

US EPA ARCHIVE DOCUMENT

109801
SHAUGHNESSEY NO.

13
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 7-26-82 OUT 9/3/82

FILE OR REG. NO. 359-685

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 7-15-82

DATE RECEIVED BY HED 7-26-82

RD REQUESTED COMPLETION DATE 9-11-82

EEB ESTIMATED COMPLETION DATE 9-4-82

RD ACTION CODE/TYPE OF REVIEW 330/Amendment -- New Food/Feed Use

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 Almonds use

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION % A.I.

109801 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-

dioxo-1-imidazolidinecarboxamide 50.0%

100.0 Pesticide Use

Rovral (Iprodione) is a wettable powder fungicide used for the control of Brown Rot, Blossom Blight, and the suppression of Shothole in almonds.

100.1 Application Rates

<u>Lbs. Prod/100 gal</u>	<u>Lbs. Prod./Acre</u>
0.25	1.0

Number of application limited to two (2) per year.

100.3 Application Methods and Directions

See attached Label (Appendix I).

100.4 Precautionary Labeling

Keep out of lakes, streams, and ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

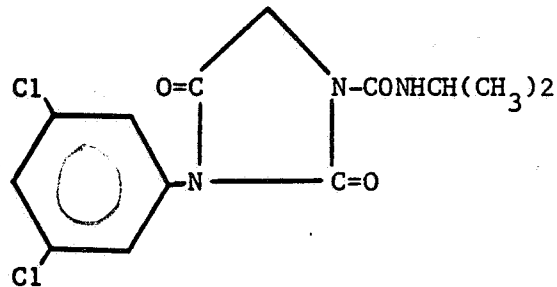
100.5 Target Pests

Monilinia Laxa = Brown Rot or Blossom Blight

Coryneum beijerinckii = Shothole

101.1 Chemical Name

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

101.2 Structural Formula101.3 Common Name

Iprodione, Rovral, Chipco.

102.0 Behavior in the Environment

See previous EEB and EFB reviews by J. Tice (12/4/78), J. Felkel (1/21/82), and H. Manning (1/21/82).

103.0 Toxicological Properties

See EEB review by J. Felkel(1/21/82).

104.0 Hazard Assessment

This review is being conducted as an incremental risk assessment for the conditional registration of Rovral on almonds. Rovral (Iprodione) is presently registered to control fungus on stone fruits (peaches, cherries, nectarines), kiwi fruits, turf, and ornamentals. Acreage estimates for registered uses in California are listed below:

<u>Crop</u>	<u>Acreages</u>
Kiwi fruit	1,898
Nectarines	21,577
Peaches	83,791
Cherries	13,791
Turf	Data not available
Ornamentals	Data not available
Totals	>121,000

Mammalian Exposure

Rovral is practically non-toxic to mammals (mouse LD₅₀=3050 mg/kg). Exposure to mammals is expected to via the ingestion of dietary items contaminated by Rovral residues. A mouse LD₅₀ of 3050 mg/kg was used to determine a mammalian classification trigger (1/5 LD₅₀) 610 mg/kg.

At the maximum proposed yearly application rate of one (1) pound active ingredient/acre, Rovral residues on potential feed items should not pose a hazard to non-target mammals.

Avian Exposure

Rovral is practically non-toxic to upland game birds (bobwhite LC₅₀ = 9200 ppm) and waterfowl (mallard LC₅₀ = >20,000 ppm). A bobwhite quail feeding study (LC₅₀ = 9200 ppm) was used establish an avian classification trigger of 1,840 ppm. Exposure to birds is expected to occur through the ingestion of seeds and insects contaminated by Rovral residues.

104.2 Estimated Environmental Concentrations

Estimated aquatic residues for lentic ecosystems contaminated by rainwater runoff and a theoretical 2X direct application.

Almonds (maximum application rate = 1 lb/active/acre)

<u>Rovral % Runoff</u>	<u>6 inches of water (ppm)</u>	<u>12 inches of water (ppm)</u>	<u>6 feet of water (ppm)</u>
0.5	0.003	0.001	0.003
1.0	0.007	0.003	0.0006
5.0	0.036	0.018	0.003
100.0 **	0.735	0.367	0.061

Estimated environmental concentrations for soil surfaces and potential avian dietary items immediately following product application.

