109801

17
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 3-18-83 OUT 4-4-83

FILE OR REG. NO. 359-685

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 2-24-83

DATE RECEIVED BY HED 3-17-83

RD REQUESTED COMPLETION DATE 5-18-83

EEB ESTIMATED COMPLETION DATE 5-14-83

RD ACTION CODE/TYPE OF REVIEW 335/Amendment

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Rovral

COMPANY NAME Rhone-Poulenc Inc.

SUBMISSION PURPOSE Proposed Conditional Registration of Garlic Use

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
109801	Iprodione	50%
	Inert Ingredients	50%

Rovral

100 Pesticide Label Information

100.1 Pesticide Use

Proposed conditional registration for use on garlic.

100.2 Formulation Information

Iprodione	50%
Inert ingredients	50%

100.3 Application Methods, Directions, Rates

Disease	Rate (lb/A)	Timing
White rot	4.0	Apply Rovral in the furrow at planting. Position nozzles to treat the cloves and the covering soil used to fill the furrow.

100.4 Target Organisms

White rot (Sclerotium cepivorum)

100.5 Precautionary Labeling

The following Environmental Hazards Labeling appears on the proposed label:

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

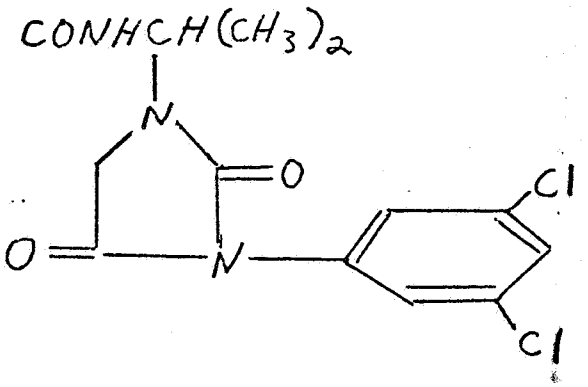
101 Physical and Chemical Properties

101.1 Chemical Name

3- (3,5 - dichlorophenyl)-N-(1-methylethyl)-

2,4-dioxo-1-imidazolidine carboxamide

101.2 Structural Formula



101.3 Common Name

Iprodione

101.4 Trade Name

Rovral™ Fungicide

101.5 Molecular Weight

330.17

101.6 Physical State

Odorless, cream-colored powder

101.7 Solubility (from 12/4/78 Review)

grams a.i. (approx.)/L solvent at 20°C

water	0.013
ethanol	25
acetone	25
methyl chloride	500

102 Behavior in the Environment

See EEB 3/21/77, 8/22/78, and 12/4/78 Reviews which abstracted information available as of 10/16/78. The following sections summarize this information and provide additional information where more current environmental fate data is available.

102.1 Soil

- Estimated half-life values of a.i. range from 7-160 days, depending on light and soil characteristics. Under natural field conditions, the half-life was 20-40 days with the majority of the material remaining in the top 4 inches.
- Leaching to ground water is not considered a problem except in soils with high pH and very fine texture.

102.2 Water

Iprodione has a low water solubility (see section 101.7 of this Review). It is stable at low pH (e.g., T 1/2 = 3 months at pH 5) but hydrolysis occurs at pH 6 (T 1/2 = 20 days) and pH 7 (T 1/2 = 1 day). With photodegradation, Iprodione half-life is between 72 and 187 hours even at pH 3 when Iprodione is extremely stable to hydrolysis.

102.3 Plant

No degradation was observed on leaves of beans or cucumbers at 35 days, indicating stability on acidic foliage.

In/on wheat or strawberry stems, parental half-life is 30-60 days. 90 days following foliar application, ca. 25% of parental material remained on stems and leaves (EFB 10/16/78 Review).

102.4 Animal

A study with catfish showed accumulation < 50X for both whole fish and edible tissue over 30 days of exposure to 0.01 ppm and 1 ppm aquatic soil concentrations. The highest accumulation occurs inthe viscera at 1 ppm exposure with a maximum of 522.37X at day 14. Accumulation is concentration dependent, with greater concentration under greater exposure.

A bluegill bioaccumulation study, reporting maximum bioaccumulation ratios (concentration in tissues/concentration in water) of 555.3 in viscera at 0.01 ppm exposure day 7 and 219.6 in viscera at 1 ppm exposure day 21 (with rapid dissipation after exposure discontinued) is presently under review by EFB.

102.5 Microorganisms

Iprodione is not biodegradable by microorganisms in activated sludge wastewater treatment plants. An 11/5/79 EFB Review estimated that concentrations up to 13 ppm entering a treatment facility could pass through. Above 13 ppm, Iprodione would settle with sludge solids.

Iprodione is reported to inhibit soil nitrification at levels of 1-100 ppm. A potential for the formation of carcinogenic azobenzene compounds from Iprodione degradates is also reported.

