DP Barcode #'s: D165908 & D165853
PC Code #: 109801
Date Out of EFGWB: DEC 6 1991

To: Susan Lewis/Robert Rose
Product Manager #21
Registration Division (H7505C)

Barbara Briscoe/Kathryn Davis
Product Manager # 51
Special Review and Reregistration Division (H7508W)

From: Emil Regelman
Supervisory Chemist, Review Section #2
OPP/EFED/EFGWB (H7507C)

Through: Henry Jacoby, Chief
OPP/EFED/EFGWB (H7507C)

Attached, please find the EFGWB review of . . .

Reg./File #'s : 109801-000264 & 000264-00482

Common Name : Iprodione

Chemical Name : 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide or 3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxoimidazolidine-1-carboxamide

Product Type : Fungicide

Product Name : Rovral, RP 26019, Glycophene, Chipco 26019, LFA 2043, NCR 910, ROP 500 F.

Company Name : Rhône-Poulenc Ag Company

Purpose : Review of Hydrolysis (161-1), Photodegradation in Water (161-2), Aerobic Aquatic Metabolism (162-4) studies.

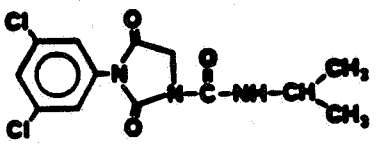
Dates Received: 5/2/91 & 7/1/91 Action Codes: 627 & 575

EFGWB # (s): 91-0712 & 91-0725/0726

Deferrals to:
_____ Ecological Effects Branch/EFED
_____ Science Integration & Policy Staff/EFED
_____ Non-Dietary Exposure Branch/HED
_____ Dietary Exposure Branch/HED
_____ Toxicology Branch I, II/HED

1. **CHEMICAL:**

Chemical Name: 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide or 3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxoimidazolidine-1-carboxamide
CAS No.: 36734-19-7
Common Name: Iprodione
Trade Names: Rovral, RP 26019, Glycophene, Chipco 26019, LFA 2043, NCR 910, ROP 500 F.
Chemical Structure:



Molecular Formula: $C_{13}H_{13}Cl_2N_3O_3$
Molecular weight: 330.15 g/mol
Physical/Chemical Properties of Active Ingredient:

Physical state: Non-hygroscopic crystals
Color: White
Odor: Odorless
Solubility at 20 °C: 13 mg/L water; 300 mg/L acetone, acetophenone, anisole; 500 g/L methylene chloride, dimethylformamide, 1-methyl-2-pyrrolidone; 25 g/l ethanol, methanol; 200 mg/L benzene.
Vapor pressure (at 20 °C): $< 1.0 \times 10^{-5}$ mm Hg (< 0.133 mPa)
Melting point: ca. 136 °C
Formulations: 50% WP or FC

Active ingredient	50%
Inert ingredients	50%

2. **TEST MATERIAL:**

In all Studies (1-3): Active ingredient.

3. **STUDY/ACTION TYPE:**

Review of Hydrolysis (161-1), Photodegradation in Water (161-2), and Aerobic Aquatic Metabolism (162-4) studies.

4. **STUDY IDENTIFICATION:**

Adrian, P.P. and J. Robles. 1991. *^{14}C-Iprodione Aqueous Photolysis.* Laboratory Project ID: Study No. 90-22. Filing Reference: AG/CRLD/AN/9115524. Unpublished study performed by Rhône-Poulenc Secteur Agro, Lyon, France, and submitted by Rhône-Poulenc Ag Company, Research Triangle Park, NC. (MRID #418619-01)

Das, Y.T. 1990. *Hydrolysis of [Phenyl(U)-^{14}C]iprodione in Aqueous Solutions Buffered at pH 5, 7, and 9.* ISSI Laboratory Project No. 89100.

2

Rhône-Poulenc Study No. EC-89-050. Unpublished study performed by Innovative Scientific Services, Inc., Piscataway, NJ, and submitted by Rhône-Poulenc Ag Company, Research Triangle Park, NC. (MRID #418854-01)

Spare, W.C. 1991. *Aerobic Aquatic Metabolism of Iprodione.* Laboratory Project ID: Agrisearch Project No. 1514. Unpublished study performed by Agrisearch Inc., Frederick, MD, and submitted by Rhône-Poulenc AG Company, Research Triangle Park, NC. (41927601)

5. **REVIEWED BY:**

María Isabel Rodríguez
Chemist, Review Section #2
OPP/EFED/EFGWB

Signature: María Isabel Rodríguez
Date: December 2, 1991.

6. **APPROVED BY:**

Emil Regelman
Supervisory Chemist
Review Section #2
OPP/EFED/EFGWB

Signature: EReg
DEC 6 1991
Date:

7. **CONCLUSIONS:**

Degradation - Hydrolysis (161-1):

1. The submitted study is acceptable and can be used to fulfill the Hydrolysis (161-1) data requirement.

2. Phenyl ring-labeled [^{14}C]iprodione hydrolyzed with half-lives of 131 days, 4.7 days, and 27 minutes in sterile aqueous buffered solutions adjusted to pH 5, 7, and 9, respectively, that were incubated in the dark at 25 °C. The degradates, 3-(isopropylcarbamoyl)-5-(3,5-dichlorophenyl)hydantoic acid (RP-35606) and 1-(3,5-dichlorophenyl)carbamoyl-3-isopropyl-hydantoin (RP-30228) were identified.

3. No additional data on the hydrolysis of iprodione are required at this time.

Degradation - Photodegradation in Water (161-2):

1. The submitted study is unacceptable and cannot be used to fulfill the Photodegradation in Water (161-2) data requirement at this time.

2. The data are considered to be of uncertain value and should not be used to predict the environmental behavior of iprodione.

3. This study is unacceptable at this time for the following reasons:

Sufficient information was not provided to adequately assess the photodegradation of iprodione; sampling intervals for irradiated and dark control test solutions were reported in terms of days of equivalent Florida summer sunlight rather than the actual post-treatment sampling intervals, and a measured total irradiant intensity of the artificial light source was not reported.

There are significant discrepancies in the formation of [^{14}C]volatiles between the reaction vessels that were only periodically flushed with air versus continuous air-flow.

The description of the methodology was vague and incomplete.

4. In order for this study to be reconsidered for review, the registrant must provide the actual post-treatment sampling intervals, report the measured total irradiant intensity of the artificial light source with a comparison to natural sunlight, address the discrepancies in the production of [^{14}C]volatiles between the intermittent versus continuous air-flow systems, and adequately describe the test methodology.

Metabolism - Aerobic Aquatic (162-4):

1. The submitted study cannot be used to fulfill the Aerobic Aquatic Metabolism (162-4) data requirement at this time.

2. Iprodione degraded with an observed half-life of 3-7 days (registrant-calculated half-life of 9 days) in a flooded silt loam sediment system that was incubated in the dark at 25 °C. The major non-volatile degradate was 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP-30228); other non-volatile degradates were 3-(3,5-dichlorophenyl)-2,4-(dioxo-1-imidazol)idinecarboxamide (RP-32490), and 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-1-ureylenecarboxamide (RP-36221).

3. The study is scientifically sound, but does not meet Subdivision N guidelines because not all degradates detected at >0.01 ppm were identified; three unidentified [^{14}C]compounds comprised up to 1.8% (0.15 ppm), 11.5% (0.93 ppm), and 1.7% (0.14 ppm) of the applied radioactivity.

4. In order for this study to fulfill the Aerobic Aquatic Metabolism data requirement, the registrant should make an earnest attempt to identify degradates present at a concentration of >0.01 ppm.

8. RECOMMENDATIONS:

The registrant should be informed that the submitted Hydrolysis (161-1) study is acceptable and that no additional data on the hydrolysis of iprodione are required at this time. However, the submitted Photodegradation in Water (161-1) and the Aerobic Aquatic Metabolism (162-4) studies were unacceptable and cannot be used to fulfill the respective data requirements at this time.

For details in the deficiencies noted in the unacceptable studies, please refer to the Conclusions Section (#7) of this review.

9. BACKGROUND:

Iprodione is a contact fungicide active against a broad spectrum of diseases including Botrytis, Sclerotinia, Monilinia, Alternaria, Helminthosporium, Fusarium, and Rhizoctonia. According to the label it is registered for use on vegetables (lettuce, broccoli, carrots, onions, garlic, beans, peanuts, potatoes, caneberries, and ginseng), orchard (apricots, cherries, nectarines, peaches, plums, prunes, almonds, and grapes) crops. The maximum application rates are 4.0 lb ai/A on field and vegetable crops and 2.0 lb ai/A on orchard crops.