<u>Pounds active/acre</u>	<u>Seeds (ppm)</u>	<u>Almond tree leaves (ppm)</u>	<u>Insects (ppm)</u>	<u>Soil Top 1 inch (ppm)</u>
.5	6	63	29	11.0
1.0	12	125	58	22.0

** Assumes two (2) repeat applications to a six (6) inch layer of water.

The degree to which non-target avian species could be exposed to Rovral residues was examined for a worst case situation (i.e., two 0.5 lbs applications) in Table 2. Comparison of estimated daily body burdens to empirical and calculated LC₅₀ values for eight species of non-target birds reveals the following:

1. Birds feeding on dietary items contaminated with " worst case " residues would not exceed the 1840.0 ppm restricted use trigger.
2. Small insectivorous birds (14-day old bobwhite, Carolina wren) could be exposed to the highest Rovral residues.
3. Expected daily dietary burdens are well below the 1000 ppm reproductive impairment level determined for bobwhite quail (Felkel 1/21/82; section 103.3.1).

Aquatic Exposure

Rovral is moderately toxic to warmwater (bluegill LC₅₀ = 6.3 ppm) and coldwater (rainbow LC₅₀ = 4.2 ppm) fishes. Bioassays conducted with both technical (94.5%) and formulated product (50% WP) have shown the this fungicide is moderately toxic to freshwater invertebrates (Daphnia magna LC₅₀ = 7.2 and 5.8 ppm, respectively). The chronic effects of Rovral on freshwater fish and aquatic invertebrates are not known. A 96 hour rainbow trout study (LC₅₀ = 4.2 ppm) was used to determine a restricted use classification trigger (1/10 LC₅₀) of 0.42 ppm. A 48-hour Daphnia magna study (LC₅₀ = 5.8 ppm) conducted with formulated product was used to calculate a freshwater invertebrate trigger (1/10 LC₅₀) of 0.58 ppm.

Exposure to non-target aquatic organisms is expected to occur via rainwater runoff and to a lesser extent from irrigation return flow waters. Estimated aquatic residues from runoff and a theoretical 2X direct application to water are shown in Section 104.2

Comparison of expected aquatic residues to fish and invertebrate classification triggers indicates the following:

1. That residue levels resulting from a direct application of Rovral (0.5 lbs/Active/Acres) to six (6) inches of water would not exceed restricted use triggers for non-target fish and invertebrates.
2. That expected residues resulting from rainwater runoff (i.e., 0.5-5%) do not exceed restricted use fish (0.42 ppm) and aquatic invertebrate (0.58 ppm) triggers.

Table 2A.

Calculated LC50 values and estimated toxicant exposure (MG/KG/DAY and MG/ANIMAL/DAY) for seven species of non-target birds.

SPECIES 2/	BODY WGT. (GMS.)	FOOD CONS. (GMS.)	F. CONS./ B. WGT (%)	CALCULATED LC50 (PPM) 6/	TOXICANT CONSUMED4/ MG/KG/DAY	1/5	1/10
						CALCULATED LC50 5/	CALCULATED LC50 7/
1. Bobwhite Quail (Young)	30.01/	6.02/	20.0	9200.0	1840.0	1840.0	920.0
2. Bobwhite Quail (Adult)	170.00	15.20	8.94	20579.0	1840.0	4116.0	2058.0
3. Robin	81.10	8.11	10.00	18377.0	1840.0	3675.0	1838.0
4. Mourning Dove	100.00	11.20	11.20	16429.0	1840.0	3286.0	1643.0
5. Eastern Cowbird	50.00	7.00	14.00	13143.0	1840.0	2629.0	1314.0
6. Field Sparrow	13.90	4.60	33.10	5560.0	1840.0	1112.0	556.0
7. Grasshopper Sparrow	13.90	4.60	33.10	5560.0	1840.0	1112.0	556.0
8. Carolina Wren	19.00	6.50	34.20	5378.0	1840.0	1076.0	537.8

1/ Milligrams body WGT. (Average weight).

2/ Average 5-day food consumption.

3/ LC50 determined by registrant's testing facility.

4/ MG/ANIMAL/DAY = MG/KG/DAY X Body weight (kg)

5/ 1/5 LC50 value for registration labeling criteria.

6/ LC50(ppm) = $\frac{1840 \text{ mg/kg/day}}{\text{F. Con. (g) / B. WGT (g)}}$

7. 1/10 LC10 value for hazard evaluation to endangered species.

Table 2B.

Dietary contamination and total estimated residues for eight species of non-target birds.

