US EPA ARCHIVE DOCUMENT

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(2)

EEE BRANCH REVIEW

DATE: IN 7/13 OUT 8/27/79 IN ____ OUT ____ IN ____ OUT ____

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. Section 5

PETITION OR EXP. PERMIT NO. 7969-EUP-13 92224

DATE DIV. RECEIVED

DATE OF SUBMISSION

DATE SUBMISSION ACCEPTED

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

DATA ACCESSION NO(S). 098252

PRODUCT MGR. NO. Pane bianco

PRODUCT NAME(S) Ronilan

COMPANY NAME BASF Wyandote

SUBMISSION PURPOSE EUP-Stonefruits and Lettuce

CHEMICAL FORMULATION Active Ingredient: 3-(3,5-Dichlorophenyl)
-5-ethenyl-5-methyl-2,4-oxazolidinedione.....50%
Inerts.....50%

1

Ronilan

100.0 Section 5 Application

Ronilan is a contact fungicide used to control sclerotina drop on lettuce and brown rot (blossom blight and fruit rot stages) on stone fruits.

100.1 Application Rates/Methods/Directions

Ronilan will be applied in not less than 100 gallons of spray solution per acre of lettuce or stone fruit.

Application of Ronilan to lettuce crops will be by ground equipment with operating pressure of 50-100 PSI. The use of cone or flat fan nozzles is recommended as opposed to flood type nozzles.

Ronilan application for stone fruit crops (cherries, peaches, plums, etc.) will be made in accordance with orchard spray practices that provide thorough coverage of trees. Spray volume is relative to tree size.

100.1.1 Rate of Application

STONE FRUIT

Time and Rate of Application: On stone fruit two applications (minimum) should be made for control of brown rot blossom and twig blight and two applications for control of fruit brown rot as specified below (see table). Additional blossom sprays may be needed if disease conditions persist.

APPLICATION	CROP	TIMING	RATE LB PRODUCT/ 100 Gallons of Spray	
			*LOW DISEASE PRESSURE	*HIGH DISEASE PRESSURE
BROWN ROT BLOSSOM AND TWIG BLIGHT				
FIRST	APRICOTS	RED BUD		
	CHERRIES	EARLY POP-CORN		
	NECTARINES	PINK BUD		
	PEACHES	PINK BUD		
	PLUMS	GREEN TIP		
	PRUNES	GREEN TIP		
SECOND	SAME AS ABOVE	14 DAYS AFTER APPLICATION	1 1/2	2
SUBSEQUENT	UP TO 3 ADDITIONAL BLOSSOM SPRAYS MAY BE NEEDED ON A 7-10 DAY INTERVAL IF WET CONDITIONS WHICH FAVOR DISEASE PERSIST.			
FRUIT BROWN ROT				
FIRST	SAME AS ABOVE	21 DAYS BEFORE HARVEST	1 1/2	2
SECOND	SAME AS ABOVE	10-14 DAYS BEFORE HARVEST		

Based on previous history of disease infestation in the orchard or adjacent orchards.

LETTUCE

Time and Rate of Applications: For control of sclerotinia "drop" up to three applications may be made under certain conditions in one season as specified in the rate table below. Do not disturb soil after application.

APPLICATION	TIMING	RATE LB PRODUCT/ACRE	
		*LOW DISEASE PRESSURE	*HIGH DISEASE PRESSURE
FIRST	DIRECT SEEDED LETTUCE APPLICATION SHOULD BE MADE IMMEDIATELY (WITHIN 2 DAYS) AFTER THINNING. TRANSPLANTED LETTUCE APPLICATION SHOULD BE MADE 7-10 DAYS AFTER TRANSPLANTING.	1	1 1/2-2
SECOND	APPLICATION SHOULD BE MADE 14 DAYS AFTER FIRST SPRAY IF COOL, WET CONDITIONS WHICH FAVOR DISEASE OCCUR FOR PERIODS LASTING 48 HOURS OR MORE.		
THIRD	APPLICATION SHOULD BE MADE 14 DAYS AFTER SECOND SPRAY IF CONDITIONS FAVORING DISEASE PERSIST.		

