

US EPA ARCHIVE DOCUMENT

113501
AUGHNESSEY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 4/29/81 OUT 6/26/81

FILE OR REG. NO. 100-607

PETITION OR EXP. PERMIT NO. _____

DATE OF SUBMISSION 4/15/81

DATE RECEIVED BY HED 4/28/81

RD REQUESTED COMPLETION DATE 6/29/81

EEB ESTIMATED COMPLETION DATE _____

RD ACTION CODE/TYPE OF REVIEW 330/Amendment -- Food Use

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

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Ridomil 2E

COMPANY NAME CIBA-GEIGY

SUBMISSION PURPOSE Proposed registration of additional uses: broccoli, cabbage, cauliflower, cotton, cucumbers, lettuce, melons, onions, potatoes, soybeans, spinach, tomatoes, & wheat

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
<u>113501</u>	<u>Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alamine methyl ester</u>	<u>25.11%</u>
_____	_____	_____
_____	_____	_____

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Pesticide Use

This review discusses the hazards associated with the use of Ridomil 2E on broccoli, cabbage, cauliflower, cotton, cucumbers, lettuce, melons, onions, potatoes, soybeans, spinach, tomatoes and wheat. Previous reviews evaluated a conifer nursery use and non-bearing citrus use. Currently the product is registered for tobacco.

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Application method, directions and rates

The application methods, directions and rates are explained in detail in the following table. Application methods generally used are ground broadcast methods. Potatoes is the only crop which provides specific instructions for aerial applications.

RIDOMIL 2E
DIRECTIONS FOR USE

Cole Crops (Cabbage, Broccoli and Cauliflower)

Downy Mildew (Peronospora spp.)

Apply 1 pt. Ridomil 2E per acre in 50-100 gals. water starting when conditions are favorable for disease development and continue at 14-day intervals throughout the season. Use a spreader-sticker at rates recommended on the product labels.

Note: Do not apply more than 4 pts. Ridomil 2E per acre per season or make the last application within 7 days of harvest.

Cotton

Seed Rots and Seedling Diseases of Cotton (Pythium spp. and Phytophthora spp. only)

Apply Ridomil 2E as a seed treatment at the rate of 1-2 fluid ounces per 100 lbs. seed.

Cucumbers and Melons

Downy mildew (Peronospora cubensis)

Apply 1 pt. Ridomil 2E per acre in 50-100 gals water per acre starting when the plants are in the two-leaf stage and continue at 14-day intervals throughout the season.

Note: Do not apply more than 8 pts. Ridomil 2E per acre per season or make the last application within 5 days of harvest.

Leafy Vegetables (Head lettuce, spinach)

Downy Mildew (Bremia lactucae and Peronospora effusa)

Apply 1 pt. Ridomil 2E per acre in 50-100 gals. of water starting when conditions are favorable for disease development and continue at 14-day intervals throughout the season.

Note: Do not apply more than 4 pts. Ridomil 2E per acre per season or make the last application within 7 days of harvest.

Onions - Dry Bulb and Green

Downy Mildew (Peronospora destructor)

Apply 1 pt. Ridomil 2E in 50-100 gals. water per acre starting when conditions are favorable for disease development and continue at 14-day intervals throughout the season. Use a spreader-sticker at rates recommended on the product labels.

Note: Green Onions - Do not apply more than 3 pts. Ridomil 2E per acre per season or make the last applications within 5 days of harvest.

Dry Bulb Onions - Do not apply more than 5 pts. Ridomil per acre per season or make the last applications within 21 days of harvest.

Potatoes

Late Blight (leaf blight and tuber rot)

Apply Ridomil 2E as a tank mix with Dithane M-45, Manzate 200, Bravo 6F or Difolatan 4F on a 14-day schedule starting when plants are six inches high or when conditions are favorable for late blight development and continue at 14-day intervals throughout the season. Use 1/2-1 pt. Ridomil and the lowest recommended rates of the protectant fungicides in a minimum of 50 gallons of water per acre for ground applications and a minimum of 3 gallons of water per acre for aerial application.