SPECIES	CALCULATED LC50 (PPM)	1/5 CALC. LC50 (PPM)	2/ FOOD CONSUMED Animal (%)	3/ Plant	MAXIMUM EXPECTED RESIDUES ^{4/} (PPM)		Plant	7/ 12.0 ppm (k)	8/ 46.4 ppm	MAXIMUM ADJUSTED RESIDUES ^{5/}		Plant	9/ 2.4 ppm	TOTAL RESIDUES (PPM)	
					Animal	Plant				Animal	Both Plant/Animal			6 /	
Bobwhite Quail (14-Day)	9200.0	1840.0	80%	20%	58 ppm (k)	7/ 12.0 ppm (k)	Plant	7/ 12.0 ppm (k)	46.4 ppm	8/ 2.4 ppm	9/ 2.4 ppm	Plant	9/ 2.4 ppm	48.8 ppm	48.8 ppm
			Beetles Weevils Grasshoppers Etc.	Seeds: Ragweed Lespedeza Corn Etc.											
Bobwhite Quail (Adult)	20579.0	4116.0	27%	73%	58 ppm (k)	7/ 12.0 ppm (k)	Plant	7/ 12.0 ppm (k)	15.7 ppm	8/ 8.8 ppm	9/ 8.8 ppm	Plant	9/ 8.8 ppm	24.4 ppm	24.4 ppm
			Beetles Weevils Grasshoppers etc.	Seeds: Ragweed Lespedeza Corn etc.											
Robin	18377.0	3675.0	40%	60%	58 ppm (k)	7/ 12.0 ppm (k)	Plant	7/ 12.0 ppm (k)	23.2 ppm	8/ 7.2 ppm	9/ 7.2 ppm	Plant	9/ 7.2 ppm	30.4 ppm	30.4 ppm
			Caterpillars Beetles Weevils Earthworms Etc.	Seeds/ Fruits: Cherry Dogwood Holly 100% Seeds: Corn Pigweed Etc.											
Mourning Dove	16429.0	3286.0	0%	100%	0	12.0 ppm (k)	Plant	12.0 ppm (k)	0.0	8/ 12.0 ppm	9/ 12.0 ppm	Plant	9/ 12.0 ppm	12.0 ppm	12.0 ppm

All footnotes on page 9.

TABLE 2C.

Dietary contamination (plant animal) and total estimated residues for eight species of non-target birds.

SPECIES	CALCULATED LC50 (PPM)	1/5 CALC. LC50 (PPM)	FOOD CONSUMED (%)	MAXIMUM EXPECTED RESIDUES		MAXIMUM ADJUSTED RESIDUES	TOTAL RESIDUES	
				Animal	Plant			Animal
Eastern Cowbird (Adult)	13143.0	2629	52%	58.0 ppm(k)	12.0 ppm(k)	30.2 ppm ^{8/}	35.9 ppm	
			Grasshoppers	48%	58.0 ppm(k)	12.0 ppm(k)	30.2 ppm ^{8/}	35.9 ppm
			Beetles Caterpillars	Seeds: Bristlegrass Oats				
Field Sparrow (Adult)	5560.0	1112.0	51%	58.0 ppm(k)	12.0 ppm(k)	29.6 ppm	35.5 ppm	
			Beetles	49%	58.0 ppm(k)	12.0 ppm(k)	29.6 ppm	35.5 ppm
			Grasshoppers Caterpillars Etc.	Seeds: Crabgrass Bristlegrass Panicgrass Etc.				
Grasshopper Sparrow (Adult)	5560.0	1112.0	61%	58.0 ppm(k)	12.0 ppm(k)	35.4 ppm	40.1 ppm	
			Grasshoppers	39%	58.0 ppm(k)	12.0 ppm(k)	35.4 ppm	40.1 ppm
			Caterpillars Ants Etc.	Seeds: Bristlegrass Ragweed Knotweed Etc.				
Carolina Wren (Adult)	5378.0	1076.0	99%	58.0 ppm(k)	12.0 ppm(k)	57.4 ppm	57.5 ppm	
			Ants	1%	58.0 ppm(k)	12.0 ppm(k)	57.4 ppm	57.5 ppm
			Flies Millipedes Etc.	Seeds Poison-Ivy Pine Oaks Etc.				

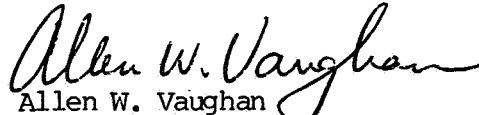
All footnotes on page 9.

