201030
RECORD NO.

109801
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 08/20/87 OUT 2-29-88

FILE OR REG. NO. 359-685

PETITION OR EXP. NO.

DATE OF SUBMISSION 02/06/86

DATE RECEIVED BY HED 08/18/87

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EEB ESTIMATED COMPLETION DATE 12/07/87

RD ACTION CODE/TYPE OF REVIEW 335

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. L. Rossi (21)

PRODUCT NAME(S) Rovral

COMPANY NAME Rhone-Poulenc, Inc.

SUBMISSION PURPOSE Proposed registration of potato use

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
109801	Rovral (Iprodione)	50.0

EEB REVIEW

100.0 Pesticide Label Information

100.1 Pesticide Use

Rovral is a wettable powder formulation of iprodione for the control of early blight (Alternaria solani) and white mold (Sclerotinia sclerotiorum) on potatoes.

100.2 Formulation Information

Active Ingredient:
Iprodione: 3-(3,5-dichlorophenyl)-N-(1-methyl-ethyl)-2,4-dioxo-1-imidazolidinecarboxamide . . 50.0%
Inert Ingredients: 50.0%

100.3 Application Methods, Directions, Rates

"HOW TO USE ROVRAL ON POTATOES

A single, flat fan, or cone nozzle should be centered and adjusted to provide complete coverage of each row. Up to 4 applications can be made per season. Do not apply within 14 days of harvest.

Apply Rovral using ground equipment in sufficient water for thorough coverage (minimum 10 GPA), in accordance with the directions in the following table:

DISEASE	Lb PRODUCT/ ACRE	TIMING OF APPLICATIONS
Early Blight (Alternaria solani)	2.0	Begin applications when conditions first become favorable for disease development. Up to 3 subsequent applications can be applied at 7-10 day intervals or as required.
White Mold (Sclerotinia sclerotiorum)	2.0	Apply immediately prior to row closing and, if conditions are favorable for disease development, again 28 days later."

"GENERAL INFORMATION

Rovral is a wettable powder formulation of iprodione for the control of certain diseases on Stone Fruits and Nuts, Grapes, Leafy Vegetables, Vegetables and Certain Field Crops.

HOW TO USE ROVRAL

Partially fill the spray tank with clean water. Measure the required amount of Rovral and pre-mix with a small volume of water, add this to the tank. Agitate to ensure thorough mixing while filling tank with remaining water. Maintain agitation during application and apply with properly calibrated application equipment. Do not allow spray mixture to stand overnight or for prolonged periods, as some chemical breakdown may occur, particularly in water with a high pH."

100.4 Target Organisms

Early blight (Alternaria solani)
White mold (Sclerotinia sclerotiorum)

100.5 Precautionary Labeling

"CAUTION

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.

ENVIRONMENTAL HAZARDS

Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes."

101.0 Chemical and Physical Properties

(From EAB review dated May 6, 1986.)

101.1 Common Name

Iprodione

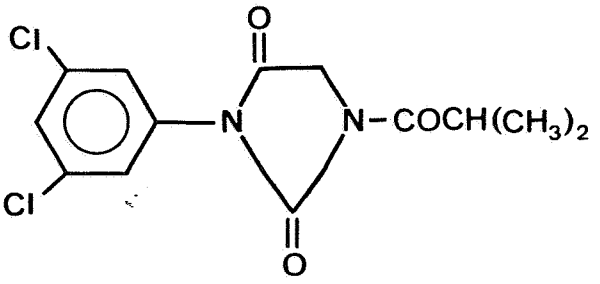
101.2 Chemical Name

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

101.3 Trade Name

Rovral Fungicide 50 WP

101.4 Chemical Structure



102.0 Behavior in the Environment

(From EAB files - mainly October 16, 1978.)

Hydrolysis

Tested in buffered solution at pH 3, 6, and 9. The half-lives/stability findings were: stable at pH 3, half-life of about 20 days at pH 6 and half-life of about 1 day at pH 9.

Photodegradation (Water)

Half-life was estimated to be between 72 and 187 hours.

Solubility

Acetone 300 mg; almost insoluble in water at 13 mg/L, and benzene 200 mg.

