Shaughnessy No.: 109801

Date Out of EFGWB: OCT 1 1990

To: Susan Lewis/James Stone
Product Manager #21
Registration Division (H7505C)

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 # : 264-EUP-TI

Common Name : Iprodione; Glycophene

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.

Type Product : Fungicide

Product Name : ROVRAL 4F

Company Name : Rhône-Poulenc Agricultural Company

Purpose : Review of an Accumulation in Confined Rotational Crops Study (165-1)

Date Received: 1/22/1990 **Action Code** : 711

Date Completed: 9/6/1990 **EFGWB # (s):** 90-0373

Deferrals to:

_____ Ecological Effects Branch, EFED
_____ Science Integration and Policy Staff, EFED
_____ Non-Dietary Exposure Branch, HED
_____ Dietary Exposure Branch, HED
_____ Toxicology Branch I, HED
_____ Toxicology Branch II, HED

1. CHEMICAL:

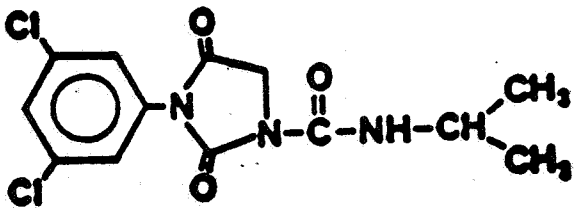
Common name: Iprodione.

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.

CAS Number: 36734-19-7

Trade name(s): Rovral, RP 26019, Glycophene, Chipco 26019, LFA 2043, NCR 910, ROP 500 F.

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.
Melting Point: ca. 136 °C.

Vapor Pressure at 20 °C: $< 1.0 \times 10^{-5}$ mm Hg (<0.133 mPa)

Formulations: 50% WP.
Active ingredient:
3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide.....50%
Inert ingredients.....50%

2

2. **TEST MATERIAL:**

^{14}C-Iprodione uniformly labeled in the phenyl ring [Specific activity 4.9 μCi/mg or 10,880 dpm/μg and radiopurity of 98% by TLC and autoradiography].

3. **STUDY/ACTION TYPE:**

Review of an Accumulation in Confined Rotational Crops study submitted by Rhone-Poulenc Agricultural Company as requested in the EFGWB Review # 90-0005 performed by María Isabel Rodríguez and dated 1/2/1990.

4. **STUDY IDENTIFICATION:**

Letter from Mr. Nick Somma -- Registration Manager, Rhone Poulenc Agricultural Company -- submitting a Confined Rotational Crop study.

Gemma, A. A.; Heinzelman, G.; and Wargo, J. P. 1985. The Potential Uptake of ^{14}C-Iprodione and/or Its Metabolites in Various Crops From Soil Treated With ^{14}C-Iprodione. Laboratory Study ID ASD No. 85/133. Unpublished study performed by Rhone-Poulenc Inc., Agrochemical Division, Monmouth Junction, NJ; Gulf South Research Institute, New Iberia, LA; Subra Company, New Iberia, LA; Borriston Laboratories, Inc., Temple Hills, MD; and Agrisearch Incorporated, Mt. Airy, MD; and submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. (MRID # 412471-01)

Copies of the letter of Mr. Somma and the EFGWB Review #90-0005 (performend by María Isabel Rodríguez and dated 1/2/1990) are attached to this review.

5. **REVIEWED BY:**

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

Signature: María Isabel Rodríguez

Date: September 6, 1990.

6. **APPROVED BY:**

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

Signature: E Regelman

Date: OCT 1 1990

7. **CONCLUSIONS:**

After reviewing the submitted study, EFGWB concluded that the study cannot be used to fulfill the environmental-fate data-requirements for the following reasons:

1. The data are considered to be of uncertain value and could not be used to predict the environmental behavior of iprodione and its metabolites.

2. The study is unacceptable because of discrepancies between the information submitted in the several independently prepared reports comprising it.

3. The test substance was applied at less than the maximum application rate.

4. Several degradates present $\geq$ 0.01 ppm were not identified.

Therefore, the Confined Rotational Crop study remains a data gap.

