RF 6-2-87

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: 87-LA-02, 87-AR-04, 87-MS-01. Proposed Secton 18 for Iprodione (Rovral® 50WP, EPA Reg. No. 359-685) on Rice. No Accession Number / No MRID Number RCB Nos. 2338, 2339 and 2340.

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To: Emergency Response and Minor Use Section
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and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The states of Arizona, Louisiana and Mississippi are requesting Section 18 Specific Exemptions authorizing application of the fungicide iprodione [3-(3,5-dichlorophenyl)N-(1-methylethyl)-2,4-dioxo-1-imidazoladinecarboxamide] Rovral® 50WP, 50% a.i. wettable powder) to rice to control Rhizoctonia Sp.

Established tolerances for the combined residues of iprodione (RP-26019), its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP-30228), and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide (RP-32490) range from 0.1 ppm in or on garlic to 300 ppm in or on raisins. Established tolerances for animal commodities include an additional metabolite, N-(3,5-dichloro-4-hydroxyphenylureidocarboxamide (RP-36115), and range from 0.5 ppm (cattle fat, meat) to 3 ppm (cattle kidney, liver) (40 CFR 180.399). All four compounds are expressed as iprodione equivalents. Tolerances are currently pending for several commodities. A Registration Standard has not been completed for iprodione.

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The proposed use for Rovral® 50WP on rice calls for two foliar applications at 0.5 lb.a.i./A to flooded rice fields in 10 gallons of water/A using aerial equipment. The first application would be made at the booting stage, and the second application 14-21 days later. The interval between final application and water removal for harvest would vary between 20 and 40 days.

The metabolism of iprodione is adequately understood in plants and animals. The residue of concern consist of the compounds included in the tolerances expression.

Residue data were submitted with a prevous Section 18 (86-LA-07; M. Metzger, 4/8/86) and with PP#6F3443/FAP#6H5507 (Acc. No. 264228). The data submitted with the previous Section 18 is a part of the data submitted with the petition. Method No. 162 was utilized to generate these residue data. In this method, the rac is extracted with acetone followed by evaporation of the organic phase, liquid-liquid partitioning with ethyl acetate in methylene chloride, and clean-up using gel permeation chromatography, acetonitrile-hexane and florisil. Analysis is accomplished by GLC using a ^{63}Ni electron capture detector. Recoveries of the parent (RP-26019), its isomer (RP-30228) and its metabolite (RP-32490) from grain, straw, bran and hulls ranged from 81-142% at fortification levels of 0.05-10 ppm. The limit of detection for this method is 0.05 ppm.

Residue data are summarized below. Two applications were made to rice after flooding at rates of either 0.5 (1X) or 1.0 (2X) lbs.a.i./A/application. Applications were made by air or using a CO_2 backpack.

Application Rate (lbs.a.i./A)	Location	PHI	Iprodione Combined Residues (ppm) Grain	Straw
0.5	LA	32	1.54	4.16
	MS	32	1.12	1.72
	LA	33	8.28	9.12
	TX	34	1.92	3.68
	TX	35	2.57	2.92
	LA	36	2.90	11.48
	AR	38	0.66	1.89
	AR	42	0.25	2.98
	AR	43	0.25	1.64
	MS	43	3.12	8.41
	MS	58	0.84	0.90
1.0	TX	35	4.25	4.59

Based on these data, we conclude that our previous recommendations of 20 ppm for rice grain and 40 ppm for rice straw cannot be revised and are the maximum combined residues of iprodione and its metabolites likely to be found as a result of the proposed use.

A Rice processing study was submitted with PP#6F3443. The results of this study are summarized in the table below.

Commodity	Combined Residues (ppm) 1X Rate	2X Rate	Average Concentration Factor
Rough rice	2.57	4.25	-
Polished rice	0.24	0.60	0.12
Hulls	10.86	20.24	4.50
Bran	6.31	7.68	2.13

Based on these data, and for the purposes of this Section 18 only, we conclude that combined residues of iprodione, its isomer and its metabolite are not likely to exceed the following values as a result of the proposed use.