*Based on previous history of disease infestation in the field or adjacent fields.

100.2.1 Nozzle Arrangement

Applying Ronilan to one row beds, the spray booms should have at least two nozzles per row. For two row beds, use three nozzles or more per bed.

100.2.2 Restrictions

Do not apply Ronilan during rain. Spray must dry on plant inorder to be effective.

Do not apply more than six pounds of Ronilan in one season on lettuce. Do not apply more than fourteen pounds of Ronilan on stone fruits in one season.

100.2.3 Precautionary Labeling

Keep out of reach of children. Causes eye and skin irritation.

Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

100.3 Target Organisms

Fungous disease - effctive in controlling *Sclerotinia sclerotiorm* (lettuce drop) in lettuce and *Monilinia fructicola*, *M.laxa* (brown rot, blossom blight) in stone fruit.

100.4 Objectives

One of the primary objectives of the proposed program is to determine the optimum rate of application to achieve satisfactory disease control. Rates of .5, .75, and 1.0 lb. a.i./A will be tested on lettuce. However, in a given trial, only two rates will be tested. They will be paired as either .5 and .75 and 1.0. The .75 lb a.i. rate is the numeric average of the proposed rates and will be used in the calculations to determine material needs.

Stone fruit: rates of .75 and 1.0 lb. a.i./A will be used on stone fruits. An average rate of 0.87 will be used in calculation of quantities.

100.5 Proposed EUP Program

The objectives of the EUP Program are as follows:

1. Propose temporary tolerance for use on stone fruits and lettuce.

2. Ascertain residue levels on lettuce and stone fruit crops.

3. Determine the optimum rate of application to achieve disease control.

4. Test the product under the widely varying environmental conditions and production practices encountered throughout the country.

100.6 Duration/Date/Amount Shipped

1. Proposed period of shipment, February 1980 - February 1981.

2. Permission is requested for 9,333 lb. a.i. or 18,666 lbs. 50W product.

	A.i.	Product
Lettuce	2,025 lbs.	4,050 lbs.
Stonefruit	7,308 lbs.	14,616 lbs.
	9,333 lbs.	18,666 lbs.

100.6.1 Geographical Distribution

Lettuce

There are nine major production areas in the USA (see figure I). They include the states of California, Arizona, Colorado, New Mexico, Texas, Florida, New York, New Jersey, Michigan, Wisconsin, and Washington.

Stone fruits

There are six major production areas (see figure II) in the USA which are best represented by the states of: 1) California, 2) Washington and Oregon, 3) Arkansas, 4) South Carolina, 5) New Jersey, and 6) Michigan. Commercial acreages can also be found in Alabama, Delaware, Georgia, Illinois, Idaho, Indiana, Kentucky, Louisiana, Montana, New York, Pennsylvania, North Carolina, Ohio, Tennessee, Utah, Virginia, West Virginia, and Wisconsin.

101 Physical and Chemical Properties

101.1 Chemical Name

3-(3.5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2.4-dione

Chemical Abstracts Usage (50471-44-8):
3-(3.5-dichlorophenyl)-5-ethenyl-5-methyl-2.4-oxazolidinedione