FOOTNOTES FOR TABLE 2B AND 2C

- / Refer to table 1 (Footnote 6) for an explanation of how the "calculated LC50's" were obtained.
- / Application of Sec. 102.11(c)(2)(iii)(B) criterion of Sec. 3 Regulations.
- / This information is taken from:
Martin, Alexander C., et al., American Wildlife and Plants; A Guide to Wildlife Food Habits, Dover Publ., Inc., N.Y., 1951
- / Based upon a 1.00 lb. active ingredient per acre, application to expected food items using following references:
- (a) Hoerger, F.D. and E.E. Kenaga, Pesticide Residues on Plants. Correlation of Representative Data as a Basis for Estimation of Their Magnitude in the Environment. Environmental Quality, Academic Press, New York, I: 9-28, 1972.
- (b) Kenaga, E.E., Factors to be Considered in the Evaluation of the Toxicity of Pesticides to Birds in Their Environment, Environmental Quality and Safety, Academic Press, N.Y., II: 166-181, 1973.
- 5/ Residue values adjusted to reflect % animal/plant matter consumed. Examples:
- | | |
|---|---|
| (a) Bobwhite Quail, Adult: | (b) Robin, Adult: |
| $58.0\text{ppm} \times 0.27$ (27%) = 15.7 ppm | $58.0\text{ppm} \times 0.40$ (40%) = 23.2 ppm |
| $12\text{ ppm} \times 0.73$ (73%) = 8.8 ppm | $12\text{ ppm} \times 0.60$ (60%) = 7.2 ppm |
- 5/ Reflects total residues expected in the diet: animal or plant alone or a total of animal and plant food items. Examples:
- | | |
|---|---|
| (a) Robin, Adult: | (b) Mourning Dove, Adult: |
| $23.2 + 7.2 = 30.4$ ppm total for animal and plant foods. | 12 ppm total expected in food items consumed
(i.e., 1.00 (100%) \times 12 ppm = 12 ppm). |
- 7/ (k) refers to maximum expected residues as per (4)(a), and (b) above.
- 8/ This is the maximum expected residue value for daily pesticide burden occurring from animal items.
- 9/ Daily pesticide burden occurring from ingested plant items.

104.5 Beneficial Insects

Data on hand at the Agency indicate that iprodione is not toxic to honey bees, even when bees are exposed to direct applications at very high rates. Thus, application to almonds in bloom should not present a hazard to bees.


Allen W. Vaughan
EPA/HED/EEB Entomologist

104.1.2 Endangered Species Consideration

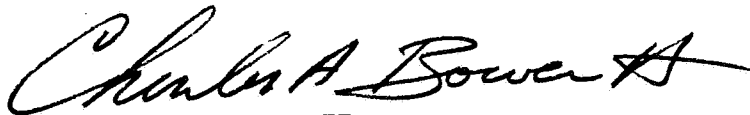
Due to the low toxicity and low bioaccumulative nature of Rovral adverse effect to federally protect species are not expected.

107.0 Conclusions107.2 Data Requests

Data referenced in Section 103 above are sufficient to support the proposed conditional registration of Rovral on Almonds.

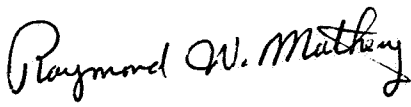
107.2 EEB' Findings

The Ecological Effects Branch (EEB) has completed an incremental risk assessment (3(c)(7) finding) of the proposed conditional registration of Rovral (iprodione) for use on almonds. Agricultural census data indicates that this fungicide could be applied to at least 121,000 acres of California cropland. As such, the proposed registration of Rovral on an additional 347,159 acres of almonds could represent a significant (286 %) increase in potential use. However, the available fish and wildlife toxicity data indicates that product registration would not pose an acute hazard to non-target organisms. Therefore, based upon the available data EEB concludes that the proposed use provides for a significant increase in exposure, but not in acute risks to non-target organisms.



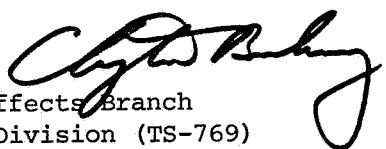
Charles A. Bowen II
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Clayton Bushong
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Hazard Evaluation Division (TS-769)

Date: 9/7/82

APPENDIX I

(PRODUCT LABEL)

I P R O D I O N E

Page is not included in this copy.

Pages 14 through 16 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) .
 - The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