103.0 Toxicological Properties

103.1 References from Toxicology Branch

Species	Results
Rat (acute oral LD_{50})	3700 mg/kg
Rat (3-generation)	500 mg/kg - NOEL

103.2 Minimum Requirement (see review dated April 4, 1983)

Mallard duck	> 20,000 ppm	Core
Bobwhite quail - Acute oral LD_{50}	930 mg/kg	Core
Bobwhite quail - LC_{50}	9200 ppm	Core

Bobwhite quail	Rep. NOEL > 300 < 1000 ppm	Core
Mallard duck	Rep. > 300 < 1000 ppm	Core
Rainbow trout - LC_{50}	4.2 ppm	Core
Bluegill sunfish - LC_{50}	6.3 ppm	Core
Daphnia magna - LC_{50}	0.43 ppm	Core
Channel Catfish - LC_{50}	3.06 ppm	Core

103.0 Maximum Expected Residues on Vegetation, Soil, and Water (ppm)

Short rangegrass	240.0
Long grass	110.0
Leaves and leafy crops	125.0
Forage - alfalfa, clover	58.0
Pod containing seeds - legumes	12.0
Soil in 0.1 inch	22.0
Water 6.0 ft depth	0.061

A Program for Pesticide Fate Simulation

Daily Accumulated Pesticide Residues on Short Grass After Multiple Applications

Chemical name	Rovral
Initial concentration (ppm)	240
Half-life	20
Number of applications	4
Application interval	7
Length of simulation (day)	21

Day	Residue (ppm)	
0	240	First applic.
1	231.8247	
2	223.9279	
3	216.3001	
4	208.9321	
5	201.8151	
6	194.9406	
7	428.3002	2nd applic.
8	413.7107	
9	399.6182	
10	386.0057	
11	372.857	
12	360.1561	
13	347.8878	
14	576.0375	3rd applic.
15	556.4155	
16	537.462	

17	519.1541	
18	501.4698	
19	484.3879	
20	467.8878	
21	691.9498	4th applic.
Maximum residue		691.9498
Average residue		389.1382

103.3 Estimated Environmental Concentration (EEC) Calculations

For foliar application

- Runoff

1 lb x 0.02 (2% runoff) x 10(A) (from 10 A drainage basin) = 0.20 lb (tot. runoff)

EEC of 1 lb ai direct application to 1 A pond 6-feet deep = 61 ppb.

Therefore, EEC = 61 ppb x 0.20 (lb) = 12.2 ppb or 0.012 ppm.

103.7 Daily Accumulated Residue in Water Resulting from Runoff (ppm)

This section is used to determine if a 2% runoff from a treated field using four 1.0 lb ai application/A will exceed 1/10th the LC_{50} value for nontarget aquatic organisms or 1/20th the LC_{50} for aquatic endangered species. A 1.0 lb ai/A application will be applied on days 0, 7, 14, and 21. The accumulated residue levels on the above-mentioned days will be used to determine if Rovral will have an impact on nontarget aquatic organisms.

A Program for Pesticide Fate Simulation

Daily Accumulated Pesticide Residues---Multp. Appl.

Chemical name	Rovral
Initial concentration (ppm)	.012
Half-life	20
Number of applications	4
Application interval	7
Length of simulation (day)	21

Day	Residue (ppm)	
0	.012	0.012 ppm
1	1.159124E-02	

2	.0111964	
3	1.081501E-02	
4	1.044661E-02	
5	1.009076E-02	
6	9.747028E-03	
7	2.141501E-02	or 0.021 ppm
8	2.068554E-02	
9	1.998091E-02	
10	1.930029E-02	
11	1.864285E-02	
12	.0180078	
13	1.739439E-02	
14	2.880188E-02	or 0.028 ppm
15	2.782078E-02	
16	.0268731	
17	.0259577	
18	2.507349E-02	
19	2.421939E-02	
20	2.339439E-02	
21	3.459749E-02	or 0.035 ppm
Maximum residue ----------		3.459749E-02
Average residue ----------		1.945691E-02

104.0 Hazard Assessment

104.1 Discussion

The proposed registration of Rovral (iprodione) is for use on potatoes for control of early blight (Alternaria solani) and white mold (Sclerotinia sclerotiorum) fungus, with a maximum of four applications at 1 lb ai/A/season at 7- to 10-day intervals or as required.

The available data indicate Rovral is highly toxic to aquatic invertebrates, moderately toxic to rainbow trout, slightly toxic to avian species, and practically nontoxic to mammalian species.

104.2 Likelihood of Adverse Effects to Nontarget Organisms

The proposed use of Rovral 50 WP is at the rate of 2.0 lb of product/A (1.0 lb ai Rovral/A, single application) as a fungus control on potatoes. Rovral should provide for minimal acute hazard to both nontarget terrestrial wildlife and fish species. The maximum expected residue on vegetative food matter and aquatic EECs from 1.0 lb ai/A are well below 1/10th the LC_{50} values (birds 920 ppm vs 240 ppm); fish 0.42 ppm vs. 0.012 ppm).