Note: Ridomil does not control early blight (Alternaria solani). When conditions are favorable for early blight, additional applications of a protectant fungicide must be made according to their use directions.

Early and Late Blight (leaf blight and tuber rot)

Apply 1/4-1/2 pt. Ridomil in a tank mix with recommended rates of Dithane M-45, Manzate 200, Bravo 6F or Difolatan 4F. Start applications when plants are six inches high or when either disease first appears and continue at 7-10 day intervals. Use the higher rates of the fungicides as disease pressure increases. Use a minimum of 50 gallons water per acre for ground applications and a minimum of 3 gallons water per acre for aerial applications.

Do not apply more than 9 pts. Ridomil 2E per acre per season nor make the last application within 7 days of harvest. Observe all precautions and restrictions that appear on labels of other products that are applied with Ridomil.

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RIDOMIL 2E

DIRECTIONS FOR USE

Soybeans

Pythium Damping Off and Seedling Phytophthora Root and Stem Rot

Broadcast 6 pt. Ridomil 2E per acre or apply 1 pt. Ridomil per 13,000 linear feet of row in a 7-inch band over the row at planting.

Note: In fields heavily infested with Phytophthora, Ridomil 2E may not provide full season control.

Wheat

Pythium Seedling Diseases

Apply 1-2 qts. Ridomil 2E per acre as a broadcast soil surface application at or before seeding.

Tomatoes

Late Blight (Phytophthora infestans)

Apply Ridomil 2E as a tank mix with Bravo 6F as a foliar spray on a 14-day schedule starting when plants are six inches high or when conditions are favorable for disease development and continue at 14-day intervals throughout the season. Use 3/4-1 pt. Ridomil plus the lowest recommended rates of Bravo 6F in a minimum of 50 gallons of water per acre. Under heavy disease pressure, use the higher rate of Ridomil.

Note: Ridomil does not control early blight (Alternaria solani). When conditions are favorable for early blight, additional applications of a protectant fungicide that controls early blight must be applied according to their use directions.

Early and Late Blight

Apply Ridomil 2E as a tank mix with Bravo 6F as a foliar spray on a 7-10 day schedule. Start applications when plants are six inches high or when conditions are favorable for disease development and continue throughout the season. Use 1/2-1 pt. Ridomil 2E with rates of Bravo 6F recommended for early blight control in a minimum of 50 gallons of water per acre.

Seedling Damping Off (Pythium spp.)

Apply 4 pts. Ridomil 2E per acre immediately before or after planting in 20-50 gallons of water. Lightly incorporate with mechanical equipment if application is made prior to planting or with sprinkler irrigation if applied after planting.

For banded applications, calculate the amount of Ridomil 2E needed as follows:

Band width in inches x Broadcast Rate per acre = Amount needed per acre

Fruit Rot (Pythium spp. and Phytophthora spp.)

Apply 4-8 pts. Ridomil 2E per acre of tomatoes as a soil surface application under the vines 6-8 weeks before harvest. Follow as soon as possible with an irrigation.

Note: Do not apply more than 12 pts. Ridomil 2E per acre per season. Observe all precautions and restrictions that appear on the Bravo 6F label.

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Ridomil Application

<u>Crop</u>	<u>Treatment Schedule</u>	<u>Maximal Annual Amount of Ridomil Applied per Acre</u>
		<u>volume of 2E lbs. Ridomil</u>
Cole crops	1 pt @ 14 day intervals; throughout growing season	4 pts = 1 lbs.
Cotton	seed treatment	2 oz/100 lbs seed
Cucumbers & melons	1 pt @ 14 day intervals throughout growing season	8 pts = 2 lbs.
Head Lettuce & Spinach	1 pt @ 14 day intervals throughout growing season	4 pts = 1 lbs.
green onions	1 pt @ 14 day intervals throughout growing season	3 pts = 0.75 lbs.
dry bulb onions	1 pt @ 14 day intervals throughout growing season	5 pts = 1.25 lbs.
potatoes	1 pt @ early blight - 7-10 day intervals 1 pt @ late blight - 14 day intervals 1 treatment at planting	9 pts = 2.25 lbs. 6 pts = 1 lbs.
wheat	at or before seeding	4 pts = 1 lb
Tomatoes	early blight - 7-10 day intervals late blight - 14 day intervals	12 pts = 3 lbs

