1-21-82

109801
SHAUGHNESSEY NO.

12
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 11/18/81 OUT 1/21/82

FILE OR REG. NO. 359-TNU

PETITION OR EXP. PERMIT NO. 8G2087

DATE OF SUBMISSION 10/29/81

DATE RECEIVED BY HED 11/17/81

RD REQUESTED COMPLETION DATE 2/1/82

EEB ESTIMATED COMPLETION DATE

RD ACTION CODE/TYPE OF REVIEW 180/Old Chemical - New Use

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

DATA ACCESSION NO(S). 070443

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Rovral

COMPANY NAME Rhone-Poulenc Chemical Company

SUBMISSION PURPOSE Proposed Conditional Registration of Use on Stone Fruits

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

100 Pesticide Label Information

Note: While the proposed label specifies use on cherries and peaches, the Registration Division has requested review for all stonefruits.

100.1 Pesticide Use

Rovral™ fungicide is a wettable powder formulation for use on cherries and peaches to control brown not, blossom blight, and fruit brown not (Monilinia sp.).

100.2 Formulation Information

Iprodione - - - - - - - -50%

Inert Ingredients - - - -50%

100.3 Application Methods, Directions, Rates

Apply as a foliar spray in sufficient water to obtain thorough coverage (20-400 gallons per acre by ground application and 15 to 20 gallons by aerial application.) 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 and apply with properly calibrated application equipment. Do not graze animals in treated orchards. Do not feed treated cover crops to animals.

Apply Rovral in accordance with directions provided in the table below.

DISEASE	Dosage Rate		SPRAY SCHEDULE
	Lbs. Prod/ 100 gal.	Lbs. Prod/ A	
Brown Rot Blossom Blight (*Monilinia sp.*)	0.25 to 0.50	1.0 to 2.0	Apply first at early bloom (Approximately 5% bloom). If conditions are favorable for disease development apply again at full bloom and at petal fall.
Fruit Brown Rot (*Monilinia sp.*)	0.25 to 0.50	1.0 to 2.0	An application should be made whenever temperatures and moisture conditions favor disease infection in the five week period prior to harvest. If these conditions persist or reoccur, a second application should be made. Preharvest applications may be made up to and including the day of harvest.

Under severe disease conditions the higher rate is recommended.

The rates of Rovral per 100 gallons are based on a standard of 400 gallons per acre diluted spray for mature trees. For less than mature trees, apply the rate per 100 gallons until runoff. If less than 400 gallons of spray solution per acre is applied to mature trees, refer to the rate per acre to insure that the proper amount of material is applied.

Do not apply more than 2.0 lbs. of Rovral per acre per application.

100.4 Target Organisms

See 100.1 of this Review.

100.5 Precautionary Labeling

The following appears under the heading "Environmental Hazards" on the proposed label:

> "Do not apply directly to lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes."

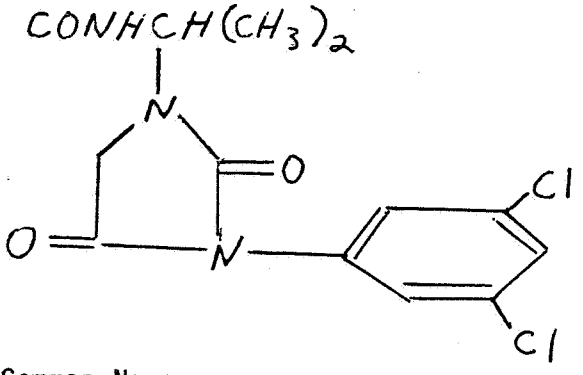
101 Physical and Chemical Properties

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 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 Toxicity 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/Felke
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 on adults reported at 300 and 1000 ppm; statistically significant reprodutive impairment (p=0.219) confirmed at 1000 ppm nominal test concentration.	Core	Felkel

104 Hazard Assessment

104.1 Discussion

EEB has previously reviewed Iprodione for full registration on turf (12/4/78). The maximum application rate proposed for stonefruits is 16X that for turf (1 oz. a.i./acre). Stone fruit acreage in the U.S., based on 1974 data in EEB crop files, is 493,929 acres, roughly double that for golf course turf (488,794 acres, based on 1979 data in EEB crop files). Also, many non-target organisms not exposed with a turf use could be exposed with a stonefruit use. This section evaluates the incremental risk to non-target organisms of the proposed conditional [3(c)(7)] registration.