8. RECOMMENDATIONS:

The following information should be given to the registrant, Rhône-Poulenc Agricultural Company:

a. The submitted Confined Rotational Crop study does not meet Subdivision N Guidelines. A new study has to be submitted.

b. It is strongly recommended that a protocol be submitted prior to a new study.

c. All degradates present at $\geq$ 0.01 ppm must be identified.

d. To support the proposed label maximum use rate, the study must be conducted at $\geq$ 4.0 lb. ai/A.

e. Studies submitted for review should be better organized, especially if several independently prepared reports, such as appendices, are to be included in it. Also, information provided by the separate reports should be in agreement.

f. Weather characterization data should be provided.

g. Sample storage stability data should be provided.

h. Method detection limits as well as recovery values from fortified plant and soil samples should be reported.

i. To support this data requirement, testing must be conducted using representative crops in the small grain, leafy vegetables, and root crop groups.

Therefore, EFGWB does not recommend that an EUP for aerial spraying of Rovral 4F on beans, potatoes, and dry bulb onions be granted until the Confined Rotational Crop study requirement is fulfilled. However, the

registrant could add a label restriction on crop destruction and submit the Confined Rotational Crop study later on.

9. **BACKGROUND**:

A. Introduction

During the years 1983 to 1987, several (7) reviewers from EFGWB had requested from the registrant, Rhône-Poulenc Agricultural Company, rotational crops data in 13 different environmental-fate data reviews and Radiolabeled, Confined-Rotational Crop studies for root crops, small grains, and leafy vegetables in order to establish the need for a rotational crop statement or rotational crop tolerances covering the use of Iprodione for Terrestrial Food Crops.

On 11/21/1988, the registrant submitted a study to fulfill the data-requirements for Field-Rotational Crops (Guidelines Reference #165-2) (MRID # 408818-01), and the study was found to be unacceptable. EFGWB did not concur with the EUP Application for aerial spraying of Rovral 4F on beans, potatoes, and dry bulb onions pending submission of a Confined-Rotational Crops Study (Guidelines Reference #165-1) (Refer to EFGWB Review #90324 dated 7/12/1989 for details).

The general use-pattern for Rovral 4F is Terrestrial Food Crop and the Environmental-fate data-requirements (40 CFR, Part 158.290) for an EUP for this use-pattern are the following:

Guidelines Reference #	Data Requirements	Status of Studies
161-1	-Degradation studies-lab -Hydrolysis	Fulfilled
162-1	-Metabolism studies-lab -Aerobic soil	Fulfilled
163-1	-Mobility studies -Leaching and adsorption/desorption	Fulfilled
165-1	-Accumulation studies -Rotational Crops (Confined)	Data gap
165-4	-In fish	Fulfilled

On 1/2/1990, the registrant requested an EUP for aerial spraying of Rovral 4F on beans, potatoes, and dry bulb prior to submission/review of previously requested Confined-Rotational Crops study

(Refer to EFGWB Review #90-0005 performed by María Isabel Rodríguez and dated 1/2/1990).

At that time, the registrant argued that tolerances and registrations have already been obtained on these crops, that ground application to these crops has already been allowed and, that some states have granted 24(c) registrations for aerial application on these crops. Tolerances established under 40 CFR, Part 180.399 for the combined residues of Iprodione, its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide in or on the following raw agricultural commodities are as follows:

Commodities	ppm
Beans, dried, vine hay	90.0
Beans, dry	2.0
Beans, folage	90.0
Beans, succulent	2.0
Onions, dry bulb	0.5
Potatoes	0.5*

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* Expiration date was June 8, 1989 but Product Manager (RD) communicated that tolerance is still in effect.

The registrant did not mention which states granted the 24(c) registrations and no evidence could be found in EFGWB files.

The registrant is now submitting the Confined-Rotational Crops study (165-1) for review.

B. Directions for Use

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 field and vegetable (lettuce, broccoli, carrots, onions, garlic, beans, peanuts, potatoes, caneberries, and ginseng) and 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.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

Refer to attached Data Evaluation Record.