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101.0 Chemical and Physical Properties

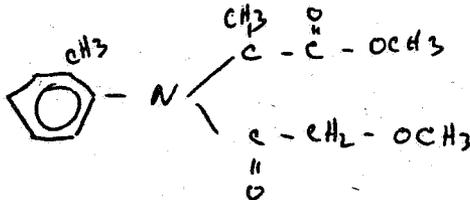
101.1 Chemical name

N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester

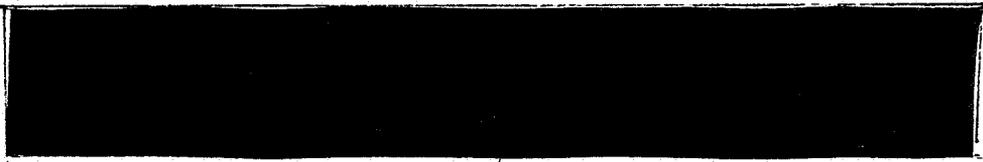
101.2 Common name

metalaxyl

101.3 Structural formula and list of inerts



Inert Ingredients: 72.1 % by weight of the



101.4 Molecular weight 279.34

101.5 Physical state

Technical: odorless tan powder or brown solid material
formulation: brown liquid

101.6 Solubility (from 6-6-80 EFB Review)
Technical CGA-48988 is soluble as follows (20%)

water	0.7%
MeOH	65%
MeCL ₂	75%
benzene	55%
isopropanol	27%

102 Behavior in the Environment

(From review by S.M. Creeger, 10/24/79, of Environmental Fate Branch)

"Under conditions likely to be found in the environment, Ridomil will be stable to hydrolysis and soil surface photolysis. However it will photodegrade in water with a half-life of 1 week forming CGA-62826 in small (5%) amounts plus 4 unidentified polar compounds (totaling 17%) and production of some (12%) volatile compounds. Aqueous photolysis in the presence of photosensitizers

greatly accelerates degradation of Ridomil to a half-life of 1 hour.

"In soil, under aerobic conditions, Ridomil can be expected to degrade with a half-life of about 7 weeks, with CGA-62826 being the principle product. The CGA-62826 then breaks down to non-extractable material and CO₂. Under anaerobic soil conditions, Ridomil degrades with a half-life of about 9 weeks with CGA-62826 being the major product but persisting longer than under aerobic conditions. Ridomil is stable in sterile soil, indicating soil microbes contribute to its breakdown under non-sterile conditions.

"At use rates, Ridomil will not affect soil microbe growth, metabolism of cellulose, protein or starch or nitrification.

"Ridomil and its aged soil residues are highly mobile via leaching in sandy soils low in organic matter but loss of Ridomil due to volatilization is not expected. Also, soil adsorption of Ridomil is minor, as supported by its high leachability.

"Under field conditions, the fate of Ridomil in soil is similar to that under aerobic and anaerobic lab conditions, as described above, except for the shorter half-life of 2 weeks under field conditions.

"Exposure of fish to the parent compound or soil aged residues will not result in accumulation values above 10X in the whole fish. Also, during 14 days of depuration, 80% and more of the accumulated residues will be discharged."

102.1 Soil

(Taken from review by S. M. Creeger, 2/26/79, of Environmental Fate Branch)

Soil Surface Photolysis - None

- Soil Degredation - Aerobic half-life of ca. 40 days with CGA-62826 the major metabolite peaking at 53.6% at 66 days.
- Anaerobic half-life of ca. 66 days with CGA-62826 again the major metabolite peaking at 52.4% at 89 days
 - Sterile (autoclaved) - no degradation

Soil Volatilization - Less than 0.5% loss

Soil Adsorption - Minor

- Field Degradation - Half-life of ca. 2 weeks with CGA-62826 as major metabolite peaking at 20% at 30 days,
- Half-life of ca. 6-8 weeks in soil sprayed 3 times at 1.1 lb. AI/acre 28 days apart,

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(J. W. Holder, 6/19/81)

Leaching

Ridomil has caused some concern in EFB regarding it's ability to leach. The following conclusions from the latest review summarize the results of the studies.