Commodity	Maximum Likely Residue (ppm)
Polished rice	2.0
Hulls	100
Bran	40

Meat, Milk, Poultry and Eggs

The dietary intake for beef cattle could consist of 149 ppm combined iprodione residues based on dry grape pomace (30%, 225 ppm tolerance), peanut hay (25%, 150 ppm), raisin waste (10%, 300 ppm), rice straw (10%, 40 ppm) and rice bran/polishings (25%, 40 ppm). The dietary intake for dairy cattle could consist of 169 ppm combined iprodione residues based on dry grape pomace (20%, 225 ppm tolerance), peanut hay (60%, 150 ppm), raisin waste (10%, 300 ppm) and rice bran/polishings (10%, 40 ppm).

The diets of turkeys/broilers could consist of 36 ppm combined iprodione residues based on dry grape pomace (5%, 225 ppm tolerance), peanut meal (10%, 0.5 ppm), soapstock (5%, 10

ppm), rice grain with hulls (40%, 20 ppm) and rice bran/polishings (40%, 40 ppm). The diets of laying hens could consist of 24 ppm combined iprodione residues based on dry grape pomace (5%, 225 ppm), peanut meal (10%, 0.5 ppm), soapstock (5%, 10 ppm), rice grain with hulls (20%, 20 ppm) and rice bran/polishings (20%, 40 ppm).

A lactating cow feeding study was submitted with PP#2F2728 and reviewed by M. Kovacs (10/25/83). Cattle were fed 200 ppm iprodione in their diets for 28 days. Maximum residues found in tissues and milk are shown below.

Commodity	Max. Residue Found (ppm)	Current Tolerance ppm
Cattle milk	0.389	0.5
" muscle	0.13	0.5 (meat, fat and meat byproducts except kidney and liver)
" fat	0.52	0.5 "
" liver	1.95	3
" kidney	2.87	3

Based on these data, we conclude that the tolerances for milk; the meat, fat and meat by-products except kidney and liver for cattle, goats, hogs, horses and sheep; and the kidney and liver of cattle, goats, hogs, horses and sheep will not be exceeded due to the increased dietary residue intake caused by iprodione use on rice as described in this Section 18.

Residue data for poultry were reviewed by R. W. Cook (PP#4F3129; memo 2/15/85). Maximum residues of iprodione and its metabolites in poultry muscle at 28 days were <0.05, 0.32 and 1.68 ppm at the 2, 20 and 100 ppm feeding levels. Levels in fat were 0.18, 2.57 and 8.62 ppm; and residues in liver were 0.61, 4.10 and 13.4 ppm and in kidney were 0.33, 2.30 and 6.87 ppm respectively at the same dietary intakes. Maximum residues in eggs at 7-28 days were 0.137, 0.75 and 2.17 ppm at feeding levels of 2, 20 and 100 ppm respectively. Based on these data, we estimate that residues will not exceed the values shown in the following table when iprodione is used as proposed in this section 18. These residues could exceed the established tolerances in each case except eggs.

Commodity	Estimated Maximum Residue (ppm)	Tolerance (ppm)
Eggs	0.8	0.8
Poultry fat	4.0	2
" liver and kidney	7.0	3
" muscle	0.7	0.5 (meat and meat byproducts except kidney and liver)

Catfish and Crayfish

The procedure used to determine residues of iprodione in crayfish was submitted with this section 18. ^{14}C labelled iprodione (location of label not specified) was dissolved in acetone, and after determination of the activity, the solution was transferred to air-dried sandy loam soil. The acetone was removed with a stream of N_2, and the soil was mixed thoroughly using a rock tumbler. This pre-mix was then mixed with stock soil and the activity of the soil was measured yeilding a ^{14}C-iprodione concentration of 1.6 ppm. The soil and untreated soil (control) were spread over the bottom of tanks to 2 cm. depth and aged for 28 days with soil moisture maintained by addition of water. Crayfish were added to both control and treated tanks and then removed at intervals (0-28 days). Total ^{14}C activity was measured at each point for both the edible portion and whole crayfish. Remaining crayfish were transferred to other tanks containing clean, flowing water, and were then removed from these tanks at intervals (0-14 days) for similar residue determination. Residue data for crayfish are shown in the table below.