11. COMPLETION OF ONE-LINER:

Last update was performed on 9/6/1990.

12. CBI APPENDIX:

All data reviewed are considered "confidential business information" by the registrant and must be treated as such.

IPRODIONE

Table of Contents

	Page
Introduction	
Scientific Studies	
1. Accumulation in confined rotational crops. (Gemma, A. A.; Heinzelman, G.; and Wargo, J. P.; MRID #412471-01)	1.1
Appendix (Structures of iprodione and its metabolites)	2.1
Attachments	3.1

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 field and vegetable (lettuce, broccoli, carrots, onions, garlic, beans, peanuts, potatoes, caneberries, and ginseng) and 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 §165-1

FORMULATION--06--WETTABLE POWDER (WP)

STUDY ID 412471-01

Gemma, A.A., Heinzelman, G. and Wargo,J. P. 1985. The Potential Uptake of ^{14}C-Iprodione and/or Its Metabolites in Various Crops From Soil Treated With ^{14}C-Iprodione. Laboratory Study ID ASD No. 85/133. Unpublished study performed by Rhone-Poulenc Inc., Agrochemical Division, Monmouth Junction, NJ; Gulf South Research Institute, New Iberia, LA; Subra Company, New Iberia, LA; Borriston Laboratories, Inc., Temple Hills, MD; and Agrisearch Incorporated, Mt. Airy, MD; and submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC.

DIRECT REVIEW TIME = 40

REVIEWED BY: C. Little TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD

TEL: 468-2500

APPROVED BY: María Isabel Rodríguez
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-7495

SIGNATURE: María Isabel Rodríguez

DATE: September 6, 1990.

CONCLUSIONS:

Confined Accumulation - Rotational Crops

1. This study cannot be used to fulfill the environmental-fate data-requirements.

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

3. This study is unacceptable because of discrepancies between the information submitted in the several independently prepared reports comprising it.

4. In addition, this study does not meet Subdivision N guidelines for the following reasons:

a. The test substance was applied at less than the maximum application rate.

b. Several degradates present $\geq$ 0.01 ppm were not identified.

4. Because of the reasons stated above, the Confined Rotational Crop study remains a data gap and, therefore, a new study is required.

METHODOLOGY:

Phenyl ring-labeled iprodione (uniformly labeled; radiochemical purity 98%, specific activity 4.9 μCi/mg, source not specified) was formulated as a 50% WP (over-the-top spray) and applied to peanut plants in 3 treatments, at 1 lb ai/A/application, for a total application of 3 lb ai/A. The applications were made on May 2, 1983, at 2 months postplanting; June 2, at 3 months postplanting; and June 27, approximately 7-14 days prior to harvest. The peanut plants were maintained in three plastic-lined metal containers (one control, two treated; 2 feet wide X 6 feet long X 27 inches deep) that were filled with 24 inches of silt loam soil (see comments). The containers were buried 12 inches into the ground at a research facility located in New Iberia, LA, and were surrounded with fencing and roofing. Following a 120-day aging period, the metal containers were relocated to a second research facility in New Iberia, LA, and were buried 20 inches into the ground.

The peanut plants were harvested 10 days after the final application of iprodione. Four months after harvest (on October 24, 1983), the top 3 inches of soil were homogenized and the plots were planted to soybeans, peanuts, wheat, and turnips. Additional plantings of soybeans, peanuts, wheat, turnips, and corn were made at 8 and 12 months post-harvest (on February 20 and June 25, 1984). Rotational crops were sampled at 30, 60, and 120 (the normal harvest time) days postplanting for each planting

interval; soil samples were taken at the 0- to 3-, 3- to 6-, and 6- to 12-inch depths at 30 and 120 days postplanting.