- "Ridomil is highly mobile in soils especially in sandy soils of low organic matter content (see EFB Ridomil File for numerous reviews on this topic).
 - "Because of the soil mobility Ridomil has been monitored at Suwanee County, Florida, Indian River, Florida, and a tobacco site in Maryland. The Indian River and Maryland sites are still being monitored for soil and well water contamination of Ridomil. EFB has concluded that these studies should be continued (S. Malak, 5/26/81).
 - "No metalaxyl, or the acid metabolite, were found in Suwanee County Florida in soil or well water. No metalaxyl (acid metabolite not determined) was found in Maryland soil or well water (memo., J. Reinert 1/12/81). The results from the worst case site at Indian River, Florida are forthcoming and have not been reviewed yet.
 - "EFB continues to express reasonable concern of the mobility of Ridomil in soils especially in sandy, low organic content soils. Although the aforementioned studies have not shown Ridomil contamination of well water to date, it is conceivable that (given enough time) Ridomil would finally contaminate well waters. This being a distinct possibility, the final decision as to the permanent registration of Ridomil will necessarily depend on the results, and review of those results, of the Indian River soil and water studies.
 - "Considerable amounts of Ridomil could enter the cropland soils in the U.S. [see section 3.4 of EFB memo of 6/15/81, J.W. Holder]. If it is assumed that Ridomil will be used on only 10% of the crops for which registration is sought, then 16.6×10^6 lbs Ridomil could be applied to U.S. soils. Because of the number of crops, and especially large acreage field crops such as soybeans and wheat, the need for fully understanding the leaching of Ridomil and any possible contamination of ground water thereby, is clear.
- "Approximately 10,000 acres of seedlings and transplants are currently planted in the U.S. (Gillespi, Forest Mgt., USDA). If the amount applied of 1.25 lbs/acre/yr. is multiplied by 10,000 acres, then the amount of Ridomil in U.S. soils from this source is 1,250 lbs. of metalaxyl. This forest use is a potential source of ground water contamination of Ridomil because of the strong leaching properties of Ridomil. However, the amount 1,250 lbs. is

inconsequential compared to the amounts possible from the cropland sources described in the 6/15/81 memo (J. Holder). EFB concludes that due to the comparatively small acreage involved in forest conifer nursery use, the incremental exposure does not seem to be a problem at this time especially in light of considerations made above in section 4.4.

102.2 Water

(S.M. Creeger, 2/26/79)

Hydrolysis - None (or very little) at pH 5, 7 and 9, and at 20-30°C.

(S.M. Creeger, 10/24/79)

Photolysis - Half-life of 6 1/2 days at pH 8.3 and 25°C.
- Half-life of 57 minutes in 1% acetone (as a photosensitizer) at pH 8.3 and 25°C.

102.3 Plants

(From review by G.P. Makhijani, 3/29/79, Residues Chemistry Branch)

Potatoes - Absorbed into potato leaves and stems with little translocation into tubers and extensively metabolized principally to CGA-62826.

(S.M. Creeger, 2/26/79)

Tobacco - Extensively metabolized to ca. 25 different metabolites with CGA-62826 never more than 1.5%.

102.4 Animal

(G.P. Makhijani, 3/29/79)

Rat - Almost all was excreted in urine and feces within 6 days; no parent compound was found.

- Within 48-hr, 62.1% of activity in urine (which was 63.5% of total) was in form of glucuronic acid conjugates.

- Metabolism proceeds by 1) methyl ester hydrolysis, 2) N-dealkylation, 3) methyl ether cleavage, 4) 2,6-methyl oxidation and 5) subsequent conjugation with glucuronic acid.

102.5 Microorganisms

(S.M. Creeger, 10/24/79)

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Cultures - No effect on cultures of 1) actinomycetes, 2) cellulose decomposing, nitrogen fixating and esterase producing bacteria, 3) algae and 4) decomposing, esterase and antibiotic producing and arsenic metabolizing fungi.