104.2 Likelihood of Adverse Effects to Non-target Organisms

Iprodione is "slightly toxic" to "practically non-toxic" to mammals and birds (following toxicity category terminology of Brooks, H., et. al., 1973) based on results of mammalian and avian acute oral and avian dietary studies (see Section 103). Avian reproduction studies show no statistically significant reproductive impairment at adult dietary levels of 100 ppm and 300 ppm nominal. At the maximum proposed application rate of 1 lb a.i./Acre, the maximum expected initial residues on vegetation would be as follows after, 1 application based on the nomagraph developed by R. Tucker (EEB), derived from Hoerger and Kenaga (1972):

Fruits (for applications made to trees after fruit exposed)----------7 ppm

Leaves of stonefruits trees (for all applications)----------125 ppm

Grass and forage surrounding orchard, if exposed to full spray (vegetation partially blocked by trees or otherwise not receiving full spray would receive less). Vegetation receiving heavy runoff from the stonefruit tree foliage will likely receive the higher amounts in this range ----------58-240 ppm

Label directions (section 100.3 of this Review) specify a maximum of 3 applications/ season to control brown not and blossom blight but are vague as to the maximum number of applications to control fruit brown pot (1-2 applications plus an unspecified number of preharvest applications). If three applications of 1 lb/acre were made at two-week intervals, maximum residues on leaves (likely the principal receptor of the fungicide since the label specifies foliar applications) after the last application would be approximately 322 ppm, given a 60-day foliar half-life (the maximum half-life with strawberries and wheat but apparently less than that with beans and cucumbers; data are not available for stonefruits). The foliar residues would be lower than this prior to a third application and would, of course, decline following the application. Residues on fruits and other wildlife food of similar size and shape would have substantially lower residues (ca. 18 ppm) immediately following a third application. In cases where the spray schedule begins before fruiting, residues would be still lower on fruits.

In sum, it does not appear that terrestrial residues from applications at the proposed label rates would present an acute mortality hazard to birds or mammals, nor a reproductive hazard to birds that may be using the sprayed orchard.

Although the proposed use on stonefruit trees (with applications at flowering) poses a potential hazard to bees, a review by EEB entomologist A. Vaughn indicates that no hazard to bees should exist, based on acute toxicity data (Atkins, et. al., 1975).

Aquatic organisms are more sensitive to Iprodione in acute toxicity studies than birds and mammals (see Section 103 of this Review). Expected residues if shallow water (6") were to accidentally receive a direct application at the proposed rates would be 0.734 ppm following 1 application. Immediately following a third such accidental application to 6" water with pH 5 (90 day half-life in such acidic water), probably an extreme worst-case situation, residues would temporarily be 1.98 ppm, still below fish LC_{50} values and 95% confidence intervals (3.2-7.7 ppm), although above the lowest aquatic invertebrate LC_{50}.

The proposed applications are not aquatic and direct application to water cannot be assumed. Iprodione has a low water solubility and high persistence in soil and on vegetation, reducing the likelihood and degree of aquatic contamination from this material in the aquatic phase of run-off. Soil erosion could bring Iprodione to aquatic environments but such erosion would appear to be less serious in orchards than other agricultural uses, since the soil is not as disturbed (trees remain in place from year to year and ground covers are often used between trees).

The principal route of Iprodione to the aquatic environment would appear to be via spray drift. A rough estimate of drift, assuming no air turbulence or evaporation of the spray droplets, however, indicates that it is unlikely that 1.6 ppm (half the lowest confidence limit for fish LD_{50} values) would be deposited initially in 6" water from a single pass of a mist blower in close proximity to a water body with a 5 mph wind in the direction of the water body. [In cases where an aplication site is in close proximity (e.g., <96') to shallow water (e.g., 6"), spray drift could theoretically deposit sufficient fungicide initially to approach the lowest aquatic invertebrate LC_{50} value, however, if no partitioning occurred.] Partitioning of Iprodione to hydrosoils would reduce concentrations in the water column. Deeper waters would also have proportionally lower residues.

