

Shaughnessy No.: 109801

Date Out of EAB: JUL 30 1987

To: Lois Rossi
Product Manager #21
Registration Division (TS-767)

From: Theresa M. Dougherty, Chief
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

THD

Attached, please find the EAB review of...

Reg./File # : 359-685

Chemical Name: Iprodione

Type Product : Fungicide

Product Name : Rovral, RP 26019, Glycophene

Company Name : Rhone-Poulenc, Inc.

Purpose : Amendment of label to include use on rice.

Action Code(s): 335 EAB #(s) : 6818

Date Received: 8/22/86 TAIS Code: 303

Date Completed: JUL 30 1987 Monitoring submitted: _____

Total EAB Reviewing Time: 3.0 days Monitoring requested: _____

Deferrals to: _____ Ecological Effects Branch
_____ Residue Chemistry Branch
_____ Toxicology Branch

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1. CHEMICAL: Common name:

Iprodione

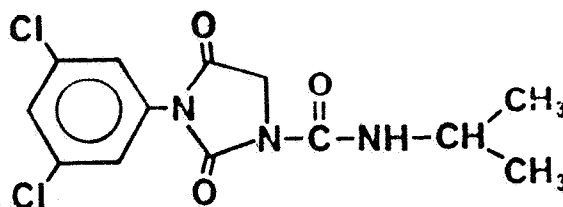
Chemical name:

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

Trade name(s):

Rovral, RP 26019, Glycophene

Structure:



Formulations:

50% WP

Physical/Chemical properties:

Molecular formula: $C_{13}H_{13}Cl_2N_3O_3$.

Molecular weight: 329.9

Physical state: White, odorless, nonhygroscopic crystals.

Solubility: Soluble in acetone and benzene. Almost insoluble in water (13 mg/L).

2. TEST MATERIAL:

See individual studies.

3. STUDY/ACTION TYPE:

Amendment of label to include use on rice.

4. STUDY IDENTIFICATION:

Gemma, A., G. Heinzelmann, and J. Wargo. 1986. Iprodione aquatic field dissipation and field irrigated crop study. Submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ. Acc. No. 264230.

McAllister, W.A., B. Bunch, and J. Burnett. 1986. Bioconcentration and depuration of [^{14}C]iprodione by crayfish (*Procambarus simulans*, Faxon), under static uptake conditions with a treated soil substrate. Report No. 33438. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Rhone-Poulenc Inc., Monmouth Junction, NJ. Acc. No. 264231.

Thomas, R.D. 1982. Aquatic metabolism of ^{14}C -RP-26019. Borriston Project No. 32201. Unpublished study prepared by Borriston Laboratories, Temple Hills, MD and submitted by Rhone-Poulenc, Chemical Co., Monmouth Junction, NJ. Acc. No. 264229.

Thomas, R.D. 1983. Anaerobic aquatic metabolism of ^{14}C -RP-26019. Prepared by Borriston Laboratories, Inc., Temple Hills, MD, and submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ. Acc. No. 264229. Reference B.

5. REVIEWED BY:

H. Manning
Chemist
EAB/HED/OPP

Signature: Hedert L. Manning
Date: July 30 1987

6. APPROVED BY:

Therese M. Dougherty
Chief
Review Section #1, EAB/HED/OPP

Signature: Therese M. Dougherty
Date: JUL 30 1987

7. CONCLUSIONS:

- Anaerobic aquatic metabolism- The study contains several major deficiencies and is unacceptable. See individual study for specifics.
- Aerobic aquatic metabolism- The study contains several major deficiencies and is unacceptable. See individual study for specifics.
- Aquatic field dissipation and accumulation in irrigated crops- Regarding field dissipation at the LA site, following a second application at 14 days (total of 1.0 lb ai/A), iprodione was undetected in water by day 47; in the sediment sampling, iprodione ranged from <0.05 to 1.29 ppm in 0-8 cm depth and <0.05 to 0.26 ppm in 8-16 cm depth. At the AR site (total of 1.0 lb ai/A) iprodione in water was undetected in 14 days; in sediment, iprodione ranged from <0.05 to 0.22 ppm in 0-8 cm depth and was undetected below that. The study is unacceptable. See DATA EVALUATION RECORD (DER) for deficiencies.

Regarding accumulation in irrigated crops, no residues were detected in soil or crops irrigated with water from treated rice plots. The study satisfies this data requirement.

- Crayfish accumulation- This is ancillary information to the fish accumulation study. Maximum bioconcentration factors were 10X in edible tissue and 20X in whole crayfish.

8. RECOMMENDATIONS:

The data required to register a pesticide for use on rice and their current status in our files is as follows:

- Hydrolysis- Data requirement is satisfied.
- Photodegradation (water)- Data requirement is satisfied.
- Aerobic aquatic metabolism- This requirement is a data gap.
- Anaerobic aquatic metabolism- Submitted study is unacceptable.
- Leaching(adsorption/desorption)- This requirement is a data gap. We recommend the unaged parent, and the degradates RP-30228 and RP-32490, be tested in four soil types representative of rice use areas.
- Aquatic field dissipation- Submitted study is unacceptable.
- Confined Rotational crop- This requirement is a data gap.
- Accumulation in irrigated crops- Data requirement is satisfied.
- Fish accumulation- Data requirement is satisfied.

Therefore, the studies that are required for registration of iprodione on rice are: aerobic and anaerobic aquatic metabolism, adsorption/desorption, aquatic field dissipation, and rotational crop. The identities of major degradates should be confirmed through the use of adequate methodology.

9. BACKGROUND:

A. Introduction

Rhone-Poulenc is requesting a change in their Rovral label to include rice and have submitted several aquatic-related studies to support the new use. In a previous review (5/6/86), the State of Louisiana requested an emergency exemption (Section 18) to use iprodione on rice.

B. Directions for Use

Iprodione is a contact fungicide active on a broad spectrum of diseases including Botrytis, Sclerotinia, Monilinia, Alternaria, Helminthosporium, Fusarium, and Rhizoctonia. See attached supplemental label.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

See individual studies.

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11. COMPLETION OF ONE-LINER:

Not applicable.

12. CBI APPENDIX:

All data reviewed here are considered company-confidential by the registrant and must be treated as such.

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IPRODIONE

Initial Draft Report

**Task 1: Review and Evaluation of
Individual Studies**

Contract No. 68-02-4250

MAY 19, 1987

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

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INTRODUCTION

Iprodione is a contact fungicide active on a broad spectrum of diseases including Botrytis, Sclerotinia, Monilinia, Alternaria, Helminthosporium, Fusarium, and Rhizoctonia.

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IPRODIONE

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DATA EVALUATION RECORD

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CASE GS -- IPRODIONE STUDY 1 PM --

CHEM 109801 Iprodione

BRANCH EAB DISC --

FORMULATION 00 - ACTIVE INGREDIENT

FICHE/MASTER ID No MRID CONTENT CAT 01
Thomas, R.D. 1983. Anaerobic aquatic metabolism of ¹⁴C-RP-26019. Prepared
by Borriston Laboratories, Inc., Temple Hills, MD, and submitted by Rhone-
Poulenc Inc., Mornmouth Junction, NJ. Acc. No. 264229. Reference B.