Nutrient Metabolism - No effect at normal use rates on cellulose, protein or starch metabolism.

Activated Sludge - Continuous treatment of activated sludge inhibits breakdown of carbon and allows parent compounds to be discharge in effluent.

102.6 Bioaccumulation

(S.M. Creeger, 10/24/79)

Bluegill - Bluegills (5.6 ± 2.5 gm, 7.3 ± 0.9 cm.) were continuously exposed to ¹⁴C-phenyl-labeled parent at 1 ppm for 29 days at 17.0°C, pH 7.0-7.2 and 60% saturation of DO. Remaining fish were placed in clean water for 14 days. The conclusions from the study follow.

1) When exposed to CGA-48988 at 1 ppm in the water, bioaccumulation levels in the whole fish are not expected to exceed 7X. Residues prefer to concentrate in the non-edible portions over the edible portions in a ratio range of 4:1 to 15:1.

2) More than half of the accumulated residues are discharged after 3 days of depuration and continue to be discharged as the depuration period continues.

3) The low levels of accumulation did not permit identification of the fish residues.

4) Previously reviewed hydrolysis data, which shows the parent to be stable under conditions of this experiment allow the conclusion that the fish were exposed to unchanged CGA-48988 during the exposure period.

Catfish - Catfish (5.1 ± 1.4 gm, 82.1 ± 7.8 mm) were placed in well water (18°C, pH 7.1, 78-87% DO saturation) for 28 days which 3 days before had been flooded onto previously 30-day aged soil containing 3-3 ppm ¹⁴C-phenyl-labeled parent. Remaining fish were placed in clean water for 14 days. The conclusions indicated that accumulations of aged residues of CGA-48988 above 1X in catfish are not expected. Also, during depuration, 80% and greater of the residues accumulated are discharged after 14 days.

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102.7 Summary

(S.M. Creeger, 10/24/79)

"Ridomil is stable to hydrolysis and soil surface photolysis but does photodegrade in water with a half-life of 1 week. Photosensitizers accelerate degradation. Aerobic and anaerobic soil half-lives are 7 and 9 weeks, respectively, with CGA-62826 forming which in turn breaks down. Soil microbes metabolize Ridomil but soil microbe functions are not affected at use rates. Ridomil and its soil residues leach strongly in soil and especially strongly in sandy soils low in organic matters. Groundwater contamination is a strong possibility considering the proposed citrus use. Ridomil dissipates under field conditions with a half-life of 2 weeks and accumulation in whole fish is not expected to exceed 10X.

Rats - 90-day Feeding NOEL = 250 ppm (body and organ wts., feed intake, blood, urine, histopathology)

Dogs (Beagles) - 90-day Feeding NOEL = 250 ppm (same above)

Rats - Teratology Study - Not Teratogenic at 120 mg/kg.

Salmonella - Mutagenicity - Negative in TA 1535
TA 1537, TA 98 and
TA 100, with and without
microsomal activation

103.0 Toxicological Properties

103.1 Mammals

(From reviews by K. K. Locke, 10/31/79 and by S.-L. Chan, Toxicology Branch 3/21/79, based in part on previous reviews by W. Woodrow 11/8 & 11/27/78)

Technical (90% A.I.)

Rats - Acute Oral LD₅₀ = 669 mg/kg

Rabbits - Acute Dermal LD₅₀ > 6 gm/kg

Rabbits - Skin Irritation Index = 0.1/8 = mild irritant

Rabbits - Eye Irritation Index = 9.5/110

Guinea pig - Skin Sensitization - Negative

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INERT INGREDIENT INFORMATION IS NOT INCLUDED

Mouse - Dominant Lethal - Negative Mutagenic Potential

Formulation - CGA-48988 5W

Rats - Acute Oral LD50 >5000 mg/kg; tremors & convulsions

Rabbits - Acute Dermal LD50 >10,000 mg/kg; depression & loss of appetite

Rabbits - Eye Irritation - Unwashed: recovery by day 10
washed: no irritation

Rabbits - Skin Irritation - None

Rats - Acute Inhalation LC50 >2.97 mg/l

Formulation - Ridomil-2E (27.8% AI; contains [REDACTED])