Plant samples (turnip roots and all preharvest samples) were rinsed with water to remove adhering soil and the roots were discarded (except for turnip plants). Immature plant samples were ground with dry ice and allowed to sublime. Mature plant samples were separated into roots, stems and leaves, and grain or fruit. Mature peanuts were separated into shells and nutmeat; soybeans into seeds and hulls; corn into kernels and cobs; and the wheat left intact as heads. The distinct portions of the mature plant samples were then ground with dry ice and allowed to sublime. Samples from each of the two test plots were analyzed for total radioactivity using LSC following combustion. Corresponding samples from the plots were then composited, re-homogenized, and analyzed as described above (data summarized in this review reflect the composited samples). Composite crop samples were then analyzed for total extractable residues (Figure 1 of the study -- included in this review). Ten-gram subsamples were weighed into a jar and mixed with 100 mL of acetone plus 1 mL of 1 N HCl then vacuum filtered. The filter cake was reextracted with acetone two times, and the jar and filter were rinsed with additional acetone. The filter cake was Soxhlet-extracted for 8 hours using methanol, and the extract was analyzed using LSC; the residues remaining in the filter cake (total bound residues) were analyzed using LSC following combustion. The acetone was evaporated from the combined extracts, and the aqueous residue was then transferred to a separatory funnel with 25 mL of water and partitioned three times with 80 mL of ethyl acetate. The resulting extracts were dried with anhydrous sodium sulfate and collected in a flask. Following the rinsing of the sodium sulfate pad with additional ethyl acetate, the extracts were combined and evaporated to dryness, and the residues were redissolved in acetonitrile. Aliquots of the acetonitrile along with aliquots of the aqueous residue were analyzed for total extractable residues using LSC. The acetonitrile was then partitioned twice with 50 mL of hexane, and the extract was analyzed by LSC. The acetonitrile fractions were combined, evaporated to dryness, redissolved in acetone, and analyzed by LSC and by one-dimensional TLC on silica gel plates developed in methylene chloride:ethyl acetate:formic acid (85:10:5, v:v:v; Solvent System #2) or toluene:ethyl acetate:acetic acid (80:15:5, v:v:v; Solvent System #7). Samples were co-chromatographed with standards; samples and standards were visualized using UV light and located using autoradiography. Radioactive areas on the silica gel were scraped and analyzed using LSC either directly or following elution with methanol and subsequent filtering.

The soil cores were separated into samples from each sampling depth and mixed. Subsamples (50 g) were weighed into a bottle, extracted with water:acetone (10:90, v:v) by shaking for 2 hours, and analyzed as described for the crop samples, except that the residues were redissolved in acetone rather than acetonitrile and the Soxhlet extraction was with methanol plus water.

DATA SUMMARY:

Phenyl ring-labeled iprodione (radiochemical purity 98%), applied as a 50% WP to peanut plants at 3 lb ai/A (3 applications at 1 lb ai/A/treatment), accumulated in confined rotational crops (soybeans, peanuts, wheat, turnips, and corn) planted in silt loam soil at 4, 8, and 12 months after harvest of the peanut crop and sampled at 30, 60, and 120 days postplanting. The major degradate was

RP-30228, an isomer of the parent compound,

at a maximum of 19.36% of total residues recovered in corn (mature stems/leaves, 12-month interval crop); 23.52% in peanuts (mature stems/leaves, 12-month interval crop); 12.28% in soybeans (immature stems/leaves, 8-month interval crop); 12.53% in turnips (immature stems/leaves, 8-month interval); and 10.73% in wheat (mature stems/leaves, 12-month interval; Table 8 of the study -- included in this review).

Other degradates identified in the crop samples were

RP-25040, present at 2.28-15.70% of total residues recovered;
RP-32490, a des-isopropylated metabolite, present at 2.39-20.53%;
RP-36112, an isomer of RP-32490, present at 1.26-13.78%; and
RP-36221, present at 0.94-24.83% (Table 8).

Residues of iprodione, reported as iprodione equivalents, in mature (120 days post-planting) peanut plants (stems and leaves) were 0.63 ppm for the 4-month (post-harvest) planting interval rotation crop, and decreased to 0.44 ppm and 0.18 ppm, respectively, for the 8-month and 12-month interval crop (Table 2 of the study -- included in this review). Residues in the nutmeat of mature peanut plants at 120 days post-planting were 0.13 ppm. Residues in immature peanut plants (stems and leaves) were 0.27-0.46 ppm for the 4- and 8-month interval crops and decreased to 0.10-0.11 ppm for the 12-month interval rotation crop. Parent material was a maximum of 30.25%, of total residues recovered (immature stems/leaves; 8-month interval) (Table 8 of the study -- included in this review). Extractable residues in the mature plant samples ranged from 66.5 to 88.0% of total residues recovered (Table 5 of the study -- included in this review).

