109801

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REVIEW NO.

EEB BRANCH REVIEW

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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 Lettuce 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 lettuce.

100.2 Formulation Information

Iprodione.....50%
Inert Ingredients.....50%

100.3 Application Methods, Directions, Rates

Geographic Area	Disease	Rate (lb/A)	Timing
California	Lettuce Drop	1.5-2.0 (0.75-1.0 a.i.)	Apply at the 3 leaf stage of growth
Remainder of U.S.	Bottom rot Lettuce drop	1.5-2.0 (0.75-1.0 a.i.)	Apply at the 3 leaf stage of growth and again 10 days later. If condition still favor disease development a third application should b made 10 days after the second spray. Do not apply within 14 days of harvest.

Not for use on winter grown lettuce in Arizona and the Imperial Valley of California.

Application should be made with tractor mounted boom sprayers equipped with flat fan or hollow cone nozzles directed to insure thorough coverage of the lower portion of the plants and the surrounding soil surface. Do not drench.

The higher rate should be used under severe disease conditions.

Do not rotate with crops other than lettuce.

100.4 Target Organisms

Lettuce Drop (Sclerotinia spp.)
Bottom Rot (Rhizoctonia solani)

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."

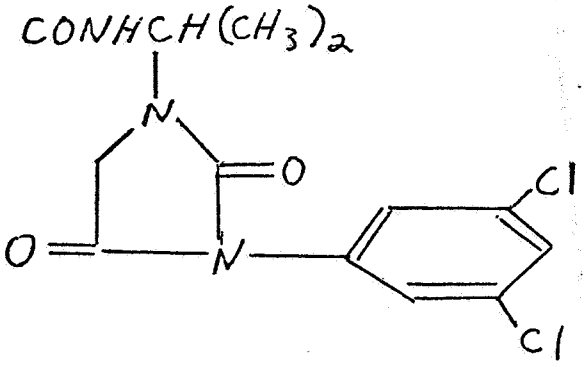
101 Physical and Chemical Properties

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 conditons, 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 accummulation < 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 in the 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 $\pm$ 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/Felkel
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 test concentration ($p<0.05$)	Core	Felkel
Mallard	Tech. (95% a.i.)	Behavioral effects in adults reported at 300 and 1000 ppm; statistically significant reproductive impairment ($p=0.219$) confirmed at 1000 ppm nominal test concentration.	Core	Felkel

104 Hazard Assessment

104.1 Discussion

According to Agricultural Statistics - 1981, total acreage of lettuce planted in the U.S. in 1980 was 242,560 acres. The major lettuce - producing states are as follows:

California	163,600 acres
Arizona	41,100 "
Florida	14,300 "
Texas	4,800 "

At the maximum label rate of 1.0 lb a.i./acre the following maximum residues are expected immediately after a single application:

Short rangegrass	240 ppm
Long grass	110 "
leaves and leafy crops	125 "
forage/small insects	58 "
pods/seeds/Large insects	12 "
fruit	7 "
Soil 0.1"	22 "
Water 6" (direct application)	734 ppb

104.2 Likelihood of Adverse Effects to Non-target Organisms

Iprodione is practically non-toxic to mammals, upland gamebirds, and waterfowl. Avian reproduction studies show no significant impairment at dietary levels of 100 to 300 ppm. At the proposed use rate of 1.0 lb a.i./acre, given the expected residue levels, minimal hazard to terrestrial organisms are expected.

Iprodione is moderately toxic to fish and moderately to highly toxic to freshwater invertebrates. This use pattern does not call for a direct application to water, so residues are expected to be somewhat less than 734 ppb. Assuming 5% runoff, estimated residue levels would be about 37 ppb in a 6" body of water. Iprodione's half-life in water at neutral pH is reportedly 1 day. Therefore, multiple (3) applications at 10 day intervals are not expected to result in residue levels that would pose a hazard to 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 lettuce. Based upon the available data EEB concludes that the proposed use may provide for a significant increase in exposure, but not in 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."

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