FIGURE I
MAJOR LETTUCE PRODUCING AREAS AND STATES DESIGNATED
FOR ALLOCATION OF MATERIAL

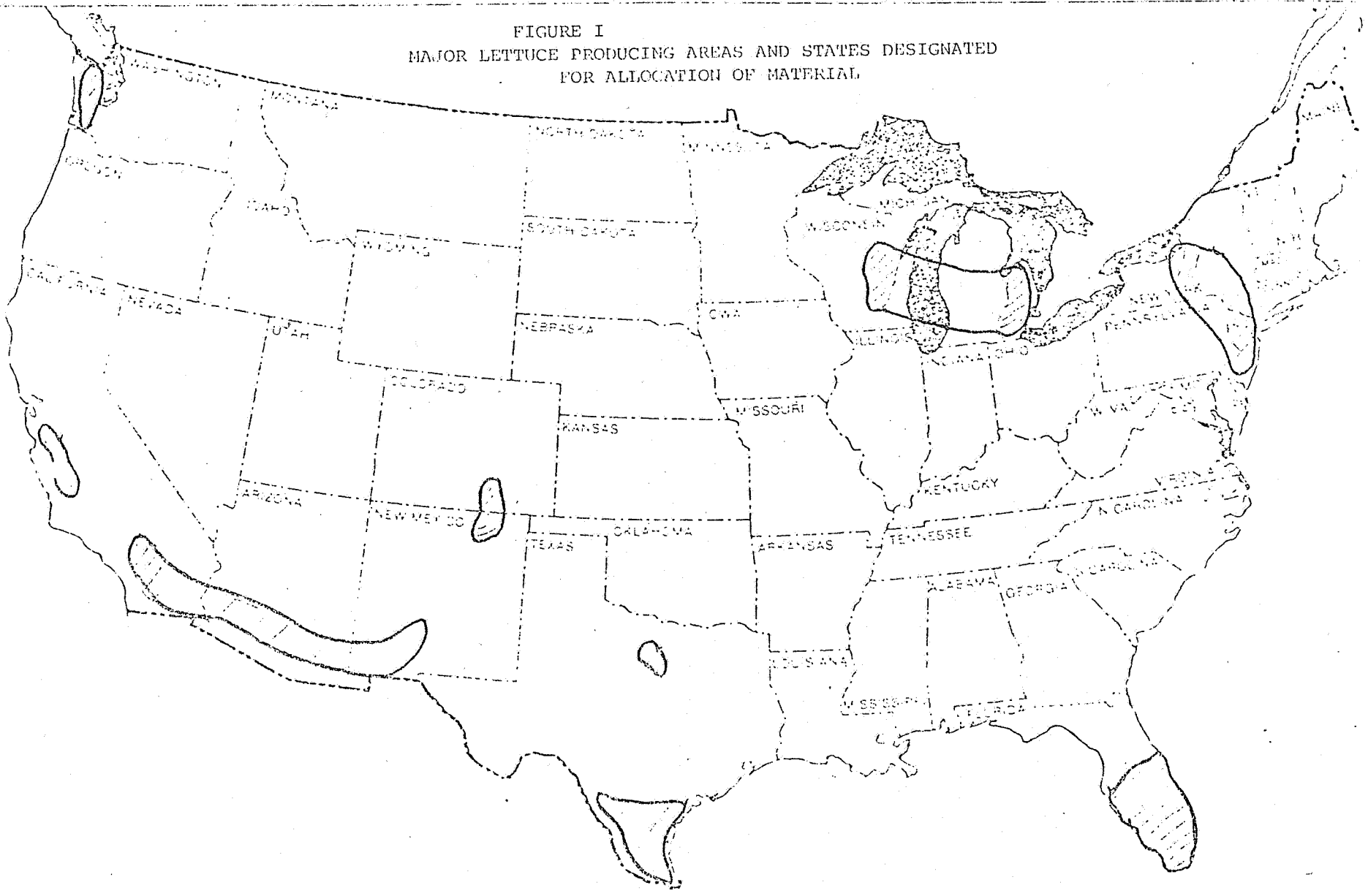
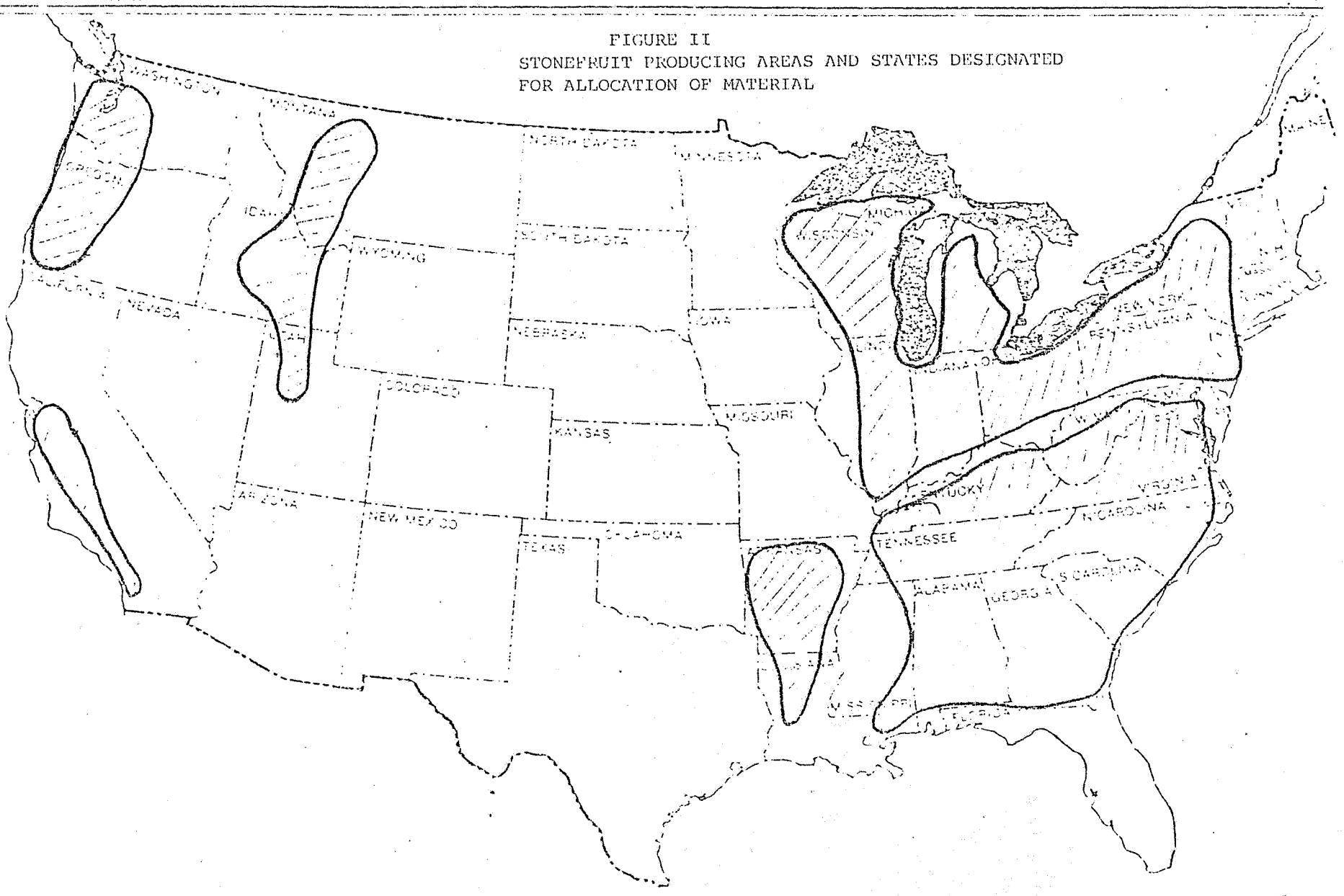
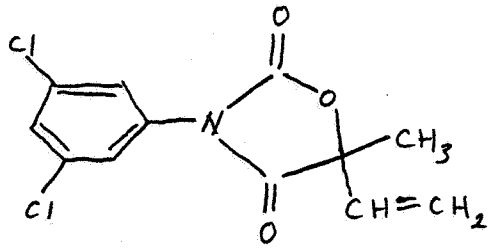