At 120 days post-planting, iprodione residues in mature soybeans (stems and leaves) were 0.34 ppm for the 4-month interval rotation crop, increased to 0.62 ppm for the 8-month interval crop, and then decreased to 0.34 ppm for the 12-month interval crop (Table 2 of the study -- included in this review). Residues in immature soybean plants were 0.39-0.47 ppm for the 4- and 8-month interval crops, and decreased to 0.08-0.19 ppm for the 12-month interval crop. Residues in seeds and hulls from mature soybean plants ranged from 0.10-0.15 ppm. Parent residues reached a maximum of 24.81% of total residues recovered (immature stems/leaves; 4-month interval) (Table 8 of the study -- included in this review). Extractable residues in mature plant samples ranged from 78.7 to 96.4% of

the total residues recovered (Table 5 of the study -- included in this review).

Iprodione residues in immature turnip plants (whole plant) for the 4- and 8-month interval rotation crops were 0.05-0.22 ppm, and increased to 0.32-0.36 ppm for the 12-month interval crop (Table 2 of the study -- included in this review). Residues in mature turnip plants from the 8-and 12-month interval crops were 0.09-0.14 ppm (stems/leaves) and 0.02-0.05 ppm (roots). Parent residues reached a maximum of 49.23% of total residues recovered (immature stems/leaves; 4-month interval) (Table 8 of the study -- included in this review). Extractable residues in mature plant samples ranged from 77.3 to 96.6% of the total residues recovered (Table 5 of the study -- included in this review).

Iprodione residues in immature wheat plants from the 4- and 8-month interval rotation crops were 0.35-0.64 (whole plant; Table 2 of the study -- included in this review). Residues in mature plants (stems/leaves) were 0.34 ppm for the 4-month interval crop, increased to 0.89 ppm for the 8-month interval crop, and decreased to 0.27 ppm for the 12-month interval crop. Residues in grain heads of mature wheat plants were 0.08 ppm for the 8-month interval rotation crop (no data reported for the 12-month interval crop). Parent residues reached a maximum of 51.13% of total residues recovered (immature stems/leaves; 8-month interval) (Table 8 of the study -- included in this review). Extractable residues in mature plant samples ranged from 78.8 to 91.7% of the total residues recovered (Table 5 of the study -- included in this review).

Iprodione residues in immature corn plants were 0.22-0.33 ppm for the 8-month interval rotation crop, and decreased to 0.08-0.19 ppm for the 12-month interval crop (Table 2 of the study -- included in this review). Residues in mature corn plants were 1.46 ppm and decreased to 0.70 ppm (stem/leaves) for the 8- and 12-month interval crops, respectively; 0.01-0.04 ppm (kernels); 0.22 and decreased to 0.02 ppm (cobs) for the 8- and 12-month interval crops, respectively; and 0.28 ppm (husks) for the 8-month interval rotation crops. Parent residues reached a maximum of 41.1% of total residues recovered (immature stems/leaves; 8-month interval) (Table 8 of the study -- included in this review). Extractable residues in mature plants ranged from 77.1 to 100.0% of the total residues recovered (Table 5 of the study -- included in this review).

Based on TLC analysis of the total extractable residues obtained from rotational crop samples, material remaining at the origin and unidentified metabolites accounted for up to 19.55 and 20.84% of total residues recovered for corn, 19.54 and 16.85% for peanuts, 23.59 and 29.72% for soybeans, 30.97 and 17.06% for turnips, and 16.81 and 11.75% for wheat, respectively (Table 8 of the study -- included in this review).