The registrant is submitting Hydrolysis (161-1), Photodegradation in Water (161-2), and Aerobic Aquatic Metabolism (164-2) studies as part of the re-registration process for iprodione.

An environmental-fate summary table for iprodione is attached to this review.

10. DISCUSSION OF INDIVIDUAL STUDIES:

Refer to the attached Data Evaluation Records (DER's).

11. COMPLETION OF ONE-LINER:

The one-liner data-base was updated with this review.

12. CBI APPENDIX:

All data reviewed are considered "Confidential Business Information" by the registrant and must be treated as such.

ENVIRONMENTAL-FATE SUMMARY TABLE FOR IPRODIONE:

Data Requirements and Guidelines Reference #	Submitted Studies/ Addendums	DER[1]/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data Required?
1. DEGRADATION -- LAB:				
161-1: Hydrolysis	418854-01	This review (EFGWB #91-0712)	Acceptable	No
161-2: Photodegradation in Water	418619-01	This review (EFGWB #91-0712)	Not acceptable	Yes
161-3: Photodegradation on Soil	419121-01	SIR[2] (EFGWB #91-0719)	SIR	SIR
161-4: Photodegradation in Air	N/A	N/A	N/A	Yes
2. METABOLISM -- LAB:				
162-1: Aerobic Soil	000682-85	No DER Sum[3] (92083-022)	N/A Not Reviewable	Yes[4]
162-2: Anaerobic Soil	N/A	N/A	N/A	Waived[5]
162-3: Anaerobic Aquatic	417558-01	SIR (EFGWB #91-0399)	SIR	SIR[6]
162-4: Aerobic Aquatic	419276-01	This review (91-0725/0726)	Not acceptable	Yes[6]
2. MOBILITY:				
163-1: Leaching and adsorption/desorption	N/A	N/A	N/A	Yes

Data Requirements and Guidelines Reference #	Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data Required?
163-2: Laboratory Volatility	N/A	N/A	N/A	Yes
163-3: Field Volatility	N/A	N/A	N/A	Yes
3. DISSIPATION -- FIELD:				
164-1: Soil	N/A	N/A	N/A	Yes
164-2: Aquatic (sediment)	001622-18	DER (SIR) Sum (92083-023)	SIR Reviewable	SIR[6]
4. ACCUMULATION:				
165-1: Confined Rotational Crops	N/A	N/A	N/A	Yes
165-3: Irrigated Crops	001622-18	DER (SIR) Sum (92083-023)	SIR Reviewable	SIR
165-4: In Fish	001622-21	No DER Sum (92083-024)	N/A Not Reviewable[7]	Yes
	001622-22	No Sum (92083-024)	N/A Not Reviewable[7]	
5. GROUND WATER MONITORING:				
166-1: Small Scale Prospective	N/A	N/A	N/A	Reserved[8]
166-2: Small Scale Retrospective	N/A	N/A	N/A	Reserved[8]
166-3: Large Scale Retrospective	N/A	N/A	N/A	Reserved[8]

...Continues...

Data Requirements and Guidelines Reference #	Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data Required?
6. SURFACE WATER:				
167-1: Field Runoff	N/A	N/A	N/A	Reserved[8]
167-2: Surface Water Monitoring	N/A	N/A	N/A	Reserved[8]
7. SPRAY DRIFT:				
201-1: Droplet Size Spectrum	N/A	N/A	N/A	Yes
202-1: Drift Field Evaluation	N/A	N/A	N/A	Yes

1 DER = Data Evaluation Record
2 SIR = Study in Review
3 Sum = Summary
4 The study, dated 8/8/1977, was conducted following the 1975 EPA Proposed Guidelines. The study was conducted using foreign soils not compared to United States soils, was not conducted at 25 °C, and experiments were not conducted with each labelled ring. Therefore, a new study following the new Guidelines should be submitted.
5 Waiver was granted because Anaerobic Aquatic Metabolism (162-3)study was conducted and might be used to substitute it (currently undergoing review).
6 Study being repeated as per terms of conditional registration on rice.
7 The experiments should be conducted with each respectively labelled ring.
8 The requirement is to be held in reserve pending results of the Field Dissipation (164-1) study.

DP BARCODE: D165850

CASE: 002908 DATA PACKAGE RECORD DATE: 07/03/91
SUBMISSION: S398504 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 575 CON REG FLW-UP DAT REQ HE
CHEMICALS: 109801 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo 50.0000%

ID#: 000264-00453 ROVRAL FUNGICIDE
COMPANY: 000264 RHONE-POULENC AG COMPANY
PRODUCT MANAGER: 21 SUSAN LEWIS 703-557-1900 ROOM: CM2 227
PM TEAM REVIEWER: ROBERT ROSE 703-557-8542 ROOM: CM2 233
RECEIVED DATE: 07/01/91 DUE OUT DATE: 10/19/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 165850 EXPEDITE: N DATE SENT: 07/03/91 DATE RET.: / /
CHEMICAL: 109801 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidaz
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 09/11/91 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	07/01/91	/ /
BRAN: EFGB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

PLEASE REVIEW THE ATTACHED AEROBIC AQUATIC METABOLISM STUDY FOR IPRODIONE. 162-4. THIS WAS REQUIRED AS A CONDITION OF REGISTRATION FOR RICE.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D165853

CASE: 002900 DATA PACKAGE RECORD DATE: 07/03/91
SUBMISSION: S398513 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 575 CON REG FLW-UP DAT REQ HE
CHEMICALS: 109801 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo 41.6000%

ID#: 000264-00482 ROVRAL 4 FLOWABLE
COMPANY: 000264 RHONE-POULENC AG COMPANY
PRODUCT MANAGER: 21 SUSAN LEWIS 703-557-1900 ROOM: CM2 227
PM TEAM REVIEWER: ROBERT ROSE 703-557-8542 ROOM: CM2 233
RECEIVED DATE: 07/01/91 DUE OUT DATE: 10/19/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 165853 EXPEDITE: N DATE SENT: 07/03/91 DATE RET.: / /
CHEMICAL: 109801 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidaz
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 09/11/91 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	07/10/91	/ /
BRAN: EFGB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

PLEASE REVIEW THE ATTACHED AEROBIC AQUATID METABOLISM STUDY FOR IPRODIONE. 162-4. THIS WAS REQUIRED AS A CONDITION OF REGISTRATION FOR RICE.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D165734 REREG CASE # 2335

CASE: 816345 DATA PACKAGE RECORD DATE: 06/27/91
SUBMISSION: S398346 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION
CHEMICALS: 109801 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo

ID#: 109801-000264
COMPANY: 000264 RHONE-POULENC AG COMPANY
PRODUCT MANAGER: 51 BARBARA BRISCOE 703-308-8065 ROOM: CS1 3H3
PM TEAM REVIEWER: KATHRYN DAVIS 703-308-8068 ROOM: CS1 4N3
RECEIVED DATE: 05/02/91 DUE OUT DATE: / /

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 165734 EXPEDITE: N DATE SENT: 06/27/91 DATE RET.: / /
CHEMICAL: 109801 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidaz
DP TYPE: 102 Phase V Review
ADMIN DUE DATE: 10/25/91 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	06/27/91	/ /
BRAN: EFGB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Reregistration data for review

MRID	GUIDELINE
41861901	161-2
41885401	161-1

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D165968

REREG CASE # 2335

CASE: 816345
SUBMISSION: S398346

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/09/91

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION
CHEMICALS: 109801 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo
Iprodione
ID#: 109801-000264
COMPANY: 000264 RHONE-POULENC AG COMPANY
PRODUCT MANAGER: 51 BARBARA BRISCOE 703-308-8065 ROOM: CS1 3H3
PM TEAM REVIEWER: KATHRYN DAVIS 703-308-8068 ROOM: CS1 4N3
RECEIVED DATE: 05/02/91 DUE OUT DATE: / /

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 165968 EXPEDITE: N DATE SENT: 07/06/91 DATE RET.: / /
CHEMICAL: 109801 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidaz
DP TYPE: 102 Phase V Review
ADMIN DUE DATE: 11/03/91 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	07/10/91	/ /
BRAN: EFGB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

This is to replace the original Bean Sheet (DP Barcode 165734) which was destroyed in PRATS.

MRID	GUIDELINE
41861901	161-2
41885401	161-1

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

0712
MIR

= Enclosures ⇒

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
IPRODIONE
Last Update on December 3, 1991
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

LOGOUT	Reviewer: MSR	Section Head:	Date: DEC 3 1991

Common Name: IPRODIONE
PC Code # : 109801 CAS #: 36734-19-7 Caswell #:

Chem. Name : 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
Action Type: FUNGICIDE

Trade Names: GLYCOPHENE; ROVRAL 4F; RP 26019; CHIPCO 26019; others.
(Formul'tn): 50% WP or FC; Granular
Physical State: Non-hygroscopic crystals

Use Patterns (% Usage) : Terrestrial food/feed/non-food, outdoor residential, aquatic food, and greenhouse non-food. Vegetables (lettuce, broccoli, carrots, onions, & others); orchard (apricots, almonds, peaches, & others).