103 Toxicological Properties

- From 12/4/78 and 6/11/79 EEB Reviews and DERS.
- IBT fish acute toxicity studies listed in the 12/4/78 Review have since been invalidated by W. Rabert of EEB and are not included here.
- mammalian toxicity information updated from 7/11/81 Toxicology Branch file summary

103.1 Mammal

Acute data include:

a) rat acute oral LD_{50} (tech.) 3700 ± 300 mg/kg (M)
4400 (3200-6100) mg/kg (F)

b) dog acute oral LD_{50} (tech.) Atoxic at 2,000 mg/kg

c) mouse acute oral LD_{50} (tech.) - 3050 (2630-3540) mg/kg
- 4000 (3300-4800) mg/kg (M)
- 4400 (3300-5900) mg/kg (F)

Chronic - Data include:

a) 24-month feeding, rat - NOEL $\geq$ 1000 ppm

b) 3-generation reproduction, rat - NOEL = 500 ppm

c) 18-month feeding, oncogenicity, mice - NOEL $\geq$ 1250 ppm

d) Teratogenicity - rat: Teratogenic NOEL $\geq$ 400 mg/kg/day

Fetotoxic NOEL = 200 mg/kg/day

e) Mutagencity - mice: no evid. of mutagencity at 1500 or 6000 ppm dose - males.

103.2 Minimum Requirements

103.2.1 Avian Acute Oral LD_{50}

Species	Material	LD50	Category	Reviewer
Bobwhite quail	Tech.	930 mg/kg	Core	not cited in DER
Mallard	Tech.	>10,400 mg/kg	Suppl.	not cited in DER

103.2.2 Avian Dietary LC_{50}

Species	Material	LC50	Category	Reviewer
Bobwhite quail	Tech.	9200 ppm	Core	not cited in DER
Mallard	Tech.	>20,000 ppm	Core	not cited in DER

103.2.3 Fish Acute LC_{50}

Species	Material	LC50	Category	Reviewer
Rainbow trout	Tech. (95.06% a.i.)	4.2 (3.2-5.6) ppm	Data suitable to support this registration; suitable for registration on a case by-case basis (Supplemental)	Matheny/Fel
Bluegill sunfish	Tech. (95.06% a.i.)	6.3 (5.2-7.7) ppm	Core	Matheny

103.2.4 Aquatic Invertebrate LC_{50}

Species	Material	LC50 (48-hr except as noted)	Category	Reviewer
Daphnia magna	Tech. (94.5% a.i.)	7.2 (6.0-8.6) ppm	Core	L. Turner
Daphnia magna	Tech (94.5% a.i.)	0.43 (0.31-0.61) ppm	Core	L. Turner
Daphnia pulex	Tech	72-hr. LC_{50} = 4.0 (2.9-5.5) mg/l	Suppl.	L. Turner
" "	Rovral W.P.	72-hr. LC_{50} = 5.8 (3.2-10.3) mg/l	Suppl.	L. Turner
" "	Inerts of Rovral W.P.	72-hr. LC_{50} = 73 (62-86) mg/l	Suppl.	L. Turner

103.3 Additional Terrestrial Laboratory Tests

103.3.1 Avian Reproduction Studies

Species	Material	Results	Category	Reviewer
Bobwhite quail	Tech.	No detrimental effects reported at dietary levels tested (0, 13, 31, and 114 ppm) but results could not be verified	Suppl.	not cited in DER
Bobwhite quail	Tech. (95% a.i.)	Adult mortality and behavioral effects seen at all test levels; However, the only confirmed reproductive impairment was in weights of hatchlings at the 1000 ppm nominal concentration ($p<0.05$)	Core	Felkel
Mallard	Tech. (95% a.i.)	Behavioral effects on adults reported at 300 and 1000 ppm; statistically significant reprodctive impairment ($p=0.219$) confirmed at 1000 ppm nominal test contration.	Core	Felkel

104 Hazard Assessment

According to Agricultural Statistics - 1981 15,200 acres of garlic were grown in the United States in 1980. The total commercial production is reported to be in California. At the maximum label rate of 4 lb (2 lb. a.i.)/acre the following maximum residues are expected immediately after one applicatoin:

Short rangegrass	480 ppm
long grass	220 "
leaves and leafy crops	250 "
forage/small insects	115 "
pods/seeds/large insects	24 "
fruit	14 "
soil 0.1"	44.1 "
Water 6" (direct application)	1.47 "

Because label directions specify application into the furrow at planting, minimal exposure to non-target terrestrial organisms is expected. Assuming 5 percent runoff from treated areas, the estimated concentration of Rovral in adjacent waters would be 16 ppb. Expected residue levels are well below the restricted use classification triggers for aquatic and terrestrial organisms. Iprodione has a low water solubility and is persistent in soil and on vegetation, reducing the likelihood of exposure to non-target aquatic organisms.

107 Conclusions

EEB has completed an incremental risk assessment (3(c)(7) Finding) for the proposed conditional registration of Rovral for use on garlic. Based upon the available data EEB concludes that the proposed use provides for no significant increase in exposure, or risks to non-target organisms.

107.1 Special Notes

The Environmental Hazards labeling should read as follows:

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

Mary L. Gessner Mary L. Gessner 3/31/83
Section 3
Ecological Effects Branch, HED

Dave Coppage Dave Coppage 3/31/83
Head, Section 3
Ecological Effects Branch, HED

Clayton Bushong Clayton Bushong 3/31/83
Branch Chief
Ecological Effects Branch, HED