (<u>Lepomis macrochirus</u>)	Ridomil 2E-G (27.9% a.i.)	27 ppm (based on formulation, not a.i.)	Core, For this formulation.	Felkel
"	Ridomil Tech. (95.1% a.i.)	139 ppm	Core	Felkel
Rainbow Trout (<u>Salmo gairdneri</u>)	Ridomil 2E-G (27.9% a.i.)	18.4 (based on formulation, not a.i.)	Core, For this formulation	Felkel
"	Ridomil Tech. (95.1% a.i.)	132 ppm	Core, for technical material	Felkel

103.2.4 Aquatic Invertebrate LC50

<u>Species</u>	<u>Material</u>	<u>LC50 (48-hr.)</u>	<u>Category</u>	<u>Reviewer</u>
<u>Daphnia</u> <u>Magna</u>	Ridomil 2E-G (27.9% a.i.)	12.5 ppm	Core, for this formulation	Felkel
"	Ridomil Tech. (95.1% a.i.)	121 ppm	Core, for technical material	Felkel

103.4 Additional Aquatic Laboratory Tests

103.4.2 Embryo-larvae and Life-cycle Studies

<u>Species/Test</u>	<u>Material</u>	<u>Results</u>	<u>Category</u>	<u>Reviewer</u>
<u>Daphnia</u> <u>Magna/</u> Life-cycle	CGA-48988 (Technical, 90.1% purity) (min. toxicant concentration to elicit an adverse response) is greater than 1.2 mg/l and less than 2.7 mg/l	Minimum Threshold Concentration	Suppl.	Felkel
Fathead Minnow (<u>Pimephales</u> <u>promelas</u>)/embryo-larvae	CGA-48988 (Technical, 90.1% purity)	Min. threshold concentration to eggs and fry greater than 9.1 mg/l	Core (if requested and if EECs are greater than 9.1 mg/l)	Felkel

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104.2

Likelihood of Adverse Effects to Non-target Organisms

The acute toxicity studies that have been submitted indicate that this formulation is only "slightly toxic" to the organisms tested. Also, the unsolicited fish embryo-larvae study showed that active ingredient levels as high as 9.1 mg/l had no adverse effects on fathead minnow reproduction, survival, or growth. The Daphnia life-cycle study indicated a minimum threshold concentration greater than 1.2 mg/l and less than 2.7 mg/l, but the statistics in this study need to be confirmed.

The acute toxicity studies on the formulated product provide clear evidence that this formulation is more toxic than the technical material, despite the much lower percent active ingredient. The formulation was 2X-9.7X as toxic to daphnids, 5-5.5X as toxic to bluegills, and 7X as toxic to rainbow trout, compared to the technical material. Thus, the "inerts" are apparently responsible for the increased toxicity, either by their own toxicity or by an interaction with the active ingredient.

The proposed high application rates on non-bearing citrus (as high as 20.4 lbs FP/acre in nurseries with repeat applications at 3-month intervals while the trees are actively growing) raise the question of whether aquatic environmental levels of this material will reach or exceed chronic toxicity levels. Since actual field monitoring in a reportedly "worst-case" situation is presently underway (Indian River area of Florida), EEB recommends that the proposed label amendments to permit the nationwide use of Ridomil on citrus be conditional upon the results of this study. Upon receipt of EEB's anticipated analysis of this study (after its completion), EEB will be able to better evaluate the potential environmental effects from this material.

The proposed application rates of Ridomil on tobacco appear to be no greater than those presently contained within Registration #100-607. In both cases, the maximum rate is 12 lbs. FP/acre (see section 100.3 of this review and section 100.3 of the 3/17/80 EEB review). Hence EEB foresees no incremental risk to non-target organisms from the proposed label changes for tobacco.

104.3 Endangered Species Considerations

As noted in section 104.2, EEB defers full evaluation of hazard to non-target organisms, including endangered species, until results of the Indian River, Florida monitoring study are available and these results can be compared to the relatively low toxicity levels of the Ridomil 2E formulation. However, based on a 10/20/80 EEB review of the fungicide chlorothalonil on citrus (section 104.3), it does not appear that federally-listed species would come in contact with fungicides used on citrus (due to their geographic distribution).

107 Conclusions

107.3 Environmental Hazards Labelling

The proposed labelling (see section 100.5) appears to be consistent with the proposed use pattern and toxicity levels.

107.4 Data Adequacy Conclusions

The acute toxicity data on the formulated product and the fish embryolarvae and invertebrate life cycle studies are sufficient to support the proposed registration except that the Daphnia life-cycle study data (within Accession # 244183) were not submitted in a format amenable to confirmation of the statistics.


107.5 Data Requests

No further studies are needed to support the proposed registration of Ridomil 2E. However, the Daphnia life-cycle study data (within Accession #244183) should be submitted in a format amenable to confirmation of the statistics. Copies of the referenced label protocols for this study and the fish embryo-larvae study (as already requested by the Registration Division) should also be submitted.

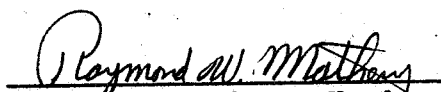
107.7 Recommendations

EEB requires no new studies at this time to evaluate the hazard to non-target organisms under the proposed registration of Ridomil 2E. However, certain existing information, as specified in section 107.5, is requested.

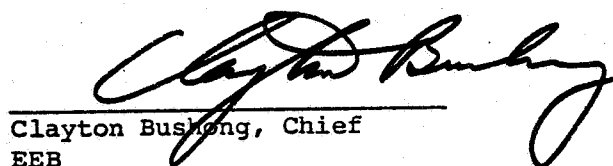
While it is unlikely that any further label restrictions over those proposed would be necessary, EEB cannot fully evaluate the high application rates proposed for non-bearing citrus until the results of the on-going monitoring study (Indian River area of Florida) are available. Hence, EEB recommends that the proposed label amendments to permit the nationwide use of Ridomil on non-bearing citrus be conditional upon a finding of "no incremental risk" following a review of the monitoring study. EEB foresees no incremental risk to non-target organisms from the proposed label changes for tobacco.


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