Empirical Form: $C_{13}H_{13}Cl_2N_3O_3$
Molecular Wgt.: 330.15 Vapor Pressure: 1.00E -7 Torr
Melting Point : ca. 136 oC°C Boiling Point: °C
Log Kow : 3.1 pKa: @ °C
Henry's : E Atm. M3/Mol (Measured) 3.34E -9 (calc'd)

Solubility in ...			Comments
Water	13.00E	ppm @20.0 °C	
Acetone	3.00E 2	ppm @20.0 °C	
Acetonitrile	E	ppm @ °C	
Benzene	2.00E 2	ppm @20.0 °C	
Chloroform	E	ppm @ °C	
Ethanol	2.50E 4	ppm @20.0 °C	
Methanol	2.50E 4	ppm @20.0 °C	
Toluene	E	ppm @ °C	
Xylene	E	ppm @ °C	
Methylene chloride	5.00E 5	ppm @20.0 °C	
Dimethylformamide	5.00E 5	ppm @20.0 °C	

Hydrolysis (161-1)
[V] pH 5.0:131 DAYS
[V] pH 7.0:4.7 DAYS
[V] pH 9.0:1 DAY (For 1991 study: 27 MINUTES)
[V] pH 3.0:STABLE
[V] pH 6.0:20 DAYS
[ ] pH :

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
IPRODIONE
Last Update on December 5, 1991
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Photolysis (161-2, -3, -4)
[V] Water:3-7 DAYS
[ ] :
[ ] :For 1991 study: 67 DAYS, pH 5/22 days
[ ] : (2 % acetone sensitized)

[V] Soil :7-14 DAYS ON ClLm
[ ] Air :

Aerobic Soil Metabolism (162-1)
[V] 20-70 DAYS, ClLm AND SiLm
[V] 50-70 DAYS ClLm
[V] 30-50 DAYS SlClLm
[ ]
[ ]
[ ]
[ ]

Anaerobic Soil Metabolism (162-2)
[V] 20-50 DAYS ClLm
[V] 50 DAYS SlClLm
[ ]
[ ]
[ ]
[ ]
[ ]

Anaerobic Aquatic Metabolism (162-3)
[S] 6.4 DAYS IN WATER AND 126 DAYS IN SiLm SEDIMENT.
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Aerobic Aquatic Metabolism (162-4)
[S] DEGRADATE RP-30228 COMPRISED UP TO 50% OF THE TOTAL RESIDUE
[ ] IMMEDIATELY POST-TREATMENT.
[ ]
[ ] For 1991 study: 3-7 DAYS in flooded SiLm SEDIMENT system.
[ ]
[ ]
[ ]

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
IPRODIONE
Last Update on December 3, 1991
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Soil Partition Coefficient (Kd) (163-1)
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Soil Rf Factors (163-1)
[V] IN SOIL COLUMN STUDIES, WITH Lm MUD, SdLm, ClLm, AND SiClLm, MOST
[ ] OF THE ACTIVITY WAS IN THE UPPER 10 CM; IN LEACHATE, 2% FROM
[ ] SiClLm, LESS THAN 1% FROM OTHERS.
[ ]
[ ]
[ ]

Laboratory Volatility (163-2)
[ ]
[ ]

Field Volatility (163-3)
[ ]
[ ]

Terrestrial Field Dissipation (164-1)
[V] 20-40 DAYS SAND, LOAM, SyClLm
[V] 20-40 DAYS SyLmClLm
[V] WITH SAMPLING AT 0-2, 2-4, AND 4-6". T1/2 VALUES WERE:
[ ] - NORTHEASTERN 15-45 DAYS; SOUTHEASTERN 8-30 DAYS;
[ ] - SOUTHWEST 15-90 DAYS; MIDWEST 40-50 DAYS
[ ]
[ ]
[ ]
[ ]
[ ]

Aquatic Dissipation (164-2)
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Forestry Dissipation (164-3)
[ ]
[ ]

Long-Term Soil Dissipation (164-5)
[ ]
[ ]

Accumulation in Rotational Crops, Confined (165-1)
[ ]
[ ]

Accumulation in Rotational Crops, Field (165-2)
[S] AFTER MAX. USE RATE APPL., DETECTABLE RESIDUES FOUND IN SORGHUM,
[ ] CORN, SOYBEANS, WHEAT, AND PEAS.

Accumulation in Irrigated Crops (165-3)
[ ]
[ ]

Bioaccumulation in Fish (165-4)
[V] BLUEGILL EDIBLE: 102X, VISCERA 555X, WHOLE 180X.
[V] CATFISH EDIBLE: < 50X, VISCERA 500X, WHOLE < 50X.

Bioaccumulation in Non-Target Organisms (165-5)
[S] EC 50, 96 HR DATA: TROUT, 4.2 PPM, OYSTER, 2.3; DAPHNIA < 0.33,
[ ] BLUEGILL 8.6.

Ground Water Monitoring, Prospective (166-1)
[ ]
[ ]
[ ]
[ ]

Ground Water Monitoring, Small Scale Retrospective (166-2)
[ ]
[ ]
[ ]
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Ground Water Monitoring, Large Scale Retrospective (166-3)
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Ground Water Monitoring, Miscellaneous Data (158.75)
[ ]
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[ ]

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
IPRODIONE
Last Update on December 3, 1991
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Field Runoff (167-1)
[ ]
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[ ]
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Surface Water Monitoring (167-2)
[ ]
[ ]
[ ]
[ ]

Spray Drift, Droplet Spectrum (201-1)
[ ]
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[ ]

Spray Drift, Field Evaluation (202-1)
[ ]
[ ]
[ ]
[ ]

Degradation Products

-Dichloroaniline (see enclosure for others)
-RP-30228 accounts for 71% of radioact. in sediment extracts in anaerobic aquatic study.
-pH and temperature have marked effect on persistence.

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
IPRODIONE
Last Update on December 3, 1991
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

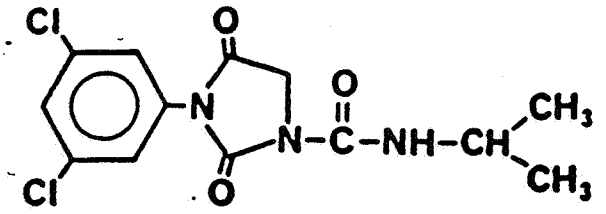
Comments

-List "B" chemical.
-Leaching-soil column study: Glycophene leached 10-15 cm in 30 cm column with 50 cm water in 30 hrs, using LmSd, SdLm,and ClLm. It leached 15-20 cm for SlClLm. Leaching is a potential problem only in soils of acidic pH and fine texture.
-Koc = 700.

References: REG STD and EFGWB Chemical File
Writer : PJH, MIR

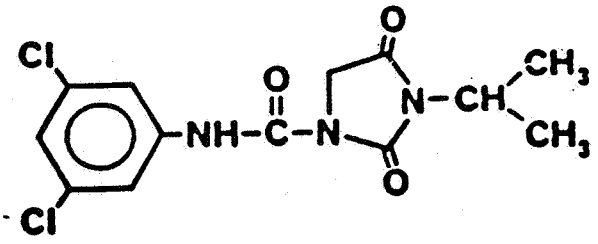
Metabolites
code vs. name

1. RP 30228 3-(1-methyehtyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide
2. RP 32490 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide
3. RP 30181 3-isopropylhydantain
4. RP 35606 1-(3,5-dichlorophenyl)carbamoyl-3-(1-methylethyl)-1-ureylene-acetic acid
5. RP 37176 3-)1-methyleth 1)-N-(3,5-dichlorophenyl)-1-ureylene acetamide
6. RP 32247 3-(3,5-dichlorophenyl)-1-ureyleneacetic acid
7. RP 32956 3,5-dichloroaniline
8. RP 36233 3-(3,5-dichlorophenyl)-N-(1-methyethyl)1-ureylene acetamide
9. MK 1 3-(3,4-dichlorophenyl-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
10. MK 21 3-(3,5-dichlorophenyl)-N-(1-oxo-ethyl)-2,4-dioxo-1-imidazolidinecarboxamide
11. RP 37677 3-(3,5-dichloro-4-hyd oxyphenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
12. MK 41 3-(3-chloro-5-hydroxyphenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
13. MK 7060 3-(dihydroxyphenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
14. RP 36221 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-1-ureylenecarboxamide
15. RP 35606 1-(3,5-dichlorophenyl)carbamoyl-3-(1-methylethyl)-1-ureylene-acetic acid