SUBST. CLASS = S.

DIRECT RW TIME = 12 (MH) START-DATE END DATE

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TEL: 468-2500

APPROVED BY: H. Manning
TITLE: Chemist
ORG: EAB/HED/OPP
TEL: 557-2243

SIGNATURE:

DATE:

CONCLUSIONS:Metabolism - Anaerobic Aquatic

This study is scientifically invalid because the study was of insufficient duration, thereby preventing all degradates from being identified. See DISCUSSION for other comments.

MATERIALS AND METHODS:

Silt loam sediment (15% sand, 62% silt, 23% clay, pH 7.9, CEC 12.4 meq) from Mississippi was placed in a flask, flooded with natural water (pH 6.7, hardness 110 mg/L CaCO₃, suspended solids 84 mg/L, obtained from the same site as the sediment), stoppered, and incubated in the dark at room

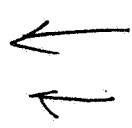
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temperature for 30 days to establish anaerobic conditions. The sediment:water ratio was 1:5. Following the incubation period, phenyl ring-labeled [^{14}C]iprodione (RP-26019, radiochemical purity 98.9%, specific activity 10.5 Ci/mg, Rhone-Poulenc, Inc.) was added at 10.26 ppm (based on the water in the system). An aliquot of a 12% glucose solution was added to the treated system to serve as a carbon source. Nitrogen gas was continuously passed over the treated water: sediment system and then through a polyurethane plug and a 1 N sodium hydroxide trap. Water and sediment were sampled at 0, 1, 3, 7, 14, 21, and 30 days and at 3 and 6 months posttreatment. The gas traps were sampled at 1, 3, 7, 14, 21, and 30 days posttreatment.

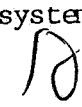
The polyurethane plugs were extracted with methanol. Radioactivity in the methanol extracts, sodium hydroxide solutions, and water samples was quantified by LSC. The water samples were extracted four times with ethyl acetate, and the extracts were combined and frozen to remove excess water. The ethyl acetate extract and the aqueous phase (from extraction step) were evaporated to near dryness, and the resulting residues were dissolved in acetone and analyzed by TLC. TLC was performed on silica gel plates developed in either methylene chloride:ethyl acetate:formic acid (85:10:5) or toluene:ethyl acetate:acetic acid (80:15:5). Unlabeled standards were cochromatographed with the extracts. Following development, radioactive areas were located by autoradiography and quantified by cutting the plate into segments and counting with LSC. Radioactivity in the sediment samples was quantified by LSC following combustion. The sediment samples were extracted (Figure 1), and the extracts were analyzed by TLC as described above.

REPORTED RESULTS:

[^{14}C]Iprodione degraded with calculated half-lives of 6.4 days in the water layer and 126 days in the sediment:water system. During the incubation period, [^{14}C]residues partitioned from the water layer and became associated with the sediment layer (Table 1). At 184 days post-treatment, the major degradate, RP-30228, accounted for 71% of the recovered radioactivity in the sediment extracts and 19% of the recovered in the water extract (Table 2).



DISCUSSION:

1. The half-lives of 6.4 days in water phase and 126 days in sediment: water were not referenced to a table showing the data. Using column 1 (parent in water) of Table 6, we ran a linear regression analysis (attached) and obtained a half-life of 13.7 days (based on first five data points). For parent in sediment:water (column 5), the first four data points gave an unreliable half-life, since the r^2 value was 0.33. Residue decline curves of parent (RP-26019) were not referenced to a data table (Table 6 data did not fit the decline curves).
 2. The test sediment was misclassified as a silt. The sediment was determined to be a silt loam according to the USDA Textural Classification system and is described as such in this report.
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3. Although the degradate data were difficult to interpret (Table 2), it appears that all degradates were not characterized.
4. At study termination (184 days posttreatment), the concentrations of the degradates were still increasing; therefore, the patterns of formation and decline of degradates were not adequately addressed and the study was conducted for an insufficient length of time.

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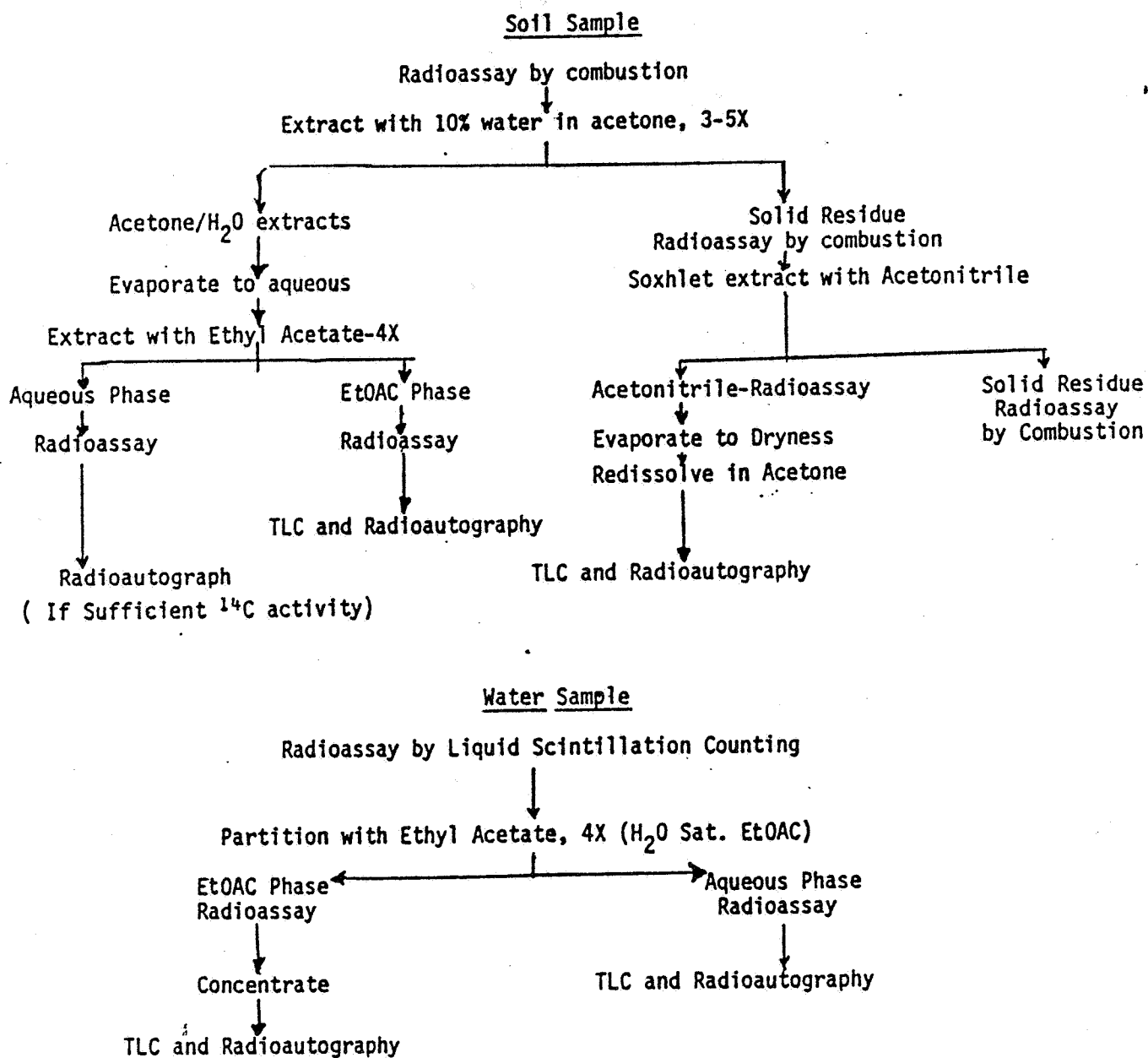


Figure 1. Extraction of [¹⁴C]iprodione residues from sediment.