Rats - Acute Oral LD50 = 1889.48 mg/kg

Rabbits - Acute Dermal LD50 = 3571.5 mg/kg

Rabbits - Eye Irritation - Corneal opacity

Rabbits - Skin Irritation - Very slight irritant

Formulation - Ridomil-2EG (27.9% AI; does not contain [REDACTED])

Rats - Intraperitoneal LD50 = 312 mg/kg

Rats - Acute Inhalation LC50 - (not determined)

103.2

Birds

Organism	Test	Results	% Active	Category
Mallard duck	acute oral LD50	1466 mg/kg	Tech	Core
Bobwhite quail	8-day dietary LC50	> 10,000 ppm	"	"
Japanese quail	"	"	"	Supp.
Mallard duck	"	"	"	Core

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103.3 Fish.

Organism	Test	Results	% Active	Category
Carp	96-hr. LC50	>100 ppm	Tech	Supp.
catfish	"	"	"	"
bluegill	"	"	"	"
guppy	"	"	"	"
trout	"	"	"	"
bluegill	"	150 mg/l	"	Core
rainbow trout	"	130 mg/l	"	"
"	"	132 mg/l	"	**
bluegill	"	139 ppm	"	**
rainbow trout	"	18.4 ppm	Ridomil ZEG	**
bluegill	"	27.0 ppm	"	**
Fathead minnow	embryo-larvae	MTC >9.1 mg/l	Tech	**

* USEPA BELTSVILLE LAB

103.4 Aquatic invertebrates

Organism	Test	Results	% Active	Category
<u>Daphnia magna</u>	48 hr. EC50	29.2 ppm	Tech	Supp.
"	"	28 mg/l	"	Core
"	"	121 ppm	"	**
"	"	12.5 ppm	Ridomil ZEG	**
"	invertebrate life-cycle	Adverse response between 1.2 & 2.7 mg/l	Tech	Core

* USEPA BELTSVILLE LAB

104.0 Discussion

Incremental Risk -

Because of a prior registration, this review will be restricted to a discussion of the incremental risk associated with the new uses. It is intuitively obvious that the areas and habitats associated with the above named uses are much greater than the areas and habitats associated with tobacco. There is a significant increase in exposure potential for non-target organisms associated with these uses.

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Toxicity to non-target organism -

The toxicity data for birds and mammals indicate there is little concern for acute and subacute problems. There are no data, however, identifying chronic toxicities nor is there sufficient information at this time to warrant the request for the data. The data for aquatic organisms indicate there may be a problem with the formulated product. Because all uses are terrestrial and label statements warn against aquatic contamination, there is little concern about aquatic problems caused by direct application.

Leaching potential -

The potential for this compound to leach or otherwise move into ground water or the aquatic environment seems to be a concern with EFB and possibly Tox. branch. The results of the invertebrate life-cycle and minnow embryo-larvae tests indicate there is little concern about chronic effects. The results of ground water monitoring study (EFB review dated 3-11-81) show the maximum residues to be below the critical levels determined by the chronic tests. The recent review from Tox Branch dated 5/18/81 (attached) also indicates mammalian acute and chronic effect levels considerably higher than the measured levels in the environment. Considering the available data, there is little chance of non-target fish or wildlife will be adversely affected by Ridomil leaching from the use site.

Adequacy of toxicity data-

The available toxicity data are sufficient to characterize Ridomil's toxicity to non-target wildlife.

Additional data required-

Additional data will not be required for this registration.

107.0 Conclusions

Ecological Effects Branch has no objection to the conditional registration of Ridomil® 2E for the use stated on the cover sheet.

John Tice *John Tice*
Fish and Wildlife Biologist, EEB

6-26-81

for Harry Craven *6/26/81*
Section Head, EEB.

Clayton Bushong *Clayton Bushong* *6/26/81*
Chief, Ecological Effects Branch, EEB

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