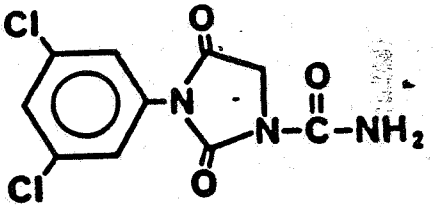
3-(3,5-Dichlorophenyl)-1-isopropyl-aminocarbonyl-2,4-dioxoimidazolidine

(Iprodione, RP-26019)

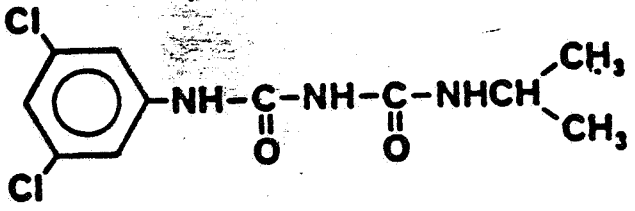


1-(3,5-Dichloroanilino)carbonyl-3-isopropylamino-2,4-dioxoimidazolidine

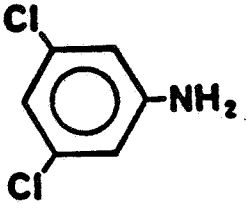
(RP-30228)



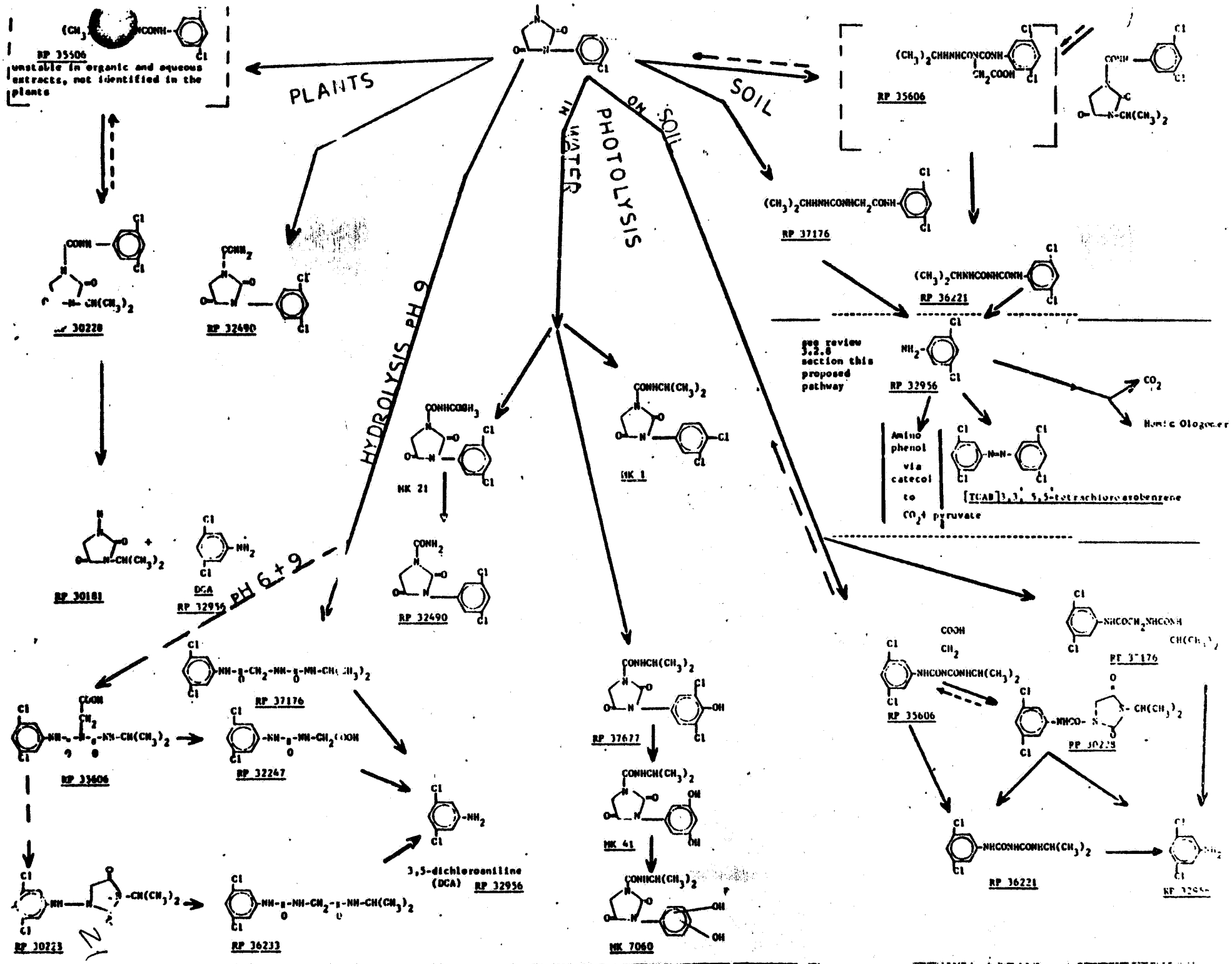
RP-32490



RP-36221



RP-32596


RP 35506
unstable in organic and aqueous extracts, not identified in the plants
PLANTS
HYDROLYSIS PH 9
IN WATER
PHOTOLYSIS
ON SOIL
SOIL
RP 35606
RP 37176
RP 36221
RP 30220
RP 32490
RP 32956
Amino phenol via catecol to CO2 + pyruvate
[TCAB] 3,3',5,5'-tetrachloroazobenzene
Humic Oligomer
HK 21
HK 1
RP 30181
DCA
RP 32956
PH 6+9
RP 37176
RP 35606
RP 32247
RP 32490
RP 37677
RP 30223
RP 36233
3,5-dichloroaniline (DCA) RP 32956
HK 41
HK 7060
RP 35606
RP 30229
RP 37176
RP 36221

IPRODIONE

TASK 1: REVIEW AND EVALUATION OF INDIVIDUAL STUDIES

CONTRACT No. 68D90058

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3262

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IPRODIONE

Table of Contents

INTRODUCTION

Iprodione is a contact fungicide active against a broad spectrum of diseases including Botrytis, Sclerotinia, Monilinia, Alternaria, Helminthosporium, Fusarium, and Rhizoctonia. According to the label it is registered for use on vegetables (lettuce, broccoli, carrots, onions, garlic, beans, peanuts, potatoes, caneberries, and ginseng), orchard (apricots, cherries, nectarines, peaches, plums, prunes, almonds, and grapes) crops. The maximum application rates are 4.0 lb ai/A on field and vegetable crops and 2.0 lb ai/A on orchard crops.

DATA EVALUATION RECORD

STUDY 1

CHEM 109801 **Iprodione** §161-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41885401
Das, Y.T. 1990. *Hydrolysis of [Phenyl(U)-^{14}C]iprodione in aqueous solutions buffered at pH 5, 7, and 9.* ISSI Laboratory Project No. 89100. Rhône-Poulenc Study No. EC-89-050. Unpublished study performed by Innovative Scientific Services, Inc., Piscataway, NJ, and submitted by Rhône-Poulenc Ag Company, Research Triangle Park, NC.

DIRECT REVIEW TIME = 4

REVIEWED BY: L. Binari TITLE: Staff Scientist

EDITED BY: W. Martin TITLE: Staff Scientist
C. Cooke Staff Scientist

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 301-417-9800

APPROVED BY[1]: María Isabel Rodríguez
TITLE: Chemist
ORG: OPP/EFED/EFGWB/Section #2

SIGNATURE: María Isabel Rodríguez

DATE: December 2, 1991.

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[1]This Data Evaluation Record (DER) was originally written by a Dynamac Corporation reviewer and edited/approved by an Environmental Protection Agency reviewer.

CONCLUSIONS:

Degradation - Hydrolysis:

1. The submitted study is acceptable and can be used to fulfill the Hydrolysis (161-1) data requirement.

2. Phenyl ring-labeled [^{14}C]iprodione hydrolyzed with half-lives of 131 days, 4.7 days, and 27 minutes in sterile aqueous buffered solutions adjusted to pH 5, 7, and 9, respectively, that were incubated in the dark at 25 °C. The degradates, 3-(isopropylcarbamoyl)-5-(3,5-dichlorophenyl)hydantoic acid (RP-35606) and 1-(3,5-dichlorophenyl)carbamoyl-3-isopropyl-hydantoin (RP-30228) were identified.