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Table 1. Distribution of radioactivity (% of applied) following the application of phenyl ring-labeled [^{14}C]iprodione at 10.26 ppm to silt loam sediment and incubated under anaerobic aquatic conditions.

Sampling interval (days)	Water layer		Silt loam sediment			CO_2	Volatiles	Total [^{14}C] recovered
	Ethyl acetate extract	Unextractable	Acetone extractable	Acetonitrile extractable	Unextractable			
0	84.2	25.7	0.57	0.44	0.17	<0.1	<0.1	111.0
1	72.0	21.5	4.4	0.61	1.15	<0.1	<0.1	99.7
3	91.3	0.3	17.9	1.9	1.12	<0.1	<0.1	112.5
7	49.0	0.2	13.8	5.1	0.94	<0.1	<0.1	68.8
14	39.4	0.1	46.9	8.2	1.5	<0.1	<0.1	96.1
21	36.0	0.1	33.4	5.1	1.3	<0.1	<0.1	75.9
30	36.9	0.1	44.3	8.1	1.4	<0.1	<0.1	90.8
90	27.8	0.1	49.9	5.2	1.2	--	--	84.2
184	24.6	<0.1	33.7	2.2	4.9	--	--	65.4

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Table 2. Distribution of radioactivity in water and sediment extracts (% of recovered from TLC plates) following the application of phenyl ring-labeled [^{14}C]iprodione at 10.26 ppm to silt loam sediment and incubated under anaerobic aquatic conditions.

Sampling interval (days)	Iprodione	RP-30228	Origin	Unknowns ^a
		<u>Water^b</u>		
0	94.4	2.8	0.2	2.6
1	63.8	30.7	0.2	5.3
3	64.7	30.2	0.4	4.7
7	75.8	21.9	0.4	2.0
14	83.2	14.5	0.4	1.9
21	85.7	12.1	0.3	1.9
30	88.5	9.1	0.4	2.0
90	87.5	3.3	0.4	9.1
184	72.3	18.5	--	9.2
		<u>Silt loam sediment^c</u>		
0	72.1	24.2	ND ^d	2.9
1	45.5	50.9	ND	3.6
3	39.9	58.5	ND	1.7
7	47.8	50.9	ND	1.3
14	40.1	59.0	ND	0.8
21	40.3	59.4	ND	0.3
30	40.2	57.6	ND	2.3
90	32.6	66.3	ND	1.1
184	23.0	70.6	ND	6.4

^a Combined concentrations of two unknowns; individual data were not provided.

^b Ethyl acetate extract.

^c Acetone and acetonitrile extracts.

^d Not detected; the detection limit was not reported.

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DATA EVALUATION RECORD

PAGE 1 OF 3

CASE GS -- IPRODIONE STUDY 2 PM --

CHEM 109801 Iprodione

BRANCH EAB DISC --

FORMULATION 00 - ACTIVE INGREDIENT

FICHE/MASTER ID No MRID CONTENT CAT 01
Thomas, R.D. 1982. Aquatic metabolism of ^{14}C -RP-26019. Report No. 3-2201.
Unpublished study prepared by Borriston Laboratories, Temple Hills, MD, and
submitted by Rhone-Poulenc, Inc., Mommouth Junction, NJ. Acc. No. 264229.

SUBST. CLASS = S.

DIRECT R/W TIME = 8 (MH) START-DATE END DATE

REVIEWED BY: R. Tamma
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APPROVED BY: H. Manning
TITLE: Chemist
ORG: EAB/HED/OPP
TEL: 557-2243

SIGNATURE:

DATE:

CONCLUSIONS:Metabolism - Aerobic Aquatic

This study is scientifically invalid because there was no soil used in the study. In addition, the material balance was incomplete and variable, ranging from 16.3 to 84.9% of the applied and all degradates were not characterized.

MATERIALS AND METHODS:

Unfiltered water (pH 6.7, hardness 110 mg/L CaCO_3 , obtained from a rice field in Mississippi) was treated with phenyl ring-labeled [^{14}C]iprodione (radiochemical purity 98.9%, specific activity 10.5 Ci/mg, Rhone-Poulenc, Inc.) at 10.26 ppm. The treated water was incubated at 23°C in flasks that were wrapped with aluminum foil. The flasks were attached to a gas collection system; air was continuously passed over the surface of the treated water, through a polyurethane plug, and through a sodium hydroxide solution. Water was sampled immediately after treatment, and water and the sodium hydroxide trapping solution were sampled on 1, 3, 7, 14, and 30 days posttreatment. At each sampling interval, the polyurethane

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plugs were removed from the systems, rinsed with methanol to remove volatiles, and returned to their original position. The methanol rinses were frozen until analysis.

Water samples were extracted four times with water-saturated ethyl acetate. The extracts were combined, frozen overnight to remove excess water, and evaporated to near dryness. The residue was diluted with acetone. The acetone and water fractions were analyzed for total radioactivity using LSC, and for iprodione and its degradates using TLC on silica gel plates developed either in methylene chloride:ethyl acetate:formic acid (85:10:5), or toluene:ethyl acetate:acetic acid (80:15:5). Unlabeled standards were cochromatographed with the extracts. After development, the unlabeled compounds were located under UV light and the radiolabeled compounds were located by autoradiography; [^{14}C]residues were identified by comparison to standards. Radioactive zones were scraped from the plates and quantified using LSC. The sodium hydroxide trapping solutions and methanol washings from the polyurethane plugs were analyzed for total radioactivity using LSC.

REPORTED RESULTS:

[^{14}C]Iprodione degraded with a half-life of 1-3 days (calculated 2.9 days) in nonsterile "natural" water (Table 1). 1-(3,5-Dichloroanilo)-carbonyl-3-isopropylamino-2,4-dioximidazolidine (maximum concentration 59.7% of the applied at day 21) was the major degradate. Three additional degradates, each 3.7% of the applied, were isolated but not identified. The material balance was variable, ranging from 16.3 to 84.9% of the applied. Volatiles totaled 0.182% of the applied after 30 days of incubation.

DISCUSSION:

1. The material balances were incomplete and variable (ranged varied from 16.3-84.9%; four of seven studies were 61.9% or lower). The registrant stated that the low recovery was due to the limited solubility of the degradate RP-30228, but no supporting evidence was provided.
2. There was no soil used in the study.
3. All degradates were not characterized.
4. Recovery from fortified samples was not reported.
5. TLC of ethyl acetate extracts developed in methylene chloride:ethyl acetate:formic acid (80:10:5) detected three unknown degradates, X, Y, and Z, with R_f values of 0.28, 0.31, and 0.41, respectively. The unknown degradate "Z" cochromatographed with the degradate RP-32490 in the above solvent system. However, the two compounds did not cochromatograph when toluene:ethyl acetate:acetic acid (80:15:5) was used as the solvent system.

