201469
RECORD NO.

109801
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 08/20/87 OUT 3-1-88

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PETITION OR EXP. NO.

DATE OF SUBMISSION 06/12/87

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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 caneberries use

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

EEB REVIEW

Pesticide Name: Rovral

100.0 Pesticide Label Information

100.1 Pesticide Use

Rovral is a fungicide used on caneberries for the control of Botrytis fruit rot (Botrytis cinerea).

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 CANEBERRIES

Apply Rovral as a foliar spray with ground equipment in sufficient water to obtain thorough coverage at bloom and/or fruit (minimum of 100 gallons) in accordance with the directions in the following table:

DISEASE	Lb PRODUCT/ ACRE	TIMING OF APPLICATIONS
Botrytis fruit rot (Botrytis cinerea)	1.0 - 2.0	Apply Rovral first at early bloom (5-10% bloom) and make a repeat application again at full bloom. Up to 3 subsequent applications can be applied at 14 day intervals or as required. The final application can be made up to and including the day of harvest."

NOTE TO USER: All crops on the EPA-registered label may be rotated after harvest.

The following crops may be rotated the year following treatment: Root crops, cereal grains, soybeans, and tomatoes.

100.4 Target Organisms

Botrytis fruit rot (Botrytis cinerea)

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."

101.1 Common Name

Iprodione

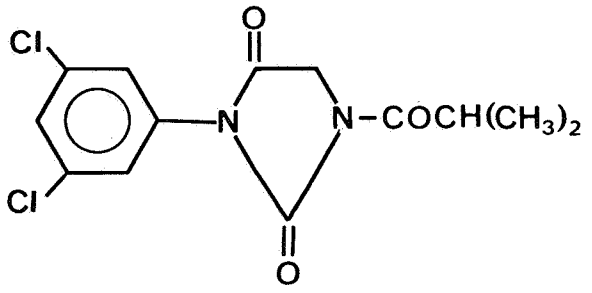
101.2 Chemical Name

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

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)

Species	LC/LD_{50}	Status
Mallard duck	> 300 ppm < 1000 ppm rep.	Core
Bobwhite quail	930 mg/kg	Core
Bobwhite quail	9200 ppm	Core
Bobwhite quail	1000 ppm rep. NOEL	Core
Rainbow trout	4.2 ppm	Core
Bluegill sunfish	6.3 ppm	Core
Daphnia magna	0.43 ppm	Core
Mallard duck	> 20,000 ppm	Core

103.3 Maximum Expected Residues on Vegetation (1.0 lb ai/A in ppm for avian)

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
Fruit - cherries, peaches	7.0
Soil in 0.5 inch depth	22.0
Water 6.0 ft depth	0.061

103.4 A Program for Pesticide Fate Simulation for Terrestrial Organisms

Daily Accumulated Pesticide Residues---Multp. Appl.

Chemical name	Rovral
Initial concentration (ppm)	240
Half-life	23
Number of applications	4
Application interval	14
Length of simulation (day)	42

Day	Residue (ppm)	
0	240	First applic.
1	232.8751	
2	225.9617	
3	219.2535	
4	212.7444	
5	206.4287	
6	200.3003	
7	194.354	
8	188.5841	
9	182.9856	
10	177.5533	
11	172.2822	
12	167.1676	
13	162.2049	
14	397.3895	2nd applic.
15	385.5921	
16	374.1449	
17	363.0375	
18	352.26	
19	341.8024	
20	331.6552	
21	321.8092	
22	312.2556	
23	302.9856	
24	293.9908	
25	285.263	
26	276.7944	
27	268.5771	
28	500.6038	3rd applic.
29	485.7422	
30	471.3219	
31	457.3296	
32	443.7528	
33	430.579	
34	417.7962	
35	405.393	
36	393.358	
37	381.6803	

Day	Residue (ppm)	
38	370.3493	
39	359.3546	
40	348.6864	
41	338.3349	
42	568.2906	4th applic.
Maximum residue		568.2906
Average residue		320.0657

103.5 EEC Calculation Sheet For Aquatic Organisms

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.

A Program for Pesticide Fate Simulation For Aquatic Organisms

Daily Accumulated Pesticide Residues---Multp. Appl.

