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THE BRANCH REVIEW

DATE: IN 7/24/78 OUT 8/22/78 IN OUT IN OUT

EFFICACY

FILE OR REG. NO..

PETITION OR EXP. PERMIT NO. 359-EUP-58 862087

DATE DIV. RECEIVED

DATE OF SUBMISSION

DATE SUBMISSION ACCEPTED

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

DATA ACCESSION NO(S) .

PRODUCT MGR. NO. (21) E. Wilson

PRODUCT NAME(S) ROVRAL

COMPANY NAME Rhodia

SUBMISSION PURPOSE EUP on cherries and peaches

CHEMICAL & FORMULATION Iprodione 3-(3,5 dichlorophenyl)-N-

(1-methylethyl)-2,4-dioxo-1-imidazolidine
carboxamide

See
Ad Chem. review
inside

100.0 Pesticidal Use

ROVRAL is a fungicide recommended for fruit brown rot and brown rot blossom ^{blight} ~~rot~~ in stone fruits. The first year of the program specified peaches and cherries.

100.1 Application Methods/Rates/Directions

ROVRAL is a wettable powder formulation recommended for blossom and fruit brown rot control on stone fruits. Apply as a foliar spray in sufficient water to obtain thorough coverage. The spray mixture should not be allowed to stand overnight as some breakdown of the product may occur from prolonged delays, particularly in water with a high pH. Maintain agitation during spray operations.

Dosage Rate and Timing

West of the Rocky Mountains - Use 0.5 lb a.i. to 1.0 lb a.i./A for ground applications and 0.5 lb a.i. to 2.0 lb a.i. for aerial applications.

Brown Rot Blossom Blight: Apply at early bloom and if conditions are favorable for disease development, make a second application at full bloom.

Fruit Brown Rot: After blossom applications, apply a preharvest spray two weeks before harvest. Make a second application up to 1 week prior to or at harvest if conditions favorable for disease development persists.

East of the Rocky Mountains - Use 0.5 lb a.i. to 1.0 lb a.i./A. Ground applications only.

Brown Rot Blossom Blight: 3 blossom sprays should be applied; the first at the pink bud to early bloom stage, the second at full bloom and the third at petal fall.

Fruit Brown Rot: After blossom blight sprays, make two preharvest applications; the first spray should be applied 2 weeks before harvest and the second up to 1 week prior to or at harvest.

100.3 Precautionary Labeling

Environmental Hazards

Keep out of lakes, streams, and ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

100.4 Proposed EUP Program

100.4.1 Objectives

1. The major objective of this program is to obtain additional efficacy and phytotoxicity data for ROVRAL applied under commercial conditions. This information is needed in order to clarify the optimum use rate. The ROVRAL treatments will be compared to a Benlate combination standard.
2. Residue samples will be taken from the aerial tests, in addition to efficacy data. This will determine if the total residue in or on the stone fruit is affected by aerial applications.
3. Long Range Testing Plans - application of ROVRAL as a fungicide for stone fruit will involve a two-year program under the Experimental Use Permit. The second year of the EUP will be devoted to testing for different diseases and will include other stone fruits (apricots, nectarines, plums and prunes). The second year EUP will include more aerial tests on a wider range of stone fruits. The objectives for the second year's testing will also be determined by the results of the first year's testing.

100.4.2 Duration/Date/Amount Shipped

Registrant requests a permit for two years, beginning in January, 1979. However, no details were included in regard to the second year. A total of 1428 pounds a.i. are requested to treat 438 acres as follows:

- GROUND APPLICATION -

PEACHES

<u>STATE</u>	<u>NO. OF TESTS</u>	<u>TOTAL ^{1/} ACREAGE</u>	<u>AVERAGE NO. APPLICATIONS</u>	<u>TOTAL lbs. a.i.</u>
AL	1	6	5	22.5
CA	6	72	3.5	189.0
GA	1	6	5	22.5
MI	2	12	5	45.0
NJ	2	12	5	45.0
NY	1	6	5	22.5
NC	2	12	5	45.0
OH	1	6	5	22.5
OK	1	6	5	22.5
OR	2	24	3.5	63.0
PA	1	6	5	22.5
SC	3	18	5	67.5
TX	2	12	5	45.0
VA	1	6	5	22.5
WA	<u>1</u>	<u>12</u>	<u>3.5</u>	<u>31.5</u>
TOTAL:	27	216		688.5