3. No additional data on the hydrolysis of iprodione are required at this time.

METHODOLOGY:

Phenyl ring-labeled [^{14}C]iprodione (uniformly labeled, radiochemical purity 97.3%, specific activity 3.3 mCi/mMol, Rhône-Poulenc), dissolved in acetone, was added at 11.0-12.3 ppm to sterile aqueous 0.01 M buffer solutions adjusted to pH's 5 (acetate), 7 (potassium phosphate), and 9 (sodium borate); the final concentration of the co-solvent (acetone) was 0.17%. Aliquots (3 mL) of the test solutions were transferred to Teflon vials that were sealed and incubated at 25 ± 1 °C in the dark. Duplicate vials of the pH 5 solutions were removed for analysis at 0, 1, 3, 7, 14, 21, and 30 days posttreatment; duplicate vials of the pH 7 solutions were removed at 0, 5.3, 17, 40.4, 76, and 124.7 hours; and duplicate vials of the pH 9 solutions were removed at 0, 14-15, 29, 45-50, 60-65, and 107-121 minutes.

Immediately after sampling, an aliquot (100 µL) of each test solution was analyzed for iprodione and its degradates using reverse-phase HPLC on a ODS-120T column eluted with acetonitrile:water (6:4, v:v) containing 0.01% acetic acid with flow-through UV (254 nm) and radioactivity detectors. Identifications of the degradates were made by comparison to the retention times of unlabeled reference standards. Additional aliquots (10 µL) of the test solutions were analyzed for total radioactivity using LSC.

Degradate identifications were confirmed using LC/MS in the positive ion discharge mode. An aliquot of the pH 5 solution sampled at 30 days posttreatment was partitioned twice with methylene chloride; organic phases were combined. The remaining aqueous phase was lyophilized; the resulting residue was redissolved in methanol, then combined with the organic phase, concentrated under a stream of nitrogen, and analyzed by LC/MS. Because of the rapid hydrolysis of iprodione with increasing pH, additional pH 7 and 9 solutions were prepared, treated, and incubated as described above then sampled at 2 hours (pH 7) or 15 minutes (pH 9) posttreatment prior to extraction and LC/MS analysis.

DATA SUMMARY:

Phenyl-ring labeled [^{14}C]iprodione (uniformly labeled, radiochemical purity 97.3%), at 11.0-12.3 ppm, hydrolyzed with calculated half-lives of 131 days, 4.7 days, and 27.2 minutes in sterile aqueous buffered solutions that were incubated in the dark at 25 °C for 30 days (pH 5), 5.2 days (pH 7), or 107-121 minutes (pH 9), respectively. The major degradates were 3-(isopropyl-carbamoyl)-5-(3,5-dichlorophenyl)hydantoic acid (RP-35606), and 1-(3,5-di-chlorophenyl)carbamoyl-3-isopropylhydantoin (RP-30228).

In the pH 5 solution at 30 days posttreatment, iprodione comprised 80.4-82.8% of the applied radioactivity, and RP-35606 had increased to 10.8-11.9% (Table V).

In the pH 7 solution at 5.2 days posttreatment (124.7 hours), iprodione comprised 40.2-41.9% of the applied radioactivity, RP-35606 comprised 4.6-5.5% (maximum 9.8-10.4% at 1.7 days), and RP-30228 had increased to 44.3-47.0% (Table VI).

In the pH 9 solution at 107-121 minutes posttreatment, iprodione comprised 3.4-5.6% of the applied, RP-35606 had increased to 1.4-1.7%, and RP-30228 had increased to 90.7-93.3% (Table VII).

Three unidentified [^{14}C]compounds were detected in the pH 7 solution at maximums of 9.2, 2.1, and 2.0% of the applied. Unidentified "other" radioactivity, described as the sum of several insignificant radioactive areas, in the pH 5, 7, and 9 solutions, was detected at maximums of 9.0, 3.8, and 4.0% of the applied, respectively. During the study, material balances ranged from 95.6 to 103.4% of the applied (Table II).

During the study, the pH's of the test solutions ranged between 5.00-5.09, 6.99-7.09, and 8.99-9.10 (Table III).

COMMENTS:

1. The study author reported a calculated half-life of 153.5 hours (6.4 days) for iprodione in the pH 7 solution. The Dynamac reviewer calculated a half-life of 113.5 hours (4.7 days). It appears that the reported 153.5 hours is a typographical error, because the slope of the line, intercept, and correlation coefficient calculated by the Dynamac reviewer concurred with that calculated by the study author. The Dynamac reviewer also confirmed the half-lives calculated by the study author for iprodione in the pH 5 and 9 solutions. Therefore, in this review, a half-life of 4.7 days (113.5 hours) was reported for iprodione in the pH 7 solution.

2. It is not clear if the solutions or the glassware were adequately sterilized. Apparently the buffer solutions were not sterilized after the final pH adjustment, and although the solutions were made with sterile water, it is unlikely that the chemicals used were sterile. Likewise, it is possible that the 80% methanol solution with low-temperature oven drying was inadequate to completely sterilize the glassware. Autoclaving and/or filter-sterilization would be more appropriate sterilization methods.

The use of a microscope is inadequate to determine the sterility of a solution because a microbial population of approximately 10^6 bacteria/mL is required to visualize contamination. A more appropriate method to determine the sterility of the solutions would be to culture the microorganisms from aliquots of the solutions. (Greenberg, A.E., R.R. Trussell, and L.S. Clesceri. 1985. *Standard Methods For the Examination of Water and Wastewater.* Sixteenth Edition. American Public Health Association)

3. The statistical estimate of the hydrolytic half-life of iprodione in the pH 5 solution that was reported in this study is of limited value because the calculations involve extrapolation beyond the experimental time limits of the study. Data are often incapable of accurately predicting trends outside of their range because differences are magnified and reactions which are linear within the scope of the experiment may become curvilinear.

PIN 5721-93

Iprodione EF Reviews

Page_____ is not included in this copy.

Pages 28 through 36 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.

DATA EVALUATION RECORD

STUDY 2

CHEM 109801 **Iprodione** §161-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41861901
Adrian, P.P. and J. Robles. 1991. *^{14}C-Iprodione Aqueous Photolysis.* Laboratory Project ID: Study No. 90-22. Filing Reference: AG/CRLD/AN/9115524. Unpublished study performed by Rhône-Poulenc Secteur Agro, Lyon, France, and submitted by Rhône-Poulenc Ag Company, Research Triangle Park, NC.

DIRECT REVIEW TIME = 8

REVIEWED BY: L. Binari TITLE: Staff Scientist

EDITED BY: W. Martin TITLE: Staff Scientist
C. Cooke Staff Scientist

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 301-417-9800

APPROVED BY[1]: María Isabel Rodríguez
TITLE: Chemist
ORG: OPP/EFED/EFGWB/Section #2

SIGNATURE: María Isabel Rodríguez

DATE: December 2, 1991.

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[1]This Data Evaluation Record (DER) was originally written by a Dynamac Corporation reviewer and edited/approved by an Environmental Protection Ageny reviewer.

CONCLUSIONS:

Degradation - Photodegradation in Water:

1. The submitted study is unacceptable and cannot be used to fulfill the Photodegradation in Water (161-2) data requirement at this time.

2. The data are considered to be of uncertain value and should not be used to predict the environmental behavior of iprodione.

3. This study is unacceptable at this time for the following reasons:

Sufficient information was not provided to adequately assess the photodegradation of iprodione; sampling intervals for irradiated and dark control test solutions were reported in terms of days of equivalent Florida summer sunlight rather than the actual post-treatment sampling intervals, and a measured total irradiant intensity of the artificial light source was not reported.

There are significant discrepancies in the formation of [^{14}C]volatiles between the reaction vessels that were only periodically flushed with air versus continuous air-flow.

The description of the methodology was vague and incomplete.

4. In order for this study to be reconsidered for review, the registrant must provide the actual post-treatment sampling intervals, report the measured total irradiant intensity of the artificial light source with a comparison to natural sunlight, address the discrepancies in the production of [^{14}C]volatiles between the intermittent versus continuous air-flow systems, and adequately describe the test methodology.