Chemical name	Rovral
Initial concentration (ppm)	.012
Half-life	20
Number of applications	4
Application interval	14
Length of simulation (day)	42

Day	Residue (ppm)
0	.012
1	1.159124E-02
2	.0111964
3	1.081501E-02
4	1.044661E-02
5	1.009076E-02
6	9.747028E-03
7	9.415008E-03
8	.0090943
9	8.784514E-03
10	8.485281E-03
11	8.196241E-03
12	7.917046E-03

Day	Residue (ppm)
13	7.647364E-03
14	1.938687E-02
15	1.872648E-02
16	1.808859E-02
17	1.747242E-02
18	1.687725E-02
19	1.630235E-02
20	1.574703E-02
21	1.521063E-02
22	.0146925
23	1.419202E-02
24	1.370858E-02
25	1.324162E-02
26	1.279056E-02
27	1.235487E-02
28	2.393402E-02
29	2.311874E-02
30	2.233123E-02
31	2.157054E-02
32	2.083577E-02
33	2.012603E-02
34	1.944046E-02
35	1.877825E-02
36	1.813859E-02
37	1.752072E-02
38	1.692391E-02
39	1.634741E-02
40	1.579056E-02
41	1.525268E-02
42	2.673312E-02

Maximum residue ----------	2.673312E-02
Average residue ----------	1.514094E-02

Four 1.0 lb ai/A applications were used to determine if residues exceed 1/10th the LC_{50} value for nontarget aquatic organisms or 1/20th the LC_{50} for aquatic endangered species. The 1.0 lb ai/A applications are to be applied on days 0, 14, 28, and 42.

104.0 Hazard Assessment

104.1 Discussion

The proposed registration of Rovral is for use on caneberries for control of Botrytis fruit rot (Botrytis cinerea), with a maximum of four 1.0 lb ai/A applications per season recommended at 14-day intervals or as required.

The available data indicate Rovral is highly toxic to aquatic invertebrates, moderately toxic to rainbow trout, slightly toxic to bobwhite quail 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/A, single application) as a fungus control on caneberries. Rovral should provide for minimal acute hazard to both nontarget terrestrial wildlife and fish species. The maximum expected residue on vegetative food matter and the concentration in 6.0 ft depth of water after four 1.0 lb ai/A applications at 14-day intervals (0, 14, 28, and 42) are below the 1/10th LC_{50} values for both birds (920 vs 568, bobwhite) and the most sensitive aquatic organisms (0.43 ppm vs. 0.027 ppm, Daphnia magna).

EEB does not have a complete data set to determine the long-term effects of Rovral to nontarget organisms. (However, based on the reproduction study and the limited nature of the use, 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 both terrestrial wildlife and fish species. The maximum expected residue level on vegetative food matter and concentration in 6.0 ft depth of water (based on a 2% runoff from a treated field) after four 1.0 lb ai application/A on day 42 are below 1/10th the LC_{50} value for an upland game bird (920 vs. 568 ppm) and 1/20th the LC_{50} value for the most sensitive fish species (0.021 vs. 0.27 ppm).

A 2% runoff from a 1.0 lb ai/A application in 6.0 ft depth of water will not exceed 1/20th the LC_{50} value for the most sensitive aquatic invertebrate species (Daphnia magna) for the first and second applications on day 0 and 14 (0.12 vs. 0.021 ppm and 0.019 vs. 0.021 ppm, respectively). However, the daily accumulated pesticide residue model shows that the third and fourth applications on day 28 and 42 will exceed 1/20th the LC_{50} value for Daphnia magna (0.024 vs. 0.021 ppm and 0.027 vs. 0.021 ppm).

The proposed label should exclude use of the product from counties where endangered aquatic species are likely to occur until all pertinent data have been received and reviewed by the Agency (see Conclusions section).

104.4 Adequacy of Toxicity Data

All six submitted fish and wildlife studies were found acceptable in support of registration.

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 contaminate water when disposing of equipment washwater." Drift or runoff from treated areas are hazardous to aquatic invertebrates in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

105.0 Conclusions

EEB has partially completed a hazard assessment of the proposed section 3 registration for Rovral for use on caneberries to control botrytis fruit rot (Botrytis cinerea).

Based on the available data, EEB concludes the proposed use provides for minimal acute hazards to nontarget terrestrial wildlife and fish species. For aquatic invertebrates, the proposed use of Rovral exceeds 1/20th the LC_{50} values for aquatic endangered species for the third and fourth application (0.024 vs. 0.021 ppm and 0.027 vs. 0.021 ppm).

EEB is unable to determine the chronic risks associated with the proposed use because pertinent ecological effects data are lacking. These data include the aquatic invertebrate life cycle study.

However, because of the limited nature of the proposed use pattern, EEB concludes that serious chronic risks to nontarget, nonendangered terrestrial, and aquatic organisms are unlikely. Therefore, EEB does not require the study mentioned above (and in §104.5) to support this use, but would require this study to support a more extensive use with greater exposure.

Relative to endangered terrestrial and aquatic organisms, the use of Rovral should be restricted from application in counties where endangered aquatic 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 U.S. Fish and Wildlife Service to determine whether or not there would be jeopardy to any endangered aquatic invertebrates in the use of Rovral or caneberries.

Curtis E. Laird 2-25-88
Curtis E. Laird, Fishery Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

Norman J. Cook 2.25.88
Norman J. Cook, Head-Section II
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

Henry T. Craven 3/1/88
Henry T. Craven, Acting Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)