FIGURE II
STONEFRUIT PRODUCING AREAS AND STATES DESIGNATED
FOR ALLOCATION OF MATERIAL



101.2 Chemical Stucture



101.3 Empirical Formula

$C_{12}H_9NO_3Cl_2$

101.4 Molecular Weight

286.1

101.5 Common Name

Vinclozolin (proposed)

101.6 Synonymy

BAS 352 04 F

101.7 Trade Name

Ronilan

101.8 Physical and Chemical Properties

101.8.1 Color

White

101.8.2 Odor

Slightly odor, characteristic of aromatic compounds

101.8.3 Melting Point

108°C

101.8.4 Solubility

(g. compound in 100g. solvent at 20°C)

Water	< 0.1
Olive oil appr.	1.5
Ethylalcohol	1.4
Acetone	43.5
Ethylacetate	25.3
Cyclohexane	0.9
Ether	6.3
Benzene	14.6
Chloroform	31.9

101.8.5 Stability

At room temperature up to 40°C the technical active ingredient has been shown to be stable for two years. After two years at 50°C, 80% of the original active ingredient could be analysed.

102 Behavior in the Environment

102.1 Soil

The aerobic study was conducted for 240 days at 20°C on a standard loamy sand (2.5% OM; 40% wet, pH 6.8) spiked with BAS 352F (14-c-phenyl) at 7.0 ppm. The data shows about 99.5% of the applied remained after 45 days either bound (38%), as metabolite B (10%), or as extractable parent (37%).[1/]

102.2 Water

"Investigation into th Hydrolytic Stability of Vinclozolin as a Function of pH Value and Temperature."[2/]

	Parent-halflife*		Product(%)*	
pH	25°C	45°C	B	E
9	14 min.	15 min.	41	9
6	55 hrs.	10 hrs.	41	9
3	70 days	12 days	4	46

* Averages for concentrations of 0.18 and 1.8 ppm
**Estimates from data at 25°C.

Product	chemical
B	3,5-dichlorophenylcarbamic acid
E	N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide

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1/ EUP review for Vinclozolin (Ronilan) Brittan, E.B, 6/16/78, "Investigation of the Degradation of BAS 352F in Soil.

2/ EUP Review for Vinclozolin (Ronilan) Brittan, E.B., 6/16/78, "Investigation into the Hydrolytic Stability of Vinclozolin as a Function of pH Value and Temperature".

102.3 Plant [3/]

Lettuce Studies

BAS 352F-^{14}C is rapidly dissipated in lettuce. When applied at the rate of 1.12 kg a.i./ha (1 lb/A) at the "two-true leaf stage" and again 19 days later, the half-life of the compound was found to be 4.3 days from the last application.

Peach Studies

When 0.75 kg a.i./ha of BAS 352F (phenyl-U-^{14}C) was applied to 1-3 cm. diameter fruit as a 50% wettable power in an aqueous solution, the half-life of the total radioactive residues was 16 days. More than 80% of the total residues was extractable at all time periods.

103 Toxicological Properties

103.1 Acute Toxicity

Mammal

Rat LD_{50} > 10,000 mg/kg.
Guinea Pig LD_{50} = 8000 mg/kg.
Mouse LD_{50} = 5000 mg/kg.

103.2 Minimum Requirements

103.2.1 Avian Acute Oral LD_{50}

Bobwhite quail (Colinus virginianus)/LD_{50} >>2150 mg/kg-(96.5%)/Wildl. Interntl. Ltd. (1978)/Core - Felthousen (7/24/78)/(Pestic. Pet. 9F2205, Book 3; Acc. No. 098255: Rept. I-1).

103.2.2 Avian Dietary LC_{50}'s

Bobwhite quail (Colinus virginianus)/LC_{50} - >>5620 ppm - (96.5%)/Fink and Beavers, 1978 (Wildl. Interntl.)/Core - Balcomb (5/9/78)/(Pestic. Pet. 9F2205; Book 3; Acc. No. 098255: Rept. I-2).

Mallard (Anas platyrhynchos)/LC_{50} >>5620 ppm - (96.5%)/
Wildl. Interntl. Ltd. (1978)/
Core - Felthousen (7/24/78)/
(Pestici. Pet. 9F2205, Book 3: Acc. No. 098255, Rept. I-E).

3/ BASF Wyandotte Corp.
Agricultural Chemicals Division "A Petition for BAS 352F Fungicide Temporary Tolerances and EUP for Lettuce and Stonefruits," May 1979.

103.2.3 Fish Acute LC_{50}'s

Bluegill (Lepomis macrochirus)/96-hr. LC_{50} = 47.3 mg/l (37.1-60.3) (96.5%, resubmitted for the review)/Calmbacher, 1978 (UCES)/Supplemental - Balcomb (5/9/78)/(Pestic. Pet. 9F2205, Book 3; Acc. No. 098255, Rept. I-4).

Rainbow Trout (Salmo gairdner:Richardson) LC_{50} > 18.0 mg/l - (96.5%) Calmbacher, 1978 (UCES)/, resubmitted for the review)/Supplemental-Balcomb (5/8/78)/(Pestic. Pet. 9F2205, Book 3:098255, Rept. I-6).