METHODOLOGY:

Phenyl ring-labeled [^{14}C]iprodione (uniformly labeled, radiochemical purity >99%, specific activity 739.8 MBq/mMol, Commissariat à l'Energie Atomique) plus unlabeled iprodione (purity 99.9%, Rhône-Poulenc Agro), dissolved in acetonitrile, was added at a nominal concentration of 5 ppm to a sterile aqueous 0.02 M citric acid-buffered solution (pH 5) contained in a Pyrex glass reaction vessel; the final concentration of the co-solvent (acetonitrile) was 1%. Reaction vessels (unspecified number) were prepared and sealed with screw-cap lids equipped with optical silica glass windows (Figure 5). The reaction vessels were placed in a photolysis apparatus (Heraeus Suntest) and irradiated continuously using a xenon arc lamp equipped with a UV filter to eliminate radiation below 290 nm (Figure 7). The test solutions were magnetically stirred during irradiation and maintained at 25 ± 1 °C using a refrigerated circulating water bath. Four additional reaction vessels were prepared, wrapped in aluminum foil, and incubated in the photolysis apparatus to serve as dark controls. Duplicate irradiated reaction vessels were removed for analysis at 0, 4, 8.6, 15.3, 16.9, and 32.9 days of irradiation equivalent to Florida summer sunlight. Dark control vessels were removed for analysis at the 16.9- and 32.9-day sampling intervals for the irradiated solutions. At each sampling interval, sterile, humidified CO_2-free air was drawn through each reaction vessel (air flow rate unspecified), then sequentially through tubes containing ethylene glycol monomethylether (one tube), 2 N sodium hydroxide (two tubes), and 2 N sulfuric acid (one tube) trapping solutions, and through a XAD-4 resin (one tube).

Samples were partitioned twice with methylene chloride and once with ethyl acetate. The methylene chloride phases were combined and aliquots of the methylene chloride phase, ethyl acetate phase, and the remaining aqueous

phase were analyzed for total radioactivity using LSC. The organic phases were concentrated (method not reported) and analyzed using one-dimensional TLC on silica gel plates developed in toluene:ethyl acetate (80:20, v:v; Solvent System 1) or methylene chloride:ethyl acetate:formic acid (90:7.5:2.5, v:v:v; Solvent System 2). Radioactive areas were detected and quantified using a TLC radioanalyzer; autoradiography was also used for visualization. Methylene chloride phases were also analyzed using reverse-phase HPLC on a C-18 deactivated C-8 column eluted with 10% acetonitrile in pH 5 phosphate buffer:acetonitrile (55:45, v:v) with flow-through UV (210 nm) and radioactivity detection. When >10% of the applied radioactivity was detected in the aqueous phase, the aqueous phase was acidified to pH 1.5 (method not reported) and repartitioned twice with ethyl acetate. The ethyl acetate phases were combined and aliquots were analyzed using TLC developed in Solvent Systems 1 and 2, plus butanol:acetic acid:water (85:15:5, v:v:v; Solvent System 3) and chloroform:methanol:formic acid:water (75:20:4:2, v:v:v:v; Solvent System 4). The remaining aqueous phase was concentrated to dryness under vacuum, the residues were redissolved in water:methanol (90:10, v:v), and the solution was applied to a Sephadex LH-20 column eluted with water:methanol. The eluate was concentrated (method not reported), and aliquots were analyzed using TLC developed with Solvent Systems 3 and 4. Degradate identifications were confirmed using HPLC/MS with electron impact and negative chemical ionization.

Trapping solutions were analyzed for total radioactivity using LSC. The presence of CO_2 in the sodium hydroxide trapping solutions was confirmed using barium chloride precipitation. The XAD-4 resin was extracted with ethyl acetate using sonication, then analyzed by LSC.

To further investigate the production of volatiles, additional reaction vessels containing [^{14}C]iprodione-treated buffer solution were prepared, attached to the gas collection system, and irradiated as described above. In this portion of the experiment, however, air was continuously passed (rate unspecified) through the reaction vessels, then through the trapping solutions and solid phase resin. The traps were changed after 6.68, 15.03, and 33.35 days of equivalent Florida summer sunlight; the trapping solutions and XAD-4 resin were analyzed as described above.

In a separate experiment, reaction vessels (unspecified number) containing [^{14}C]iprodione-treated buffer solution were prepared as described above and the test solutions were sensitized with 2% acetone (by volume). Two of the reaction vessels were irradiated as described above and one was maintained as a dark control; the vessels were attached to a gas collection system with continuous air flow (rate unspecified). At unspecified sampling intervals, an aliquot (100 μL) was removed from each reaction vessel and analyzed for iprodione using reverse-phase HPLC. At the final sampling interval, the test solutions were extracted with methylene chloride and the extracts were analyzed using reverse-phase HPLC and HPLC/MS as previously described.

DATA SUMMARY:

Phenyl ring-labeled [^{14}C]iprodione (uniformly labeled, radiochemical purity >99%), at a nominal concentration of 5 ppm, photodegraded with a registrant-calculated half-life of 67 days in sterile aqueous citric acid-buffered solutions (pH 5) that were irradiated continuously with a UV-filtered xenon arc lamp at 25 °C for 33 days of equivalent Florida summer sunlight. In contrast, [^{14}C]iprodione did not significantly degrade in a similar solution incubated in the dark; at the 16.9- and 32.9-day sampling intervals for the control samples, iprodione comprised an average of 90.6% and 97.8% of the applied, respectively (Table VI). The major degradate in both the irradiated and dark control non-sensitized solutions was 1-(3,5-dichlorophenyl)carbamoyl-3-isopropylhydantoin (RP-30228).

In the irradiated non-sensitized solutions after 33 days of equivalent Florida summer sunlight, iprodione comprised an average of 67.8% of the applied radioactivity, RP-30228 comprised an average of 1.9% (maximum 2.73% at 16.9 days), and 1-isopropylcarbamoyl-3-(3,4-dichlorophenyl)hydantoin (RP-40837) comprised an average of 1.3% (maximum 2.75% at 4 days). Unidentified organosoluble radioactivity comprised ≤5.89% of the applied during the study. Polar extractables (pH 1.5 ethyl acetate extracts) and aqueous-soluble [^{14}C]compounds comprised a maximum of 10.42 and 17.09% of the applied radioactivity, respectively, after 15.3 days of equivalent Florida summer sunlight; analysis of the extracts and organic phases detected [^{14}C]compounds each comprising an average of ≤7.2% of the applied (Table IV). In irradiated non-sensitized solutions where volatiles were flushed from the reaction vessels only at each sampling interval, [^{14}C]volatiles totalled an average of 0.7% of the applied after 33 days of equivalent Florida summer sunlight (Table IV). However, when exposed to a continuous air-flow system, volatilization (primarily $^{14}CO_2$) from the irradiated non-sensitized solutions totaled an average of 23.5% after 33 days of equivalent Florida summer sunlight (Table V); these test solutions were not analyzed for parent iprodione. During the study, material balances ranged from 87.99% to 102.89% of the applied (Tables IV and V).

Uniformly phenyl ring-labeled [^{14}C]iprodione, at a nominal concentration of 5 ppm, photodegraded with a registrant-calculated half-life of 22 days (r^2 = 0.74) in irradiated, sensitized (2% acetone), sterile, aqueous citric acid-buffered solutions (pH 5); quantitative data were not provided (Figure 36). In the irradiated sensitized solutions, the primary degradate was RP-40837. Other degradates identified included carbamoyl-1-(3,5-dichlorophenyl)-3-hydantoin (RP-32490), isopropylcarbamoyl-1-(3,5-dichloro-4-hydroxyphenyl)-3-hydantoin (RP-37677), 1-isopropylcarbamoyl-3-(3-chlorophenyl)hydantoin (RP-25331), and two isomers of iprodione.

COMMENTS:

1. The actual intervals that irradiated and dark control samples were removed from the photolysis apparatus were not reported. The study authors reported sampling intervals in days equivalent to Florida summer sunlight. Numerous equations were provided to show how the intensity of the xenon arc lamp was converted to days of equivalent Florida summer sunlight, but actual calculations were not reported.

2. A spectral distribution of the xenon arc lamp was provided; however, a measured total irradiant intensity of the light source was not reported. It was reported that the radiant intensity of the light source at the height of the reaction vessel was measured at each sampling interval using a radiometer, but that information was not provided.

3. There is a significant discrepancy in the production of [^{14}C]volatiles between the test solutions that had air drawn through the reaction vessels only at each sampling interval, and the test solutions that had air drawn through the vessels continuously. After approximately 33 days of equivalent Florida summer sunlight, [^{14}C]volatiles totaled 0.58-0.77% of the applied radioactivity in the test solution with intermittent volatile collection and 22.8-24.1% of the applied (primarily $^{14}CO_2$) in the test solution with continuous air-flow. Material balances were essentially equivalent for the test solutions; 92.7-93.4% of the applied for the test solution with intermittent volatile collection and 93.9-94.1% for the test solution with continuous air-flow. The test solution with continuous air-flow was not analyzed for parent iprodione and its degradates, and a dark control was not conducted for this separate experiment. The study authors did not attempt to explain the discrepancy.