Iprodione residues in soil samples (reported as iprodione equivalents) were 1.00-1.86 ppm at the 0- to 3-inch depth, 0.02-3.16 ppm at the 3- to 6-inch depth, and 0.03-0.17 ppm at the 6- to 12-inch depth (Table 4 of the study -- included in this review). Parent residues (RP-26019) were 80.58-84.65% of total residues for the 4-month interval crop, and

decreased to 30.69-52.12% for the 12-month interval crop (Table 9 of the study -- included in this study). The major degradate was

RP-30228,

obtained at a maximum of 15.64% of total residues at 120 days post-planting for the 12-month interval planting (Table 9 of the study -- included in this review).

Other metabolites,

RP-25040, RP-32490, RP-36112, and RP-36221,

were present in soil at 0.41-6.59% of total residues recovered. Extractable residues in soil taken from the 0- to 3-inch depth decreased from 92.0-95.4% of the total residues in soil for the 4-month interval soil sample to 62.0-75.5% for the 12-month interval soil sample (Table 7 of the study -- included in this review).

COMMENTS:

1. All degradates present at $\geq$ 0.01 ppm must be identified. In this study, extractable residues from mature rotational crops up to 0.28 ppm in corn, 0.8 ppm in wheat, 0.13 ppm in soybeans, and 0.06 ppm in peanuts were not identified.

2. Iprodione was applied to peanut plants in 3 treatments at a nominal application rate of 1 lb ai/A/application, for a total application rate of 3 lb ai/A. However, the maximum application rate for field and vegetable crops is 4.0 lb ai/A.

3. The study presented for review was poorly organized and included several additional, independently prepared reports as appendices. Also, there were apparent discrepancies between the information (which should have been redundant) provided by the separate reports. For example, the report prepared by Gulf South Research Institute characterized the test plot soil as 20% sand, 68.8% silt, 11.2% clay, pH 5.2, organic matter 9.0%, and CEC 28.9 meq/100 g; the report prepared by Agrisearch Inc., characterized the test plot soil as 44.4% sand, 52.0% silt, 3.6% clay, pH 6.1, organic matter 4.6%, and CEC 14.6 meq/100 g. Likewise, the values reported for the accumulation of iprodione in plant tissue did not agree in the two reports submitted by the companies mentioned above.

4. The study authors noted that no mature crops were obtained from the 4-month aging interval due to cold weather.

5. Data reported in the study for the total residues found in plants included values for samples taken from each of the two test plots as well as from a composite sample; the values reported in this review are for the composite samples.

6. The values given for the amount of residues detected in immature soybean plants (stems and leaves) planted 8 months post-harvest, appeared to be anomalous and were not reported in this review.

7. The distributional characterization of degradates present (as determined by TLC analysis) was based on as little as 41.5% of total residues recovered (Table 8 of the study -- included in this review). Also, levels of degradates present were given only as a percentage of total residues recovered; no accumulation data were provided in terms of ppm. In order to derive more usable values from the data provided, the reviewer would have been required to perform numerous calculations and to make several assumptions. Therefore, no attempt was made to transform the data to ppm.

8. In some cases, separation on TLC plates between RP-25040 and RP-32490, and between RP-36112 and RP-36221 was poor. In such cases, the percentage of the degradates present was given by the study authors as a sum of the two unresolved, respective compounds; these data are not included in the data summary of this review.

9. Weather characterization data were not provided.

10. Although the methods indicated that a control was used, no data were provided for such in the primary report prepared by Rhône-Poulenc Inc.. Control plot data was included in the report by Agrisearch Inc.; however, it is questionable as to whether this data is transferrable to the primary report (Refer to comment 3).

11. The methods presented did not detail the length of storage between sample collection and analysis. Also, sample storage stability data were not provided.

12. Neither method detection limits nor recovery values from fortified plant and soil samples were reported.

13. According to the report submitted by Gulf South Research Institute, other pesticides were applied to the peanut crop receiving the direct application of iprodione. Thiodan was applied to the crop at 0.27 oz ai/plot on April 12; malathion (50 EC) was sprayed at 15 mL concentrate/plot (diluted to 24 oz with tap water) on May 24.