CHERRIES

<u>STATE</u>	<u>NO. OF TESTS</u>	<u>TOTAL ^{1/} ACREAGE</u>	<u>AVERAGE NO. APPLICATIONS</u>	<u>TOTAL lbs. a.i.</u>
CA	3	36	3.5	94.5
MI	5	30	5	112.5
NY	3	18	5	67.5
OR	3	36	3.5	94.5
PA	2	12	5	45.0
WA	2	24	3.5	63.0
WI	<u>1</u>	<u>6</u>	<u>5</u>	<u>22.5</u>
TOTAL	19	162		499.5

- AERIAL APPLICATION -

<u>STATE</u>	<u>NO. OF TESTS</u>	<u>PEACHES</u>		
		<u>TOTAL ^{2/} ACREAGE</u>	<u>AVERAGE NO. APPLICATIONS</u>	<u>TOTAL lbs a.i.</u>
CA	4	60	4	240

The second year will require an estimated 2500 pounds a.i. to treat an estimated 750 acres. State assignments will be finalized after the results of the first year program are in.

100.4.3 Application Procedures

See Section 100.4.1

100.4.4 Target Pest

Monilinia fructicola

101.0 Chemical and Physical Properties

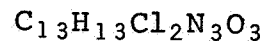
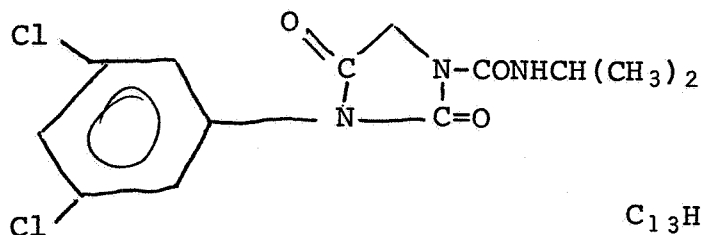
101.1 Chemical Name

3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidine carboxamide

101.2 Common Name

Iprodione, chipco 26019 (trade name), glycophene, RP 26019

101.3 Structural Formula



101.4 Molecular Weight

330.17

101.5 Physical State

Odorless, cream colored powder

101.6 Solubility

At 20°C

water ~ 13 ppm
ethanol ~ 24 gm/l
acetone ~ 25 gm/l
methyl chloride ~ 500 gm/l

102.0 Behavior in the Environment

The environmental chemistry file was consulted on 8/18/78. The EC data for the current EUP was previously reviewed for another EUP by R.F. Carsel on 3/14/77. This information was abstracted in Environmental Safety review by G. L. Gavin (3/21/77) and is summarized below. Some additional data is currently being processed by EFB in conjunction with a turf grass registration.

102.1 Soil

The soil half-life following application of 2-5 ppm was 30 days aerobic and 50 days anaerobic at 25°C. Bound residues exist in soil after 80 - 100 days at pH 7.3. Half-life is shorter at higher temperatures and/or in light soils. In leaching studies in 30 cm columns, this product leached 10 - 15 cm under simulated rain conditions of cm in 30 hours.

Under natural field conditions, the half-life was 20 - 40 days with the majority of the material remaining in the top 4 inches.

102.2 Water

Although not very soluble in water, Ipodione is stable under acid conditions ($T_{1/2}$ = 3 months at pH 5), but hydrolysis occurs at pH 6 ($T_{1/2}$ = 20 days)

and pH 9 ($T_{1/2}$ = 1 day).

R. F. Carsel (personal communication) indicated that photodegradation does occur, both in water and soil; this is based on new data.

103.0 Toxicological Properties

103.1 Acute Toxicity

103.1.1 Mammal

(reference: Environmental Safety review by G. L. Gavin, 3/21/77)

Rat acute oral LD_{50} (technical) = 3700 mg/kg

Rat acute oral LD_{50} (50% WP) = 12,500 mg/kg

103.1.2 Bird

(reference: ES review by L. A. Windberg, 7/15/77)

Bobwhite acute oral LD_{50} (technical) = 930 mg/kg
supplemental

Mallard acute oral LD_{50} (technical) >10,400 mg/kg
supplemental

103.1.3 Fish

(reference: ES review by L. A. Windberg, 7/15/77)

Rainbow trout 96-hour LC_{50} (technical) = 6.70
ppm, core

Channel catfish 96-hour LC_{50} (technical) = 2.63
ppm, core

Bluegill sunfish 96-hour LC_{50} (technical) - 2.25
ppm, invalid*

*This study was originally classified as invalid due to missing information. This information has since been submitted and the study has been reclassified as core.