4. It was reported in the Experimental section (specifically section 2.10) of the study write-up that the non-sensitized test solutions were irradiated in duplicate; however, it could not be determined if three photolysis reaction vessels were prepared for irradiation (including one dark control) and aliquots were collected from these vessels at each sampling interval, or if fourteen vessels were prepared for irradiation (including four dark controls) and two vessels were collected at each interval. The wording of the study write-up implied that duplicate irradiated vessels were prepared for each sampling interval. If, however, only three reaction vessels were prepared (two irradiated and one dark control), the volume of the aliquot removed from the reaction vessels at each sampling interval must be reported.

all vessels separately

Likewise, in the sensitized test solutions experiment, the number of reaction vessels was indeterminable.

5. Apparently degradate identifications were made by comparison to unlabeled reference standards, but for the TLC analyses it was not specified if the reference standards were co-chromatographed with the samples, or if identifications were made by comparison to predetermined R_f values; it was also not reported how unlabeled reference standards were visualized. For the HPLC analyses, it was not reported if unlabeled reference standards were run with each set of samples.

yes. UV visualization

yes.

6. The absorption spectrum of iprodione in the test solution was not provided.

OK.

7. For the experiment using sensitized (2% acetone) test solution, the sampling intervals were not specified; however, according to Figure 36, the intervals were reviewer-estimated to be 3, 7, 10.5, and 24 days of irradiation equivalent to Florida summer sunlight. In addition, quantitative data to support the calculated half-life were not provided. Figure 36 indicated, as did the half-life linear regression correlation coefficient ($r^2 = 0.74$), that the data were highly variable.

$r \cong 0.86$

actual ones stated in addendum.

half-life was determined graphically.

8. In the results for the sensitized irradiated solution, one of the degradates was listed as RP-42290. However, it was not identified in the degradation pathways nor was it identified as a reference standard. The degradate carbamoyl-1-(3,5-dichlorophenyl)-3-hydantoin (RP-32490) was identified in the degradation pathways and reference standards list. The Dynamac reviewer considered the use of RP-42290 to be a typographical error and used RP-32490 in this review.

yes it was a typo error.

LIN 5721-93

Iprodione EF Reviews

Page_____ is not included in this copy.

Pages 42 through 54 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) _____.

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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.

DATA EVALUATION RECORD

STUDY 3

CHEM 109801 Iprodione §162-4

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41927601
Spare, W.C. 1991. *Aerobic Aquatic Metabolism of Iprodione.* Laboratory Project ID: Agrisearch Project No. 1514. Unpublished study performed by Agrisearch Inc., Frederick, MD, and submitted by Rhône-Poulenc AG Company, Research Triangle Park, NC.

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[1]This Data Evaluation Record (DER) was originally written by a Dynamac Corporation reviewer and edited/approved by an Environmental Protection Agency reviewer.

CONCLUSIONS:

Metabolism - Aerobic Aquatic:

1. The submitted study cannot be used to fulfill the Aerobic Aquatic Metabolism (162-4) data requirement at this time.

2. Iprodione degraded with an observed half-life of 3-7 days (registrant-calculated half-life of 9 days) in a flooded silt loam sediment system that was incubated in the dark at 25 °C. The major non-volatile degradate was 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP-30228); other non-volatile degradates were 3-(3,5-dichlorophenyl)-2,4-(dioxo-1-imidazol)idinecarboxamide (RP-32490), and 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-1-ureylenecarboxamide (RP-36221).

3. The study is scientifically sound, but does not meet Subdivision N guidelines because not all degradates detected at >0.01 ppm were identified; three unidentified [^{14}C]compounds comprised up to 1.8% (0.15 ppm), 11.5% (0.93 ppm), and 1.7% (0.14 ppm) of the applied radioactivity.

4. In order for this study to fulfill the Aerobic Aquatic Metabolism data requirement, the registrant should make an earnest attempt to identify degradates present at a concentration of >0.01 ppm.

METHODOLOGY:

Water (pH 8.5, total hardness 6.8 mg cations/L, total alkalinity 348 mg $CaCO_3$/L, total suspended solids 2.0 mg/L) collected from a rice paddy was treated with phenyl ring-labeled [^{14}C]iprodione (uniformly labeled, radiochemical purity 98.9%, specific activity 10.5 uCi/mg, Rhône-Poulenc), dissolved in acetone, at 8.12 ppm. Samples (25 g dry weight equivalent) of silt loam sediment (6.64% sand, 68.96% silt, 24.4% clay, 1.53% organic matter, pH 6.3, CEC 7.67 meq/100 g) collected from the same paddy were placed in flasks and flooded with 50 mL of the [^{14}C]iprodione-treated water; twelve soil:water systems were prepared. The flasks were wrapped in foil, stoppered with polyurethane foam plugs, and incubated in darkness at 25 ± 1 °C. Two of the flasks were attached to a gas collection system; humidified air was drawn (40-60 mL/minute) through the flasks for 1 hour each weekday, then sequentially through one tube each of ethylene glycol and 1 N potassium hydroxide trapping solutions (Figure 2). Duplicate soil:water systems were collected and trapping solutions were changed at 1, 2, 3, 7, 14, and 30 days posttreatment; the [^{14}C]iprodione-treated water was analyzed as the time 0 sample.

At each sampling interval, the water fraction was decanted from the sediment and centrifuged; the pelleted sediment was combined with the remaining sediment fraction. Aliquots of each water sample were analyzed for total radioactivity using LSC. Additional aliquots of the water samples were acidified with 0.05 M potassium phosphate buffer (pH 2) and partitioned twice with methylene chloride:ethyl acetate (9:1, v:v). The aqueous phase was neutralized with 1 N sodium hydroxide and repartitioned twice with methylene chloride:ethyl acetate. All organic phases were combined, concentrated by rotary evaporation, and analyzed by two-dimensional TLC on silica gel plates developed in toluene:ethyl acetate (9:1, v:v) followed by methylene chloride:ethyl acetate:formic acid (80:15:5, v:v:v). Radioactive areas were visualized and quantified using a radioanalytical imaging system; identification was made by comparison with unlabeled reference standards

cochromatographed with the samples and visualized by UV absorbance (254 nm). Selected samples were also analyzed using GC with electron capture detection. The limits of detection for TLC analyses of the water and soil samples were 0.014 ppm.

Sediment fractions were extracted three times with acetone:methanol:water:hydrochloric acid (50:40:10:0.2, v:v:v:v) for 20 minutes using sonication; the slurries were centrifuged, and the extracts were combined and analyzed for radioactivity using LSC. The 14- and 30-day sediment samples were further extracted with a 2-hour reflux using the extraction sequence described above; the extracts were analyzed by LSC. The 30-day sediment was further extracted three times with acetone:water:phosphoric acid (66:33:1, v:v:v) for 20 minutes using sonication followed by 2- and 16-hour refluxes in fresh solvent; extracts were analyzed by LSC. Organic solvents were removed from the various sonication and reflux extracts by rotary evaporation; the remaining aqueous solutions were acidified, partitioned, and analyzed as previously described for the water samples. Unextracted [^{14}C]residues remaining in the extracted sediment were quantified by LSC following combustion.

Aliquots of the trapping solutions were analyzed for total radioactivity using LSC. The presence of $^{14}CO_2$ in the potassium hydroxide trapping solutions was confirmed using barium chloride precipitation.

Two additional flasks of silt loam sediment were autoclaved at 15 psi and 121 °C for 1 hour prior to treatment. The rice paddy water was autoclaved (under the same conditions) separately from the sediment, and was treated with [^{14}C]iprodione at 15.46 ppm. Aliquots (50 mL) of the treated sterile water were added to the sterilized sediment, and the flasks were stoppered and incubated as previously described. The two sterile soil:water systems were sampled at 30 days posttreatment and analyzed as previously described.

DATA SUMMARY:

Phenyl ring-labeled [^{14}C]iprodione (uniformly labeled, radiochemical purity 98.9%), at 8.12 ppm, degraded with an observed half-life of 3-7 days in a flooded silt loam sediment system that was incubated in the dark at 25 ± 1 °C for 1 month; the registrant-calculated half-life was 9 days (r^2 = 0.987). Iprodione decreased from an average of 98.7% of the applied radioactivity at time 0 to 36.5-40.3% at 7 days, and 7.1-8.5% at 30 days (Tables VII and VIII). The major non-volatile degradate was the isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP-30228). RP-30228 increased to 64.0-64.6% of the applied at 14 days posttreatment and was 52.0-59.7% at 30 days (Tables VII and VIII). Other nonvolatile degradates identified during the study were 3-(3,5-dichlorophenyl)-2,4-(dioxo-1-imidazol)idinecarboxamide (RP-32490; maximum concentration 11.9-14.6% of the applied at 2 days posttreatment) and 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-1-ureylenecarboxamide (RP-36221; 1.2% at 30 days).