Table 1. Distribution of radioactivity (% of the applied) in water treated with [^{14}C]iprodione (radiochemical purity 98.9%) at 10.26 ppm and incubated in the dark 23°C.^a

Sampling interval (days)	Iprodione	RP-30228 ^b	Unknown ^a (R_f 0.11)	Origin	Cumulative volatiles	Total [^{14}C]
0	82.7	1.4	0.3	0.4	--	84.8
1	52.4	28.9	2.3	1.3	0.024	84.9
3	25.9	38.3	2.7	1.0	0.037	67.9
7	6.2	25.4	3.2	1.1	0.079	36.0
14	1.8	11.7	1.8	0.9	0.132	16.3
21	0.5	59.7	0.9	0.6	0.169	61.9
30	0.6	51.5	1.0	0.7	0.182	54.0

^a Data are for the TLC plates developed in toluene:ethyl acetate:acetic acid. Data for the methylene chloride:ethyl acetate:formic acid solvent system were similar, except that three unidentified degradates (R_f 0.28, 0.31, and 0.41) were isolated. Each was <3.7% of the applied.

^b 1-(3,5-Dichloroanilino)carbonyl-3-isopropylamino-2,4,-dioxoimidazolidine.

CASE GS -- IPRODIONE STUDY 3 PM --

CHEM 109801 Iprodione
BRANCH EAB DISC --

FORMULATION 07 - WETTABLE POWDER (WP)

FICHE/MASTER ID No MRID CONTENT CAT 01
Gemma, A., G. Heinzelmann, and J. Wargo. 1986. Iprodione aquatic field
dissipation and field irrigated crop study. Submitted by Rhone-Poulenc,
Inc., Morrmouth Junction, NJ. Acc. No. 264230.

SUBST. CLASS = S.

DIRECT RW TIME = 24 (MH) START-DATE END DATE

REVIEWED BY: R. Tamma, L. Binari
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APPROVED BY: H. Manning
TITLE: Chemist
ORG: EAB/HED/OPP
TEL: 557-2243

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DA'

CONCLUSIONS:

Field Dissipation - Aquatic and Aquatic Impact

This study is scientifically valid. However, certain data were not consistent with an acceptable study: the initial concentration of parent iprodione ranged from 0.02 to 0.70 ppm, and the degradate RP-30228 comprised up to 50% of the total residues immediately posttreatment. See DISCUSSION for additional comments.

Field Accumulation - Irrigated Crops

1. This study is scientifically valid.
2. Parent iprodione and its degradates, RP-30228 and RP-32490, were not detected (<0.05 ppm) in sorghum (whole plant), soybeans (seed, pods, trash), sweet potatoes (roots), cotton (whole plant, bolls), or in soil (0- to 8- and 8- to 16-cm depths) irrigated with water from flooded plots of silt loam soil planted to rice and treated twice with iprodione (50% WP) at 0.5 lb ai/A. Iprodione, RP-30228, and RP-32490 concentrations were 0.13, 0.07, 0.08 ppm, respectively, in the irrigation water.

3. This study satisfies this data requirement.

MATERIALS AND METHODS:

Iprodione (Rovral, 50% WP, Rhone-Poulenc Inc.) was applied twice at 0.5 lb ai/A to flooded rice plots (20 m x 30 m) containing silt loam soil (Table 1) located in New Iberia, Louisiana, and Cotton Plant, Arkansas, during July and August, 1985. There were two treated plots and one untreated control plot at each test site. The plots were seeded with rice on April 29 and May 13, 1985, at the Louisiana and Arkansas sites, respectively. The plots were flooded (15-20 cm) at the 4-leaf stage, and the iprodione was applied at the booting and heading stages. At day 0 posttreatment (initial application), adjacent untreated plots (8 m x 20 m; Figure 1) were planted to sorghum, soybeans, sweet potatoes, and cotton. These adjacent plots were irrigated at 8, 15, 28, and 47 days posttreatment (second application) with water from the rice plots. Water samples were taken from the rice plots before treatment and at 0, 3, 7, and 14 days after the first application and at 0 (14 days after initial application), 3, 7, 14, 28, and 47 days after the second application. Sediment samples (0- to 8- and 8- to 16-cm depths) were taken from the rice plots before treatment and at 0, 7, and 14 days after the first application and up to 179 days after the second application. Soil samples were taken from the irrigated plots at 9, 16, 29, and 48 days after the second application. At the Louisiana site, rice grain was sampled at 28 days, sorghum (whole plant) and soybeans (seed, pods, trash) at 109 days, and sweet potatoes (roots) at 121 days after the second application; it was not specified when the cotton was harvested. At the Arkansas site, rice grain was sampled at 28 and 47 days; sweet potatoes, sorghum, and cotton (whole plant and bolls) at 105 days; and soybeans at 119 days after the second application. All samples were frozen until analysis.

Hydrochloric acid (1 N) and 1% aqueous sodium sulfate were added to filtered water samples which were then extracted three times with methylene chloride:ethyl acetate (9:1). Extracts were dried over anhydrous sodium sulfate, combined, and evaporated to dryness. The remaining residue was dissolved in toluene and analyzed for iprodione and its degradates, RP-30228 and RP-32490, by GC with nitrogen-phosphorus detection. Sediment/soil samples were extracted according to the procedure presented in Figure 2 and analyzed by GC. Plant samples were extracted with acetone:water (9:1) in the presence of 1 N hydrochloric acid. The extracts were partitioned with ethyl acetate:methylene chloride:water, hexane:acetonitrile, ethyl ether:pet ether:acetonitrile, cleaned up on a Florisil column, and analyzed by GC; details of the procedure were not provided. Reported recoveries from various substrates fortified with iprodione or its degradates, RP-30228 and RP-32490, are presented in Table 2. The limit of detection in water is 0.01 ppm and in soil and plant samples is 0.05 ppm.

REPORTED RESULTS:

Louisiana site

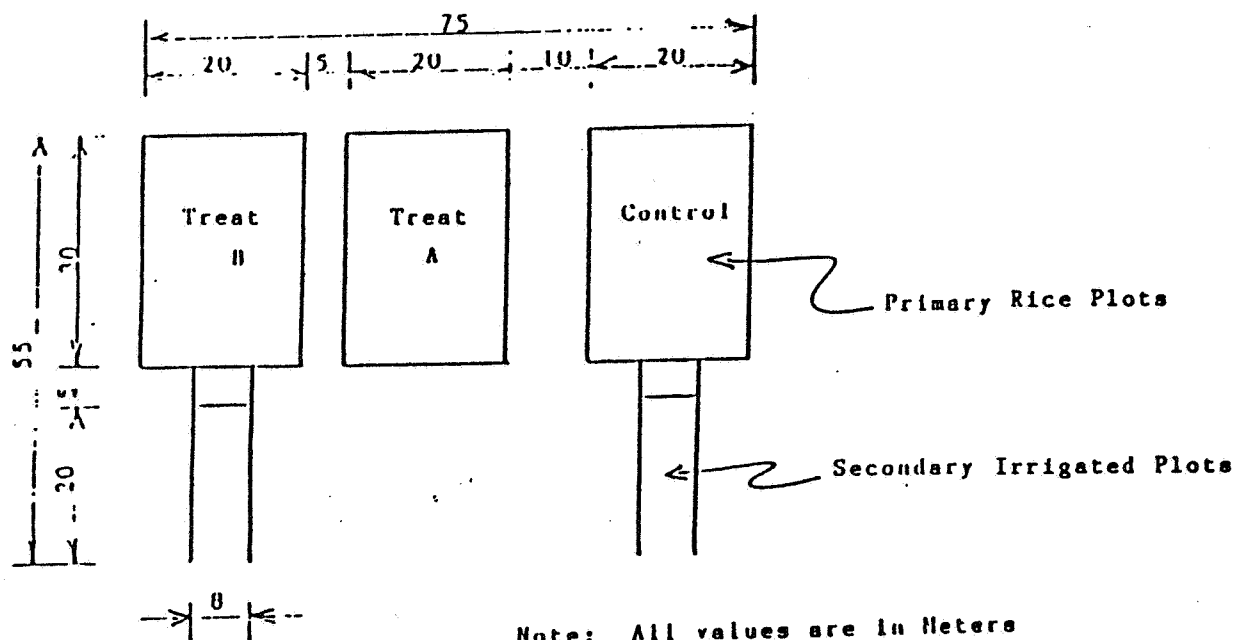
Approximately 52.3 inches of precipitation fell during the test period. High and low air temperature ranges were 38 to 101°F and 24 to 80°F, respectively. Relative humidity ranged from 58 to 100%. During July to September of the test period, the pH of the well water used to flood the rice plots ranged from 6.51 to 6.71, alkalinity ranged from 118 to 130 mg/L CaCO₃, and hardness ranged from 126 to 132 mg/L CaCO₃.

Following the initial application to the flooded rice plots, parent iprodione concentrations in the water were 0.11-0.63 ppm and declined to <0.01 ppm by 14 days posttreatment (Table 3). Following the second application, iprodione concentrations were 0.23 ppm and declined to <0.01 ppm after 47 days. Concentrations of the degradate RP-30228 ranged from <0.01 to 0.30 ppm, while RP-32490 was <0.02 ppm at any sampling interval. In the sediment, iprodione concentrations ranged from <0.05 to 1.29 ppm and <0.05 to 0.26 ppm in the 0- to 8- and 8- to 16-cm depths, respectively. RP-30228 concentrations ranged from <0.05 to 0.53 ppm and were <0.15 ppm in the 0- to 8- and 8- to 16-cm depths, respectively. RP-32490 was not detected (<0.05 ppm) in the sediment. No iprodione, RP-30228, or RP-32490 were detected (<0.05 ppm) in the soil or crops irrigated with the flood waters from the treated rice plots.

Arkansas site

Meteorological data from July 29 (initial application) through September 7, 1985 and January 1 through February 7, 1986 were not reported. From September 8 through December 31, 1985, ~12.9 inches of precipitation fell. High and low air temperatures ranges were 24 to 93°F and 11 to 75°F, respectively. Relative humidity ranged from 46 to 100%. During July to October of the test period, the pH of the well water used to flood the rice plots ranged from 6.38 to 6.85, alkalinity ranged from 32 to 78 mg/L CaCO₃, and hardness ranged from 39 to 76 mg/L CaCO₃.

Following the initial application to the flooded rice plots, parent iprodione concentrations in the water were 0.02-0.70 ppm and declined to <0.01 ppm by 14 days posttreatment (Table 4). Following the second application, iprodione concentrations were 0.15-0.49 ppm and declined to <0.01 ppm after 8 days. Concentrations of the degradates RP-30228 and RP-32490 ranged from <0.01 to 0.70 and <0.01 to 0.17 ppm, respectively. In the sediment (0- to 8-cm depth), iprodione and RP-30228 concentrations ranged from <0.05 to 0.22 ppm and were not detected (<0.05 ppm) at lower depths. RP-32490 was not detected in the sediment. Iprodione, RP-30228, or RP-32490 were not detected (<0.05 ppm) in the soil or crops irrigated with the flood waters from the treated rice plots.



Note: All values are in Meters
 Plot size: Primary 20m x 30m, Secondary 20m x 8m
 Scale: 1 inch = 30 meters

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Figure 1. Field plot design.

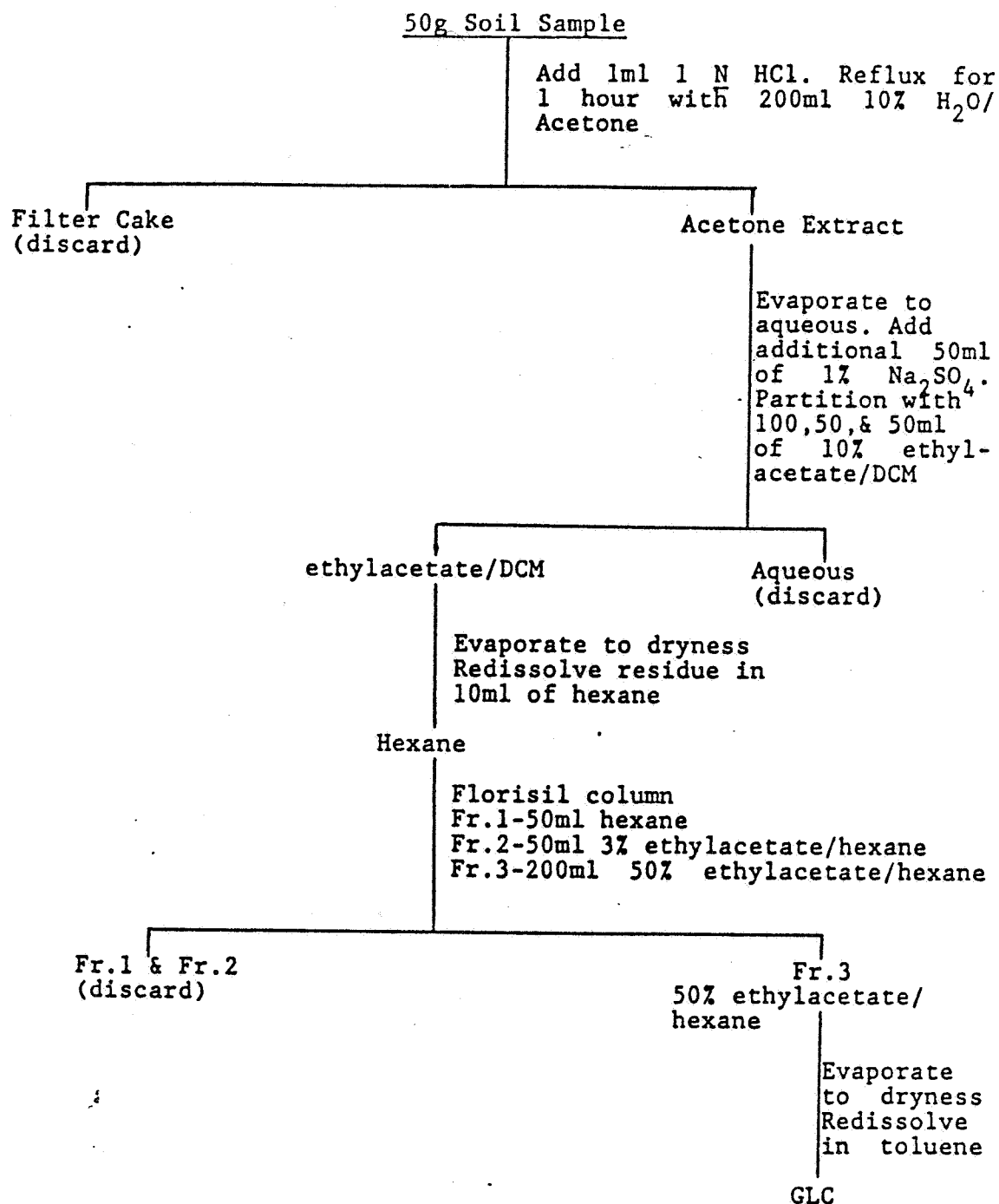


Figure 2. Soil extraction scheme.