A 2% runoff from a 1.0 lb ai/A application rate will result in 0.012 ppm concentration in 6.0 ft depth of water which is less than 1/10th the LC_{50} value for the most

sensitive aquatic invertebrate species (Daphnia magna) 0.012 vs. 0.043 ppm. A 2% runoff after four (1.0 lb ai/A) applications on day 21 will not exceed 1/10th the LC_{50} value for nontarget nonendangered aquatic invertebrates (0.035 ppm vs 0.043 ppm). However, the 21 day average estimated concentration (0.019 ppm) in water will exceed 1/100 the EC_{50} (0.004 ppm): Therefore, a chronic aquatic invertebrate is required.

EEB does not have a complete data set to determine the long-term effects of Rovral to nontarget organisms. (However, based on the mallard and bobwhite reproduction studies, it appears that minimal chronic hazards are likely for nontarget, nonendangered terrestrial wildlife.)

104.3 Endangered Species Considerations

Based on the available data, Rovral should provide for minimal acute hazard to terrestrial wildlife and fish species. The maximum expected residues on vegetative food matter are below 1/10th the LC_{50} value for avian species (720 vs. 920 ppm). and in water are below 1/20th the LC_{50} value for fish (0.035 vs. 0.21 ppm).

In telephone conversations with U.S. Fish and Wildlife Service (USFWS) personnel, Roger Hogan of Maine and Jay Gore of Idaho on April 10 and 14, 1987, respectively, confirmed that there are no listed endangered aquatic invertebrates in the potato-producing areas in Idaho or in Aroostook, Penobscot, Somerset, and Oxford counties in Maine.

A 2% runoff from a 1.0 lb ai/A application will not exceed 1/20th the LC_{50} value for the most sensitive aquatic invertebrate species (Daphnia magna) 0.012 vs. 0.021 ppm. However, the daily accumulated pesticide residue model shows that the second application on day 7 will equal 1/20th the LC_{50} value for Daphnia magna (0.021 vs. 0.021 ppm) and the third and fourth applications on day 14 and 21 will exceed 1/20th the LC_{50} value (0.028 vs. 0.021 ppm and 0.035 vs. 0.021 ppm).

The registrant should not apply more than one application (1.0 lb ai/A) of Rovral to potatoes in areas other than the areas mentioned above for the State of Idaho and Maine. If the intended use sites do not contain endangered aquatic invertebrates, then four applications can be applied. Rovral should be restricted to one application or precluded its use in counties where endangered aquatic invertebrates species exist.

104.4 Adequacy of Toxicity Data

Species	Results	Status
Mallard duck	> 20,000 ppm	Core
Bobwhite quail - Acute oral LD_{50}	930 mg/kg	Core
Bobwhite quail - LC_{50}	9200 ppm	Core
Bobwhite quail	Rep. NOEL 1000 ppm	Core
Mallard duck	Rep. > 300 < 1000 ppm	Core
Rainbow trout - LC_{50}	4.2 ppm	Core
Daphnia magna - LC_{50}	0.43 ppm	Core
Channel catfish - LC_{50}	3.06 ppm	Core
Bluegill Sunfish - LC_{50}	6.3 ppm	Core

104.5 Additional Data Required

Aquatic invertebrate life cycle study.

104.6 Adequacy of Labeling

The labeling should include the statement:

> This pesticide is toxic to aquatic invertebrates. Do not apply directly to water or wetlands. Drift or runoff from treated areas are hazardous to aquatic invertebrates in neighboring areas. Do not contaminate water when disposing of equipment washwater.

105.0 Conclusions

EEB has partially completed the proposed section 3 registration for Rovral for use on potatoes to control early blight and white mold fungus. Based on the available data, EEB concludes the proposed use provides for minimal acute hazard to nontarget terrestrial wildlife and fish species. For aquatic organisms, the proposed use of Rovral exceeds the presumption of unacceptable risks level (1/20th LC_{50}) for endangered aquatic invertebrate species. EEB is unable to complete a full risk assessment for this use because pertinent ecological effects data are lacking. In order to assess the risks associated with this use, EEB requires the following study:

- Aquatic invertebrate life cycle study.

Relative to endangered terrestrial and aquatic organisms, the use of Rovral should be restricted from application in counties where endangered species are likely to occur. We conclude this because:

1. The proposed four applications provide for EECs which exceed the concern value (1/20th Daphnia

LC_{50} - see above) for Daphnia: and

2. Chronic effects data are lacking making any determination of chronic risks to endangered aquatic species difficult.

Pending receipt and review of the above-mentioned study, EEB may require formal consultation with the USFWS to determine whether or not there would be jeopardy to any endangered aquatic invertebrates in the use of Rovral on potatoes.

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