14. No leafy vegetables were used on the study.

Use this form for individual studies & to submit pesticide applications.

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain National Security Information (E.O. 12065)

Pack Number	Date Received
50135 EFED	2/16/90

1. Product Name: Rovral 4 Flowable

Chemical Name: Iprodione

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
264-EUP-II	259816	711	412471101	165-1

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ (EFED)/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
1	1/22/90	Lewis/Stone	21	2/16/90	5/16/90	

Instructions

Confined Rotational Crop Study requested by Maria Isabel Rodríguez's review dated 12/7/89

This Section Applies to Review of Studies Only

14. Check Applicable Box

- [ ] Adverse 6(a)(2) Data (405)
- [ ] Special Review Data (870)
- [ ] Generic Data (Reregistration) (660)
- [ ] Product Specific Data (Reregistration) (655)

15. No. of Individual Studies Submitted

16. Have any of the above studies *(in whole or in part)* been previously submitted for review?

- [ ] Yes *(Please identify the study(ies))*
- [ ] No

17. Related Actions

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	SAC, PC	A. Policy Note No. 31
		Toxicology/HFA	TOX/HFA, PL	
		Toxicology/IR	TOX/IR	[ ] 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
		Dietary Exposure	DEB, EA	
		Nondietary Exposure	NDE, AC	
EFED		Ecological Effects	BA	[ ] 2 = data of particular concern from registration standard
	X	Environmental Fate & Groundwater	EEB	
SRRD		Special Review	EFGWB	[ ] 3 = data necessary to determine tiered testing requirements
		Reregistration		
		Generic Chemical Support	SR	
RD		Insecticide-Rodenticide	RER	B. Section 18
		Fungicide-Herbicide	GSC	[ ] 1 = data in support of section 3 in lieu of section 18
		Antimicrobial		
		Product Chemistry	IR	
		Precautionary Labeling	FH	C. Inert Ingredients
BEAD		Economic Analysis	AM	[ ] 1 = data in support of continued use of List 1 inert
		Analytical Chemistry		
		Biological Analysis		

- [ ] Confidential Statement of Formula (EPA Form 8570-4) Attached *(Trade Secrets)*
- [ ] Label Attached

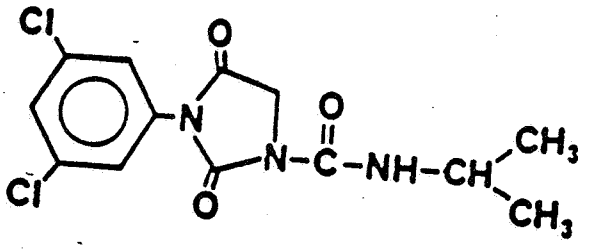
17

EPA Form 8570-17 (Rev. 11-88) Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review

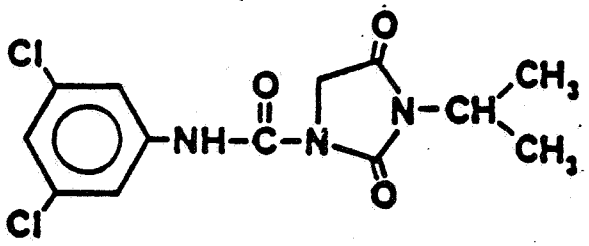
Appendix

Structures of Iprodione and Its Metabolites



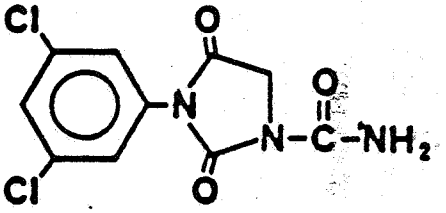
3-(3,5-Dichlorophenyl)-1-isopropyl-aminocarbonyl-2,4-dioxoimidazolidine

(Iprodione, RP-26019)