Table 1. Soil characteristics.

Soil type	Site	Sand	Silt %	Clay	Organic matter	pH	CEC (meq/100 g)
Silt loam	New Iberia, Louisiana	25.2	52.4	22.4	2.0	4.9	9.4
Silt loam	Cotton Plant, Arkansas	33.2	52.4	14.4	1.3	5.0	5.7

Table 2. Reported recoveries from various substrates fortified with iprodione or its degradates (RP-30228 and RP-32490).

Substrate	Iprodione		RP-30228		RP-32490	
	Fortification level (ppm)	Recovery (%)	Fortification level (ppm)	Recovery (%)	Fortification level (ppm)	Recovery (%)
Water	0.01-0.20	85-116	0.01-0.20	89-122	0.01-0.20	80-135
Soil	0.05-0.50	89-116	0.05-0.50	87-112	0.05-0.50	68-136
Rice grain	0.05-0.10	100-122	0.05-0.10	78-95	0.10	112
Soybeans						
Seed	0.05	87-99	0.05	70-86	0.05	60-119
Pods	0.10-0.25	70-102	0.10-0.25	61-92	--	--
Trash	0.10	80-89	0.10	67-80	0.10	92
Sweet potatoes	0.05-0.25	94-114	0.05-0.25	74-103	0.05-0.10	61-128
Sorghum	0.05-0.10	94-106	0.05-0.10	85-93	0.10	81
Cotton						
Bolls	0.05	90	0.05	80	0.05	86
Whole plant	0.10-0.25	113-116	0.10-0.25	107-118	0.10-0.25	77-141

Table 3. Iprodione and its degradates (ppm) in silt loam soil and water from flooded rice plots in New Iberia, Louisiana, treated twice with iprodione (50% WP) at 0.5 lb ai/A.

Sampling interval (days)	Date	Rice plot	Water			Sediment sampling depth (cm)			
						0-8		8-16	
			Iprodione	RP-30228	RP-32490	Iprodione		RP-30228	
0a	7/28/85	A	ND ^b	ND	ND	ND	ND	ND	ND
		B	ND	ND	ND	ND	--	ND	--
0c	7/28/85	A	0.63	0.17	ND	0.12	ND	ND	ND
		B	0.11	0.06	ND	0.11	ND	ND	ND
3	7/31/85	A	0.09	0.30	ND	0.40	0.09	0.27	0.08
		B	0.06	0.23	ND	0.11	ND	0.05	ND
7	8/4/85	A	0.02	0.12	ND	0.09	ND	0.11	ND
		B	0.03	0.14	ND	ND	ND	ND	ND
14	8/11/85	A	ND	0.02	ND	0.10	ND	0.07	ND
		B	0.01	0.03	ND	ND	ND	ND	ND
0d	8/11/85	A	0.23	0.02	ND	0.23	ND	0.06	ND
		B	0.23	0.03	ND	0.33	ND	0.10	ND
4	8/15/85	A	0.23	0.13	0.02	0.07	ND	0.06	ND
		B	0.15	0.18	0.01	1.29	ND	0.53	ND
8	8/19/85	A	0.08	0.07	0.01	0.35	ND	0.22	ND
		B	0.13	0.05	0.01	0.17	ND	0.09	ND
15	8/26/85	A	0.06	0.04	0.02	0.14	ND	0.11	ND
		B	0.04	0.03	0.01	0.55	0.26	0.24	0.15
28	9/8/85	A	0.01	0.01	ND	0.10	ND	0.13	ND
		B	0.03	0.01	ND	0.11	ND	0.06	ND
47	9/27/85	A	ND	ND	ND	0.41	ND	0.19	ND
		B	ND	ND	ND	0.24	ND	0.07	ND
78	10/28/85	A	--	--	--	ND	ND	ND	ND
		B	--	--	--	0.13	0.08	ND	ND
179	2/6/86	A	--	--	--	ND	ND	ND	ND
		B	--	--	--	ND	ND	ND	ND

a Pretreatment.

b Not detected; the detection limits in water and soil were 0.01 and 0.05 ppm, respectively.

c Initial application.

d Second application; 14 days after initial application.

Table 4. Iprodione and its degradates (ppm) in silt loam soil and water from flooded rice plots in Cotton Plant, Arkansas, treated twice with iprodione (50% WP) at 0.5 lb ai/A.

Sampling interval (days)	Date	Rice plot	Water			Sediment sampling depth (cm)			
			Iprodione	RP-30228	RP-32490	0-8		8-16	
						Iprodione	RP-30228	Iprodione	RP-30228
0a	7/29/85	A	ND ^b	ND	ND	ND	--	ND	--
		B	ND	ND	ND	ND	ND	ND	ND
0c	7/29/85	A	0.70	0.70	ND	ND	ND	ND	ND
		B	0.02	0.14	ND	ND	ND	ND	ND
3	8/1/85	A	0.23	0.24	ND	ND	ND	ND	ND
		B	0.01	0.01	ND	ND	ND	0.06	ND
7	8/5/85	A	0.09	0.15	ND	ND	ND	ND	ND
		B	0.02	0.02	ND	ND	ND	0.07	ND
14	8/12/85	A	ND	0.02	ND	ND	ND	ND	ND
		B	ND	ND	ND	ND	ND	ND	ND
0d	8/12/85	A	0.49	0.30	0.15	0.07	ND	ND	ND
		B	0.15	0.07	0.17	0.08	ND	0.12	ND
4	8/16/85	A	0.15	0.14	0.09	ND	ND	ND	ND
		B	0.07	0.14	0.15	ND	ND	0.05	ND
8	8/20/85	A	0.01	0.01	0.03	ND	ND	ND	ND
		B	0.01	0.03	0.08	ND	ND	ND	ND
15	8/27/85	A	0.01	0.02	ND	ND	ND	0.06	ND
		B	0.01	0.02	0.01	0.10	ND	0.13	ND
28	9/9/85	A	0.01	0.01	ND	ND	ND	ND	ND
		B	0.01	0.01	ND	0.11	ND	0.10	ND
47	9/28/85	A	ND	ND	ND	0.07	ND	0.05	ND
		B	ND	ND	ND	ND	ND	ND	ND
78	10/29/85	A	--	--	--	0.08	ND	0.13	ND
		B	--	--	--	0.07	ND	0.15	ND
179	2/7/86	A	--	--	--	ND	ND	ND	ND
		B	--	--	--	0.13	ND	0.22	ND

a Pretreatment.

b Not detected; the detection limits in water and soil were 0.01 and 0.05 ppm, respectively.

c Initial application.

d Second application; 14 days after initial application.