		Crayfish Residues (ppm)	
	Day	Edible	Whole
Uptake			
	0		
	1	0.094	0.28
	3	0.10	0.32
	7	0.16	0.46
	10	0.20	0.38
	14	0.19	0.48
	21	0.19	0.22
	28	0.25	0.29
Depuration			
	1	0.14	0.34
	3	0.21	0.44
	7	0.079	0.12
	10	0.051	0.33
	14	0.039	0.12

These data do not reflect conditions which might be present if iprodione were applied as described in the proposed use. The soil concentration used in the study (1.6 ppm) does reflect the approximate maximum soil concentration found for application at the proposed use rate. However, the concentration of pesticide in water is lower in the study than under actual use conditions by a factor of 10 (30 in one sample) for approximately the first week of crayfish exposure.

Additionally, studies are not available showing residues in catfish tissues.

However, for the purposes of this section 18 only, we estimate that residues of iprodione in or on whole crayfish and catfish will not exceed 2.0 ppm, and in the edible portion of crayfish and catfish will not exceed 1.0 ppm when iprodione is applied as described in the proposed use.

Conclusions

(1) The metabolism of iprodione in both plants and animals is adequately understood.

(2) Residues are not likely to exceed the values shown in the following table when Rovral® 50WP is applied as proposed in this section 18.

Commodity	Max. Likely Residue (ppm)	Tolerance (ppm)
Rice grain	20	-
Rice straw	40	-
Polished rice	2.0	-
Rice hulls	100	-
Rice bran/germ/polishings	40	-
Meat and meat byproducts except kidney and liver of cattle, goats, hogs, horses and sheep	0.5	0.5
Kidney and liver of cattle, goats, hogs, horses and sheep	3	3
Milk	0.5	0.5
Eggs	0.8	0.8
Poultry fat	4.0	2
Poultry liver and kidney	7.0	3
Poultry muscle	0.7	0.5
Crayfish (whole)	2	-
Crayfish (edible portion)	1	-
Catfish (whole)	2	-
Catfish (edible portion)	1	-

(3) For the purposes of this Section 18, we consider the following analytical methods to be adequate for enforcement:

Rhodia Method No. 162 for rice grain, straw and processed fractions.
Method ADC No. 623 for iprodione and its non-hydroxylated metabolites in animal and fish (shellfish) tissues.
Rhone-Poulenc Method No. 159 for the hydroxylated metabolites of iprodione in animal and fish (shellfish) tissues.

Note: Neither Method No. 623 nor Method No. 159 has been validated for fish tissues. These methods will be considered adequate for enforcement only for the purposes of this Section 18.

RCB does not currently have non-CBI copies of any of these methods. These must be submitted by the producer of the pesticide so that the methods can be made available for enforcement purposes.

(4) Analytical reference standards are available from the Pesticides and Industrial Chemicals Repository for iprodione (RP-26019), its isomer (RP-30228) and its metabolite (RP-32490). Standards are not available for the animal metabolite RP-36115. RCB will contact Rhone-Poulenc regarding their supplying the repository with this chemical.

Recommendations

TOX considerations permitting, and providing that non-CBI analytical methods are provided as discussed in (3) above, and that analytical reference standards are supplied as described in (4) above, RCB has no objections to this Section 18. Agreements should be made with the FDA and the USDA regarding the legal status of the treated commodities in commerce since the proposed use may result in residues exceeding the existing tolerances for poultry.

cc: Iprodione (Rovral®) S.F., R.F., Section 18 S.F., Circu, M.Metzger, PMSD/ISB
RDI:E.Zager:EZ:5/27/87:RDS:5/27/87
TS-769C:RCB:M.Metzger:MM:Rm.803a:CM#2:5/27/87