103.2.4 Aquatic Invertebrate LC_{50}

Water Flea, (Daphnia magna straus) 48 hr. LC_{50} = 4.0 mg/l, the no effect level = 1.0 mg/l, (96.5%) Morrissey, 1978, (UCES),/ Core Data, Felthousen, (6/28/78), (Pestic. Pet. 9F2205, Book 3:098255, Rept. I-8).

104 Hazard Assessment

104.1 Discussion

Ronilan will be applied to lettuce and stonefruits at experimental rates of 1 lb. a.i. (2 lbs product) per acre per season. The time and frequency of application differs with the crop.

Lettuce

Three applications at 14 day intervals beginning at thinning or within 7 days of transplanting. The total amount is limited to 6 pounds of products per acre per season.

Stonefruits

Two applications in the early blossom period at a 14 day interval followed by as many as three more blossom sprays at 7-10 intervals. This is followed by two preharvest applications, one at 21 days before harvest and a second at 10-14 days before harvest.

104.1.1 Hydrolysis

At pH 6, the half-life of Vinclozolin was found to be 61 hrs. Metabolite B and E (page 6 Report J-2) were the predominant hydrolysis products at pH 6. The n-octanol/water partition coefficients are 1000 and <10, respectively.

104.1.2 Geographical Site Features

Refer to section 100.6.1 of this report.

Average Plot Size For EUP Lettuce

The average plot size in the western producing states of California, New Mexico, Texas, should be a minimum of 5A. However, in the Northeast and Central States, a plot size of 1/2 acre will be used. A total of 4,050 lbs of Ronilan will be used in 11 different states.

Stone fruits

The average plot size for stone fruits is 5A. A total of 14,616 lbs. of Ronilan will be distributed in 25 states.

104.1.3 Residue Estimates

Residue estimates for the maximum rate of application are given below:

Vegetation type	Residues from 1.0 lb a.i./acre[4/]	.5 lb. a.i./acre
Dense Foliage	58 ppm	29 ppm
Fruits	7 ppm	3.5 ppm
Soil (0.1 inch)	22 ppm	11.0 ppm
Water (0.5 ft.)	734 ppb	367 ppb

Strawberry plots in California received a total of 24 applications at a rate of 0.25-2 lbs a.i./A each. Twelve of the applications were applied in 1977, followed by 12 applications in 1978. Residue data obtained from the 1977 portion of the trials ranged from 0.16 ppm to 7.8 ppm, depending upon treatment rate, interval between treatments, and the TSI. The samples from the 1978portion of the trial were taken 0-7 days after the 18th and 24th application. Residue values ranged from 0.48-6.89 ppm, depending on the same factors as above. There appears to be very little difference in the residue data obtained from strawberries treated only in 1977 and those receiving an equivalent number of applications in both 1977 and 1978. A significant build-up of residues after continued multiple applications was not demonstrated.[5/]

4/ Expected Residues from Hoerger and Kenaga (1972) and Kenaga (1973). Expected Residues from 1.0 lb a.i./acre application.

5/ PP#9F2205 BAS 352F in or on strawberries. Evaluation of analytical methodology and residue data, M. Nelson, Chemist, RCB, HED (TS-769).

104.2 Likelihood of Adverse Effects to Non-Target Organisms

1. Vinclozolin appears to be moderately toxic to aquatic invertebrates (48 hr. LC_{50} = 4.0 ppm). The 96 hr. Bluegill Sunfish and Rainbow Trout study for BAS 352F produced LC_{50} = 47.3 mg/l and >18.0 mg/l, respectively. A white Flocculent formed in the trout study at concentrations >18 mg/l, and in the Bluegill study on the water surface in all concentrations. Although the technical material may be relatively insoluble in water, the formulated product may behave differently, creating a potential hazard to aquatic organisms. Most pesticides are applied as formulated products containing solvents, carriers, emulsifiers, wetting agents, etc.[6/]

   The expected method of application to stone fruits (spray mist blowers) and the number of applications (7 per growing season) can increase the potential for hazardous exposure to aquatic organisms. Concentrations in water greater than 0.01 of the LC_{50} (>.4 ppm) can create a potential hazard to aquatic life and fish embryo-larvae stages.