Three unidentified [^{14}C]compounds were isolated and detected at maximums of 1.7% (Unknown 10), 1.8% (Unknown 6), and 11.5% (Unknown 9) of the applied. [^{14}C]Residues remaining at the origin of the TLC plates increased to 5.0-8.9% of the applied by 30 days posttreatment. At 30 days posttreatment, evolved $^{14}CO_2$ totaled 2.2-2.6% of the applied radioactivity, organic volatiles totaled 0.2-0.5%, and unextracted [^{14}C]residues accounted for 6.1-8.3% (Table VI). [^{14}C]Residues associated with the water fraction of the sediment:water systems decreased from 57.9-67.8% of the applied at 1 day posttreatment to 7.4-8.4% at 30 days. Material balances ranged from 97.2% to 111.1% of the applied (Table VI).

In sterilized sediment:water systems, iprodione comprised 5.4-15.9% of the applied by 30 days posttreatment. At 30 days posttreatment, RP-30228 was

the major degradate comprising 77.2-87.0% of the applied; RP-32490 and RP-36221 were also detected at ≤2.3% of the applied.

COMMENTS:

1. Not all degradates detected at >0.01 ppm (0.12% of the applied) were identified. Three unidentified [^{14}C]compounds were isolated; Unknown 6 comprised up to 1.8% (0.15 ppm) of the applied, Unknown 9 up to 11.5% (0.93 ppm), and Unknown 10 up to 1.7% (0.14 ppm). [^{14}C]Residues remaining at the origin of the TLC plates increased to 5.0-8.9% of the applied by 30 days posttreatment.

2. The test water was not completely characterized; the dissolved oxygen content of the rice paddy water was not determined.

3. It was reported that "bulk" incubations were conducted to produce sufficient material for degradate identifications. Two samples (100 g equivalent dry weight) of silt loam sediment were flooded with 200 mL of [^{14}C]iprodione-treated (8.12 ppm) water and incubated as described above for the nonsterile soil:water systems. However, it was not reported at what sampling interval the bulk incubations were collected, and quantitative data concerning the bulk incubations were not reported.

4. In a hydrolysis study (MRID 41885401), the degradate 3-(isopropylcarbamoyl)-5-(3,5-dichlorophenyl)hydantoin (RP-35606) was detected at a maximum 10.8-11.9% of the applied at 30 days posttreatment in pH 5 solution and 9.8-10.4% at 40.4 hours in pH 7 solution. Apparently, RP-35606 was not analyzed for in this study, since a reference standard was not received for TLC cochromatography.

5. A storage stability study was conducted by analyzing the time 0 water extracts for parent iprodione after 0, 11, 20, and 31 days of frozen storage. The data indicate that the extracted iprodione was stable under the storage conditions up to 31 days (Table III). It was not reported how long the study sample extracts were stored prior to analysis.

EIN 5721-93

Iprodione EF Reviews

Page_____ is not included in this copy.

Pages 59 through 66 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.

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____ 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.

REFERENCES

The following studies were reviewed:

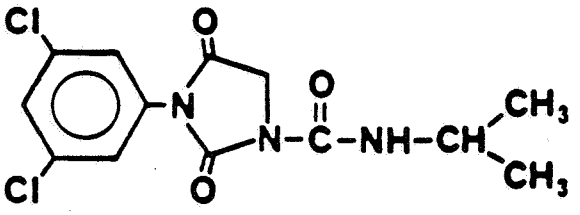
Adrian, P.P. and J. Robles. 1991. *^{14}C-Iprodione Aqueous Photolysis.* Laboratory Project ID: Study No. 90-22. Filing Reference: AG/CRLD/AN/911-5524. Unpublished study performed by Rhône-Poulenc Secteur Agro, Lyon, France, and submitted by Rhône-Poulenc Ag Company, Research Triangle Park, NC. (MRID #418619-01)

Das, Y.T. 1990. *Hydrolysis of [Phenyl(U)-^{14}C]iprodione in aqueous solutions buffered at pH 5, 7, and 9.* ISSI Laboratory Project No. 89100. Rhône-Poulenc Study No. EC-89-050. Unpublished study performed by Innovative Scientific Services, Inc., Piscataway, NJ, and submitted by Rhône-Poulenc Ag Company, Research Triangle Park, NC. (MRID #418854-01)

Spare, W.C. 1991. *Aerobic Aquatic Metabolism of Iprodione.* Laboratory Project ID: Agrisearch Project No. 1514. Unpublished study performed by Agrisearch Inc., Frederick, MD, and submitted by Rhône-Poulenc AG Company, Research Triangle Park, NC. (MRID #419276-01)

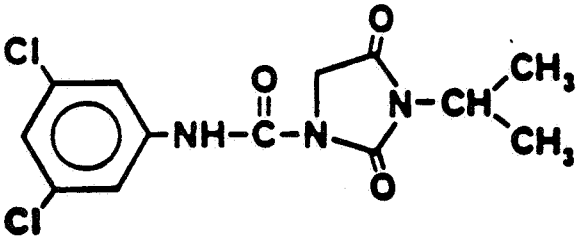
APPENDIX

IPRODIONE AND ITS DEGRADATES



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

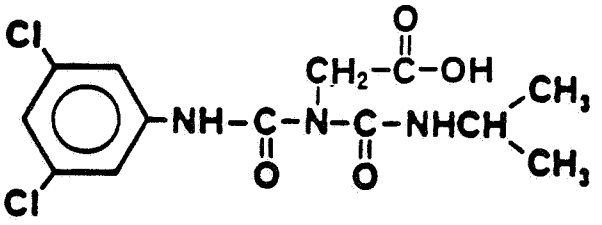
(Iprodione)



1-(3,5-Dichlorophenyl)carbamoyl-3-isopropylhydantoin (Studies 1 and 2)

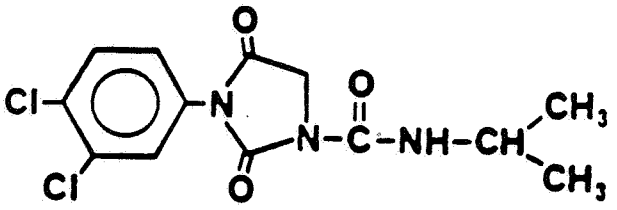
3-(1-Methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (Study 3)

(RP-30228)



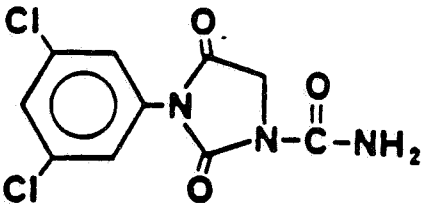
3-(Isopropylcarbamoyl)-5-(3,5-dichlorophenyl)hydantoic acid

(RP-35606)



1-Isopropylcarbamoyl-3-(3,4-dichlorophenyl)hydantoin

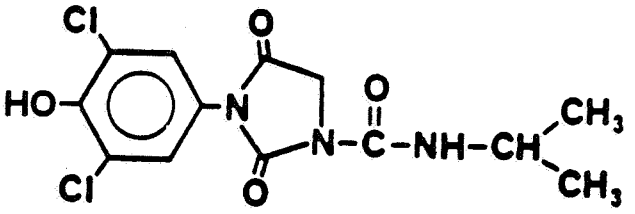
(RP-40837)



Carbamoyl-1-(3,5-dichlorophenyl)-3-hydantoin (Study 2)

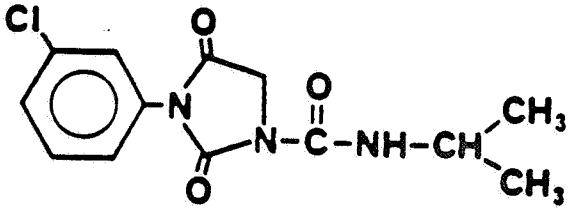
3-(3,5-Dichlorophenyl)-2,4-(dioxo-1-imidazol)idinecarboxamide (Study 3)

(RP-32490)



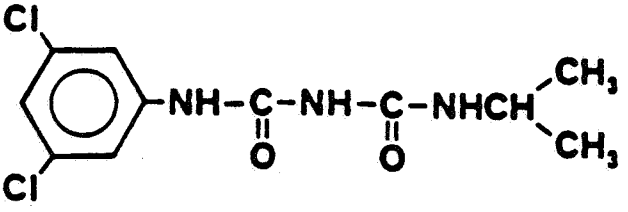
Isopropylcarbamoyl-1-(3,5-Dichloro-4-hydroxyphenyl)-3-hydantoin

(RP-37677)



1-Isopropylcarbamoyl-3-(3-chlorophenyl)hydantoin

(RP-25331)



3-(1-Methylethyl)-N-(3,5-dichlorophenyl)-1-ureylenecarboxamide

(RP-36221)