103.1.4 Aquatic Invertebrate

(see attached validation sheets)

Daphnia pulex 72-hour LC₅₀ (tech) = 4.0 mg/l
supplemental, ES-H1 ✓

Daphnia pulex 72-hour LC₅₀ (50% W.P.) = 5.8 mg/l
supplemental, ES-H1 ✓

Daphnia magna 48-hour LC₅₀ (tech) = .43 ppm,
core, ES-H2 ✓

Daphnia magna 48-hour LC₅₀ (tech) = 7.2 mg/l
core, ES-H3 ✓

103.3 Subacute Toxicity

(reference: E.S. Review by L. A. Windberg, 7/15/77)

Bobwhite quail dietary LC₅₀ = 9200 ppm, core ✓

Mallard duck dietary LC₅₀ >20,000 ppm, core ✓

103.4 Chronic Toxicity

(reference: E.S. Review by J. T. Tice, 7/6/78)

In an invalid study, no apparent effect of dietary iprodione up to 114 ppm was observed on body weight, food consumption, mortality, egg production, fertility, or hatchability.

104.0 Hazard Assessment

104.1 Discussion

ROVRAL is proposed for application to peaches and cherries at a maximum rate of 2 pounds a.i./acre for aerial application and 1 pound a.i./acre for ground application. Residues expected from the 2 pounds/acre rate have been calculated assuming that 1/3 of the pesticide will fall upon the leaves of trees and 2/3 would reach the ground below.

Sum
2-22-

short grass (below trees)	-	320 ppm
leaves (trees)	-	42 ppm
forage (below trees)	-	77 ppm
forage (edge of orchard)	-	116 ppm
fruits	-	14 ppm
soil (top 1" below trees)	-	29 ppm
water (top 6", edge of orchard)	-	1.5 ppm

Applications may be made at early bloom, full bloom, and (in the east) petal fall in the spring, and 1 - 2 times preharvest.

104.1.1 Likelihood of Exposure to Non-target Organisms

According to Gusey and Maturgo (Wildlife Utilization of Croplands, 1972. Shell Oil Co.), both cherries and peaches are utilized by a number of wildlife species. Most upland game birds use these orchards primarily for non-feeding purposes, but many songbirds and others do feed on buds, fruits, and associated insects. Mammalian use of cherry and peach orchards is higher than for many crops. Deer, rabbits, racoons, and squirrels feed in the orchards on plant materials, and others use orchards for cover. There is also a moderate use by small predators.

In spite of the moderate to high use of orchards by non-target animals, the toxicity of iprodione to birds and mammals is fairly low, with the rat oral LD₅₀ being 3700 mg/kg and the bobwhite dietary LC₅₀ being 9200 ppm. All expected residue maximums (Section 104.1) are well below these values. Iprodione is only moderately toxic to fish, with 96 hour LC₅₀ values from 2.25 to 6.70 ppm. These values are also above the expected residues in water, even if the water was subjected to a label rate spray.

This reviewer concludes, on the basis of toxicity well below expected residue levels and the limited acreage, that the hazard to non-target animals is zero to negligible.

104.1.2 Endangered Species Consideration

For the same reasons noted above, no adverse impact is expected on endangered species.

104.1.3 Adequacy of Data

In prior submissions, both avian dietary studies and both fish studies were found acceptable. The avian acute oral and avian reproduction studies were not acceptable. In the current submission, 2 of 3 daphnia studies were found acceptable.

104.1.4 Additional Data Required

1. Avian acute oral LD₅₀
2. Avian reproduction studies because of persistence and repeat applications.

107.0 Conclusions

107.1 Environmental Fate and Toxicology

Environmental fate information was obtained from EFB Review by R. F. Carsel (3/14/77), personal communication from R. F. Carsel (8/21/78), and Environmental Safety Review by G. L. Gavin (3/21/77). Toxicology data was also taken from the review by Gavin.