2. Wildlife use of lettuce and/or stone fruit crops is estimated (Wildlife Utilization of Cropland, Shell Oil, 1973) to range from low to high throughout the country. Major concern to wildlife is where birds may be subjected to repeated or continued exposure of Vinclozolin especially preceding or during the breeding season. the expected method of application to stone fruits (spray mist blowers) and the number of applications (7 per growing season) can create a potential for hazardous exposure for breeding species.

104.3 Endangered Species Considerations

No hazard is anticipated.

104.4 Adequacy of Toxicity Data

The following studies have been validated as "Core" and are considered adequate to support the registration of Vinclozolin for use as a fungicide on stone fruits and lettuce.

1. Avian acute oral LD_{50} >2510 mg/kg - Bobwhite Quail; Wildl. Interntl. Ltd. (1978); Felthousen (7/24/78).

2. Avian dietary LC_{50} >5620 ppm Bobwhite Quail; Fink and Beavers. (1978), Wildl. Interntl. Ltd., Balcomb (5/9/78).

6/ Fred Betz, Environmental Safety Section, EPA, "Use of Solvents in Aquatic Testing," 2/27/78.

3. Avian dietary LC_{50} >5620 ppm Mallard Duck; Fink and Beavers (1978), Wildl. Interntl. Ltd. Felthousen (7/24/78).

4. Aquatic invertebrate LC_{50} >4.0 mg/l. Daphnia magna; UCES, (1978) UCES; Felthousen (7/24/78).

The following studies have been validated as "Supplemental" and are not considered adequate to support the registration of Ronilan TM (Vinclozolin).

Fish acute LC_{50}

1. Bluegill Sunfish; Calmbacher (1978) Balcomb (5/9/78); - Objections are as follows: White Flocculent produced on the surface of the water in all concentrations - inadequate dose response data.

   Fish acute LC_{50} 96 hr Rainbow trout; Calmbacher (1978); Balcomb (5/9/78); Objections noted were as follows: lack of adequate dissolution of test material as evidenced by the presence of white flocculent material above 18 ppm - inadequate dose-response data.

104.5 Additional Data Required

Prior to consideration of registration of the proposed use, certain basic studies are required:

a) 96-hour LC_{50}'s for a coldwater species (Rainbow Trout) and a warmwater species (Bluegill Sunfish) of Fish. Refer to Conclusions 104.6.

b) An avian reproductive study is required for Bobwhite Quail and Mallard Duck. This test is triggered by the multiple application (7x) rate of Vinclozolin to stone fruits.

104.6 Conclusions

The Ecological Effects Branch does not object to this proposed EUP. The registrant should be informed of the following data inadequacies that will need to be addressed prior to consideration of registration for stone fruit and lettuce crops.

a) The solubility problem (refer to 104.4) encountered with the technical of the active ingredients for the Fish acute LC_{50} tests, must be corrected prior to registration. Please submit a list of solvents used.

   No standard protocol exists for such solubility problems. However, you may wish to contact Dr. Wesley

J. Birge at the University of Kentucky, Lexington, Kentucky. Dr Birge has developed a flow through system for testing various suspensions.

If the registrant submits the acute aquatic test using a satisfactory suspension testing system the studies will be reconsidered.

b) The use pattern on stone fruits requires an avian reproduction study be conducted on bobwhite quail and mallard duck. The material tested must be the technical grade of the active ingredient.

c) The registrant should report to the Ecological Effects Branch any adverse effects that occur to non-target species from both the stone fruit use and lettuce use of Vinclozolin.

The registrant should contact the Ecological Effects Branch for assistance concerning test methods and protocols.

Michael Rexrode 9/10/79

Michael Rexrode
Ecological Effects Branch
August 27, 1979

David Coppage 9/10/79

David Coppage, Section Head
Ecological Effects Branch

Clayton Bushong 9/11/79

Clayton Bushong, Chief
Ecological Effects Branch
Hazard Evaluation Division