Stonefruits are more frequently grown on hillsides (better protection from cold) rather than lowlands, according to EEB crop file information. Hence, proximity to water bodies appears to be lower than for many crops.

Based on the characteristics of Iprodione (low water solubility, high persistence in terrestrial environment), application site characteristics (relatively low soil disturbance and not a relatively high proximity to water), application rate and toxicity information, it does not appear that there wold be an acute hazard to most aquatic organisms.

To evaluate the potential for chronic aquatic hazard, it is necessary to evaluate the likelihood of chronic exposure. Rovral is proposed for repeat applications, and if it were to enter waters with pH $\leq$ 6, without much sunlight, it could be expected to be relatively persistent (half life $\geq$ 20 days). However, photodegradation occurs in 72-187 hours even at extremely low pH (pH 3), when Iprodione is very stable to hydrolysis. Further, due to the chemical and site characteristics described earlier, most transport of the applied pesticide to water would appear to be via spray drift. Since available information indicates that stonefruit orchards are not usually in close proximity to water (proximity is more important for drift than runoff, since drift residues drop off quickly with distance), there is not a strong case for chronic aquatic exposure. Further, available information indicates that Iprodione is not a strong bioaccumulator. Hence, unless the concurrent review of the bluegill bioacumulation study and the stonefruits use pattern by EFB indicates a potential for hazard to nontargets, there does not appear to be a sustantial potential for chronic aquatic effects.

104.3 Endangered Species Considerations

A hazard to endangered species is not foreseen at this time, for the same reasons discussed in Section 104.2.

104.4 Adequacy of Toxicity Data

See Section 107.4

104.5 Additional Data Required

See Section 107.5

107 Conclusions

107.3 Environmental Hazards Labeling

In addition to the labeling proposed (Sedion 100.5), it is suggested that the following statement be added: "Do not apply if conditions favor drift to bodies of water (e.g., lakes, streams, ponds, canals)."

107.4 Data Adequacy Conclusions

Avian reproduction studies on bobwhite quail and mallard duck submitted with this registration proposal (within Accession #070443) meet the intent of proposed subpart E guidelines (7/10/78) and are sufficient for registration purposes. Statistically significant reproductive impairment, relative to controls, was not seen at 100 ppm and 300 ppm nominal test concentrations. Some adult effects, most notably with the quail, were seen at these levels. Statistically significant reproductive impairment, relative to controls, was confirmed at the 1000 ppm test concentrations. Complete Data Evaluation Records are on file at EEB.

107.5 Data Requests

Unless a concurrent review of a bluegill bioaccumulation study and this conditional registration request by EFB indicates a potential for hazard to nontarget organisms, there would not be a need for additional fish and wildlife data at this time.

107.7 Findings

EEB has reviewed the proposed conditional registration of Iprodione (Rovral™) for use on stonefruits. Based upon available data, EEB concludes that the proposed use provides for a substantial increase in exposure to terrestrial organisms over the turf registration reviewed 12/4/78 by EEB, but that expected residues are not likely to present an acute hazard to birds, mammals, or bees (based on data on file at EEB), nor a chronic hazard to birds (based on avian

reproduction studies submitted and reviewed with this request). While mammalian chronic data from the Toxicology Branch do not appear to indicate a chronic hazard to mammals from the proposed registration, we defer full evaluation of this data to TB. Based upon available aquatic data, EEB concludes that any potential increase in exposure to aquatic organisms would not be sufficient to pose substantial acute or chronic hazards to aquatic organisms (see Section 107.3 for environmental hazard labelng suggestion and 107.5 regarding a concurrent review being conducted by EFB).

References:

Atkins, E., et. al. 1975. Effect of pesticides on agriculture. Project #1499. 1975 Ann. Report. Dept. of Entomol., Univ. of Calif. Riverside.

Brooks, H., et. al. 1973. Insecticides. Cooperative Ext. Service, Kansas State Univ., Manhattan, Kansas.

Hoerger, F. and E. Kenaga. 1972. Pesticide residues on plants: correlation of representative data as a basis for estimation of their magnitude in the environment. In Coulston, F. and F. Korte (eds.), Environmental Quality Safety, Vol. I, Academic Pr., NY.

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