CASE GS -- IPRODIONE STUDY 4 PM --

CHEM 109801 Iprodione

BRANCH EAB DISC --

FORMULATION 00 - ACTIVE INGREDIENT

FICHE/MASTER ID No MRID

CONTENT CAT 01

McAllister, W.A., B. Bunch, and J. Burnett. 1986. Bioconcentration and depuration of [^{14}C]iprodione by crayfish (*Procambarus simulans*, Faxon), under static uptake conditions with a treated soil substrate. Report No. 33438. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Rhone-Poulenc Inc., Monmouth Junction, NJ. Acc. No. 264231.

SURST. CLASS = S.

DIRECT RVW TIME = 8 (MH) START-DATE END DATE

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CONCLUSIONS:Ancillary Study - Accumulation in Crayfish

1. This study is scientifically valid.
2. Total [^{14}C]iprodione residues accumulated in crayfish with maximum bio-concentration factors of 10x in edible tissue and 20x in whole organisms during 28 days of exposure to residues of phenyl ring-labeled [^{14}C]iprodione (radiochemical purity 99%). During the study, the concentrations of [^{14}C]iprodione residues in the exposure system were 7.6-26 ppb in the water and 840-1400 ppb in the soil; <17% of the [^{14}C]residues in the system were iprodione and 30-50% were 1-(3,5-dichloroanilo)carbonyl-3-isopropylamino-2,4-dioximidazolidine. After 28 days of exposure, the edible crayfish tissue contained 33 ppb of iprodione, 35 ppb of 1-(3,5-dichloroanilo)carbonyl-3-isopropylamino-2,4-dioximidazoline, 41 ppm of RP-44274, and ~90 ppb of all other [^{14}C]residues, including RP-32490, RP-36112, and RP-36114. Similar degradates were identified in the viscera; iprodione was 83 ppb and 1-(3,5-dichloroanilo)carbonyl-3-isopropylamino-2,4-dioximidazolidine was 79 ppb at 28 days posttreatment. By

day 14 of depuration, edible crayfish tissue contained 39 pph total [^{14}C]residues and whole organisms contained 120 pph total [^{14}C]residues.

MATERIALS AND METHODS:

One epoxy-coated tank (148-cm long x 57-cm wide x 60-cm deep) was filled to a depth of 2 cm with air-dried, sieved sandy loam soil (73% sand, 23% silt, 4% clay, pH 8.2, 0.1% organic matter, CEC 9.5 meq/100 g) that had been treated with 1.6 ppm of phenyl ring-labeled [^{14}C]iprodione (radiochemical purity 99%, specific activity 2.326 $\mu\text{Ci/mMol}$, Rhone-Poulenc). A similar tank containing untreated soil was prepared as a control. The soil in both the treated and control tanks was aged aerobically for 28 days at a soil moisture of $>75\%$ of field capacity. The soils were sampled at 0, 1, 15, and 28 days during the aging period. Following aging, the tanks were filled with water (soil:water, 1:42) and allowed to equilibrate for 3 days. Aerated water (Table 1) was provided to each tank at a rate of 300 mL/minute (~ 5 turnovers per day).

Crayfish (*Procambarus simulans*; average length 60 ± 5.8 mm; average weight 5.8 ± 2.0 g) were held in culture tanks for ~ 7 days on a 16-hour daylight photoperiod prior to the study initiation. After the tanks had equilibrated, the crayfish (130) were placed in wire mesh cages (61 x 46 x 30 cm) in the bottom of each tank. The tanks were maintained at $18 \pm 2^\circ\text{C}$ and $\sim 40\%$ dissolved oxygen during the study. The soil, water, and crayfish were sampled at various intervals during exposure up to 28 days posttreatment. Following the 28-day exposure period, crayfish remaining in the iprodione-treated tanks were transferred to an aquarium containing untreated well water. During the 14-day depuration period, water and crayfish were sampled on days 1, 3, 7, 10 and 14.

The crayfish were dissected into edible tissue (muscle portion of abdomen) and viscera (pincers, carapace, walking legs, exoskeleton, and telson). Edible tissue and whole crayfish were homogenized and analyzed for total radioactivity by LSC following combustion. Crayfish samples taken on days 21 and 28 of the exposure period and day 14 of the depuration period were extracted twice with acetone:1 N hydrochloric acid (15:1). The extracts were filtered and the acetone was evaporated. The remaining aqueous solution was mixed with 1% sodium sulfate and partitioned three times with ethyl acetate. Aliquots of the extracts were analyzed for total radioactivity using LSC. Additional aliquots were analyzed with unlabeled standards using TLC on silica gel plates developed in methylene chloride:ethyl acetate:formic acid (85:10:15) and toluene:ethyl acetate:acetic acid (80:15:5). Radioactive areas were located using autoradiography, identified by comparison to the reference standards, and quantified using LSC.

Soil samples were analyzed for total radioactivity by LSC following combustion. Water samples were analyzed for total radioactivity by LSC. Water samples taken on days 14, 21, and 28 of the exposure period and day 14 of the depuration period and soil samples taken on day 28 of aging were extracted with ethyl acetate and analyzed by LSC and TLC as previously described.

Recoveries from fortified samples ranged from 99-101% for edible tissues, whole crayfish, and soil samples. Detection limits were 0.19 ppb for water, 9.4 ppb for soil, and 9.2 ppb for edible tissue and whole crayfish.

REPORTED RESULTS:

Total [^{14}C]iprodione residues increased from 7.6 to 26 ppb in the water and decreased from 1400 to 840 ppb in the soil during the exposure period (Table 2). In both the water and soil, 1-(3,5-dichloroanilo)-carbonyl-3-isopropylamino-2,4-dioximidazolidine was the major [^{14}C]residue; iprodione was 2 and 77 ppb in the water and soil, respectively, at the end of the 28-day exposure period (Table 3). Throughout the study, the temperature, pH, and dissolved oxygen content of the treated water ranged from 15 to 20°C, 7.8 to 8.3, and 9.2 to 10.1 ppm, respectively, and were comparable to the control tanks.

In the crayfish, maximum bioconcentration factors were 10x in the edible tissue (day 28) and 20x in the whole crayfish (days 1-7 during the 28-day exposure period; radioactive residues in the edible tissue ranged from 94 to 250 ppb and in whole crayfish ranged from 220 to 480 ppb (Table 2). The major [^{14}C]residues in the edible tissue after 28 days of exposure were iprodione (33 ppb), 1-(3,5-dichloroanilo)carbonyl-3-isopropylamino-2,4-dioximidazolidine (35 ppb), and RP-44274 (41 ppb). After 14 days of depuration, [^{14}C]residues decreased to 39 ppb in the edible tissue and 120 ppb in the whole crayfish.

Mortality of the crayfish in the treated tank was not significantly different than that in the control tank.