107.4 Data Adequacy

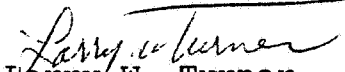
Previously submitted avian dietary and fish acute studies were found acceptable to support registration; avian acute oral and avian reproduction studies were not acceptable to support registrations. For rationale on these determinations, refer to previous Environmental Safety reviews by L. A. Windberg (7/15/77) and J. T. Tice (7/6/68). Of the three daphnia studies reviewed in this submission, the two conducted by Cannon Laboratories and Union Carbide Environmental Services were acceptable, the third was not acceptable for various reasons including no 48-hour LC₅₀ determination, variable temperature, and high control mortality.

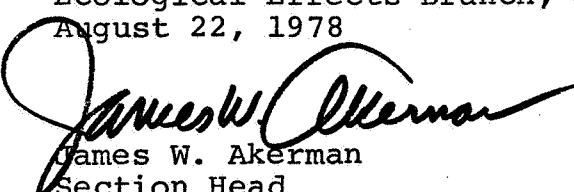
107.5 Data Requests

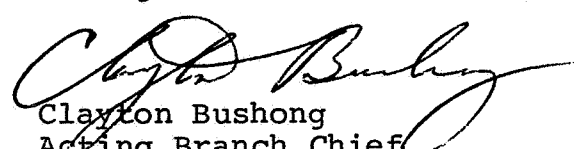
Prior to consideration of registration, an avian acute oral LD₅₀ study on either mallard duck or bobwhite quail is required to satisfy the minimum requirements for registration. In addition avian reproduction studies for both bobwhite quail and mallard duck are required for this use pattern because of the repeat applications, the timing of applications, and the persistence of Iprodione. All the above studies must be conducted using the technical grade of Iprodione. The registrant should contact the Ecological Effects Branch prior to starting the avian reproduction studies.

107.7 Recommendations

The Ecological Effects Branch has made a preliminary hazard assessment for the first year of this 2-year proposed EUP, and has concluded that there is little hazard to non-target organisms. Because the crops, details, states, and acreages were not specified for the second year of the program, no hazard assessment could be made beyond the first year.


Larry W. Turner
Ecological Effects Branch, Section 1
August 22, 1978


James W. Akerman
Section Head
Ecological Effects Branch, Section


Clayton Bushong
Acting Branch Chief
Ecological Effects Branch

VALIDATION SHEET

CRF # _____ PAGE 1 OF 1

FORMULATION: % a.i. SC # CHEMICAL NAME (a) Technical Iprodione (b) 50% W.P.			IA	IB	T	FW	EC	R				
			Validator: Larry Turner						Date: August 14, 1978			
			Test Type: Aquatic invertebrate acute toxicity <u>Daphnia pulex</u>									
			Test ID.# ES-H1									

CITATION: Ambrosi, D., J. Desmoras, and L. Lacroix. 1977. Toxicity of R.P. 26 019 to Daphnia (Daphnia pulex). 5 p. Submitted by Rhodia, Inc.; 359-EUP-58; Acc #232703, 1/13/78.

RESULTS: Daphnia pulex 72-hour LC_{50} (tech) = 4.0 mg/l (95% c.i. 2.9 - 5.5 mg/l); for the 50% W.P., 72-hour LC_{50} = 5.8 mg/l (95% c.i. 3.2 - 10.3 mg/l). For the technical product, 32% mortality occurred at the lowest dose of 1 mg/l; 100% mortality occurred at the lowest dose of 16 mg/l; 100% mortality occurred at the highest dose of 32 mg/l. Control mortality was 14%. Data was included, but no calculations made for 48 hour mortality.

VALIDATION CATEGORY: Supplemental

CATEGORY RATIONALE: This study was classified as supplemental because, although it provided useful information, the temperature was too variable, the control mortality was slightly excessive, the 48 hour LC_{50} could not be determined except as an estimated value, and procedural details were extremely brief.

CATEGORY REPAIRABILITY: No repair is possible.

ABSTRACT: Daphnia pulex were exposed for 72 hours to technical Iprodione in concentrations of 1, 2, 4, 8 and 16 mg/l and to the 50% WP in concentrations of 1, 2, 4, 8, 16, and 32 mg/l. Concurrent controls were also tested. Each concentration, and the controls, had two replicates with each replicate having from 46 - 106 daphnids. Daphnids were less than 3 days old. Temperature was $25 \pm 1^{\circ}C$ during the day and at night. No other procedural details were reported.

Complete mortality data was included, but only as estimated figures for 24 and 48 hours. With 14% control mortality, Abbot's formula was used to correct mortality data. The method of LC_{50} determination was not reported however, it was stated that mortality was converted to probits. No statistical check was run since this study will not support registration.

For the 50% W.P., 30% mortality occurred at the lowest dose of 1mg/l.

VALIDATION SHEET

CRF # _____ PAGE 1 OF 1

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC #	CHEMICAL NAME	Validator:					Date:		
94.5%		Iprodione	Larry Turner					8/14/78		
			Test Type:							
			Aquatic invertebrate acute toxicity <u>Daphnia magna</u>							
			Test ID.# ES-H2							

CITATION: Roberts, Steven. 1977. Report: 48-hour static LC₅₀ of RP 26019 technical in Daphnia magna. 9 p. Study conducted by Cannon Laboratories. Submitted by Rhodia, Inc.; 359-EUP-58, Acc # 232703, 1/13/78.

RESULTS: Daphnia magna 48-hour LC₅₀ = 0.43 ppm (95% c.i. 0.31 - 0.60 ppm). Mortality was 20% at the lowest concentration of 0.1 ppm and 90% at the highest concentration of 1.0 ppm. Vehicle control mortality was 10%; untreated control mortality was 5%.

VALIDATION CATEGORY: Core

CATEGORY RATIONALE: Meets requirements for this test type.

ABSTRACT: Young Daphnia magna, 12 + 12 hours old, were exposed to iprodione in concentrations of 0 (control and acetone control), 0.1, 0.3, 0.5, 0.7 and 1.0 ppm for 48 hours. An initial range-finding test was conducted with 5 daphnids per concentration. For the definitive test, 4 replicates of 5 daphnids each were tested at each level. Tests were conducted in beakers containing 200 ml of water. The source of the water was not given, but most water chemistry data was reported, excepting D.O. Test temperature was 17 ± 1°C. Vessels were not aerated during the test, nor were daphnids fed.

The LC₅₀ was determined by the method of Litchfield and Wilcoxon. When checked with Finney probit, an LC₅₀ value of .382 ppm was obtained, which is within the confidence limits reported.

VALIDATION SHEET

CRF # _____ PAGE 1 OF 1

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC #	CHEMICAL NAME	Validator:					Date:		
94.5%		Iprodione	Larry Turner					8/14/78		
			Test Type:							
			Aquatic invertebrate acute toxicity <u>Daphnia magna</u>							
			Test ID.# ES-H3							

CITATION: Vilkas, Algirdas G. 1977. The acute toxicity of RP 26019 technical to the water flea Daphnia magna straus. 7 p. Study conducted by Union Carbide Environmental Services. Submitted by Rhodia, Inc.; 359-EUP-58, Acc # 232703, 1/13/78.

RESULTS: Daphnia magna 48 hour LC_{50} = 7.2 mg/l (95% c.i. 6.0 - 8.6 mg/l). Mortality was 20% at the lowest concentration of 3.2 mg/l; 100% mortality occurred at the highest concentrations of 18 and 32 mg/l. No control or solvent control mortality occurred.

VALIDATION CATEGORY: Core

CATEGORY RATIONALE: Meets requirements for this type of test.

ABSTRACT: First instars of Daphnia magna were exposed for 48 hours to Iprodione in concentrations of 0 (control and acetone control), 3.2, 5.6, 10.0, 18.0, and 32.0 mg/l. Four replicates of 5 daphnids each were tested at each dose level. The test was conducted in beakers containing 200 ml of water. Water was obtained from a small lake and was filtered before use. Water chemistry data was reported. Temperature was $17 \pm 1^{\circ}C$. Investigators stated that practices followed Stefan (1975).

The LC_{50} was determined by the Spearman-Kärber estimator as given by Finney (1971). When checked by our α -trimmed Spearman-Kärber, a similar value of $>.79$ mg/l was obtained.

✓