DISCUSSION:

1. As an ancillary study to fish accumulation for an aquatic food crop use, crayfish were shown not to significantly bioaccumulate iprodione.

Table 1. Well water characteristics.

Parameters	Concentration
Temperature	15-20°C
Dissolved oxygen (after aeration)	9.2-10.1 ppm
pH	7.8-8.3
Hardness (CaCO ₃)	225-275 ppm
Alkalinity (CaCO ₃)	325-375 ppm
Conductivity	700 μ mhos/cm
NO ₃ - and NO ₂ -N	0.74 ppm
PO ₄ -P	<0.10 ppm
Aluminum	<20 ppb
Arsenic	<0.2 ppb
Cadmium	<2 ppb
Chromium	<3 ppb
Cobalt	<4 ppb
Copper	<3 ppb
Iron	12 ppb
Lead	<5 ppb
Mercury	<0.5 ppb
Nickel	<15 ppb
Silver	<5 ppb
Zinc	11 ppb
Measured organophosphorus pesticides	<0.10 μ g/L
Measured organochlorine pesticides plus PCB's	<0.50 μ g/L

Table 2. Total [^{14}C]iprodione (ppb) residues in water, soil, and whole crayfish (edible tissue and whole animal) from an aquarium treated with [^{14}C]iprodione.

Sampling interval (days)	Water	Soil	Edible tissue		Whole crayfish	
			ppb	BCFa	ppb	BCF
Exposure						
0	7.6	1400	--	--	--	--
1	14	1300	94	6.7	280	20
3	16	1200	100	6.2	320	20
7	23	1000	160	7.0	460	20
10	25	1000	200	8.0	380	15
14	26	840	190	7.3	480	18
21	25	1000	190	7.6	220	8.8
28	25	940	250	10	290	12
Depuration						
1	ND ^b	--	140	--	340	--
3	ND	--	210	--	440	--
7	ND	--	79	--	120	--
10	ND	--	51	--	330	--
14	ND	--	39	--	120	--

^a Daily bioconcentration factor obtained by dividing the tissue concentration by the mean measured water concentration for that respective sampling day.

^b Not detected; the detection limits were <0.19 ppb for water, <9.4 ppb for soil, and <9.2 ppb for edible tissue and whole crayfish.

Table 3. Distribution of radioactivity (pph) in water, soil, and crayfish treated with [¹⁴C]iprodione.

Sampling interval	Ethyl acetate extract								Aqueous extract	Unextractable
	Iprodione	RP-30228 ^a	RP-32490	RP-44274	RP-36112	RP-36114	Origin	Other		
<u>Water</u>										
14-day Exposure	3	9	ND ^b	2	2	1	0.4	2	5	--
21-day Exposure	2	8	ND	2	1	0.4	0.3	2	5	--
28-day Exposure	2	8	ND	2	1	0.4	0.4	1	6	--
14-day Depuration	ND	ND	ND	ND	ND	ND	ND	ND	ND	--
<u>Soil</u>										
28-day Aged	237	703	27	72	50	ND	20	51	15	255
21-day Exposure	57	262	5	7	19	ND	6	11	2	297
28-day Exposure	77	270	ND	5	20	ND	7	13	3	214
<u>Crayfish - edible tissue</u>										
21-day Exposure	18	19	7	28	17	13	66	31	15	2
28-day Exposure	33	35	6	41	15	17	30	45	15	3
14-day Depuration	?	0.7	3	20	ND	4	4	2	1	1
<u>Crayfish - viscera</u>										
21-day Exposure	97	42	9	26	36	32	32	25	114	52
28-day Exposure	83	79	9	40	35	30	37	73	82	110
14-day Depuration	2	2	2	18	3	1	4	2	8	31

^a 1-(3,5-Dichloroanilo)carbonyl-3-isopropylamino-2,4-dioximidazolidine.

^b Not detected; the detection limit was not reported.

REFERENCES

The following studies are new submittals reviewed in this report:

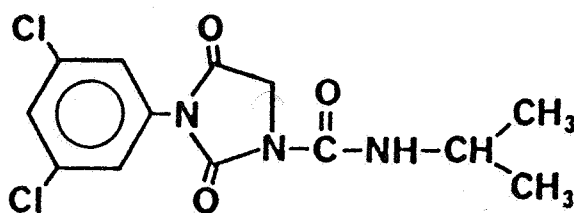
Gemma, A., G. Heinzelmann, and J. Wargo. 1986. Iprodione aquatic field dissipation and field irrigated crop study. Submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ. Acc. No. 264230.

McAllister, W.A., B. Bunch, and J. Burnett. 1986. Bioconcentration and depuration of [^{14}C]iprodione by crayfish (Procambarus simulans, Faxon), under static uptake conditions with a treated soil substrate. Report No. 33438. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Rhone-Poulenc Inc., Monmouth Junction, NJ. Acc. No. 264231.

Thomas, R.D. 1982. Aquatic metabolism of ^{14}C -RP-26019. Report No. 3-2201. Unpublished study prepared by Borriston Laboratories, Temple Hills, MD, and submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ. Acc. No. 264229.

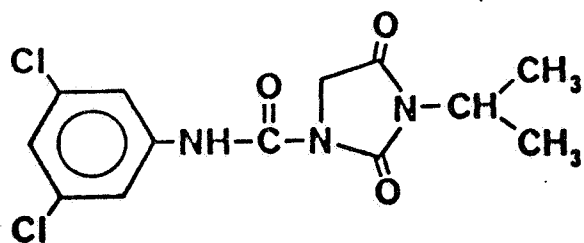
Thomas, R.D. 1983. Anaerobic aquatic metabolism of ^{14}C -RP-26019. Prepared by Borriston Laboratories, Inc., Temple Hills, MD, and submitted by Rhone-Poulenc Inc., Monmouth Junction, NJ. Acc. No. 264229. Reference B.

APPENDIX
IPRODIONE AND ITS DEGRADATES



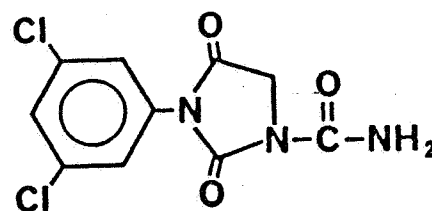
3-(3,5-Dichlorophenyl)-1-isopropyl-aminocarbonyl-2,4-dioxoimidazolidine

(Iprodione, RP-26019)

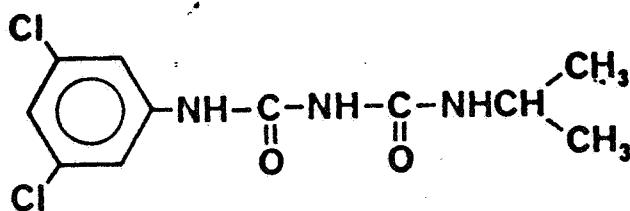


1-(3,5-Dichloroanilino)carbonyl-3-isopropylamino-2,4-dioxoimidazolidine

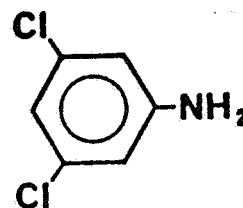
(RP-30228)



RP-32490



RP-36221



RP-32596

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