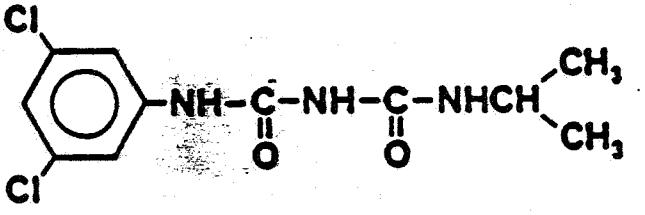
1-(3,5-Dichloroanilino)carbonyl-3-isopropylamino-2,4-dioxoimidazolidine

(RP-30228)



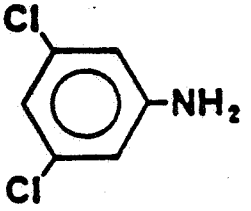
3-(3,5-Dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide

(RP-32409)



(RP-36221)

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



(RP-32596)

3,5-dichloroaniline

Attachments

ATTACHMENT #1

Letter from Mr. Nick Somma.

1/25/90
C15

RHÔNE-POULENC

RHÔNE-POULENC AG COMPANY

January 19, 1990

Susan Lewis
Product Manager (21)
Office of Pesticide Programs
Environmental Protection Agency
Crystal Mall, Building 2
Arlington, Virginia 22202

Dear Ms. Lewis:

SUBJECT: Rovral 4 Flowable-EPA Reg. No. 264-482
EUP 264-EUP-TI
Your Letter of January 16, 1990

Thankyou for the EFGW Branch review of the EUP Application for aerial spraying of Rovral 4F on beans, dry bulb onions and potatoes. In their review they stated that the EUP could not be issued until a confined crop rotational study was submitted.

A confined crop rotational study was submitted on September 21, 1989 under Phase II of FIFRA 88. This study was assigned MRID Number 41247101. Rhone-Poulenc would appreciate having the EFGW Branch be made aware of this study.

If you have any questions or if any further information is needed, please let me know.

Sincerely,

Nick Somma

PO BOX 12014, 2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, N.C. 27709
(919) 549-2000
INTERNATIONAL TELEX NUMBER 4999378–ANSWERBACK APC RTP
INTERNATIONAL DISTRIBUTION SERVICES TELEX NUMBER 4999377–ANSWERBACK APC IDS

22

Attachment #1

ATTACHMENT #2

EFGWB Review # 90-0005

Shaughnessy No.: 109801

Date Out of EFGWB: 1/2/90

TO: Susan Lewis/James Stone
Product Manager #21
Registration Division (H7505C)

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

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

Attached, please find the EFGWB review of:

Reg./File #(s): 264-EUP-TI

Common Name: Iprodione; Glycophene

Chemical Name: 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide

Type of Product: Fungicide

Product Name: ROVRAL 4F

Company Name: RHÔNE-POULENC Agricultural Company

Purpose: Experimental Use Permit - New Chemical - Food or Feed Use - Resubmission - Comment on Company's response to review dated 7/10/1989 on Field-Rotational Crops Study.

Date Received: 8/31/1989 Action Code: 711

Date Completed: 11/27/1989 EFGWB #(s): 90-0005

Total Reviewing Time: 1 day

Deferrals to: _____ Ecological Effects Branch/EFED

_____ Science Integration & Policy Staff/EFED

_____ Non-Dietary Exposure Branch/HED

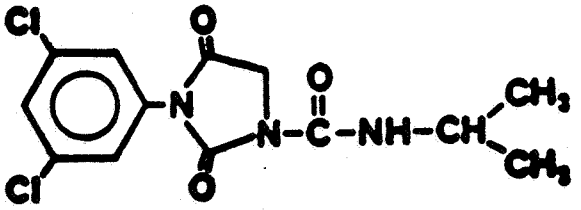
_____ Dietary Exposure Branch/HED

_____ Toxicology Branch I, II/HED

Attachment #2

1. CHEMICAL:

Chemical Name: 3-(3,5-Dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
Common Name: Iprodione; Glycophene
Trade Name: ROVRAL 4F
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
Water solubility: Almost insoluble in water
Organic solubility: Soluble in acetone and benzene

2. TEST MATERIAL:

ROVRAL 4F 50% WP.

3. STUDY/ACTION TYPE:

RHÔNE-POULENC Agricultural Company has requested that an Experimental Use Permit (EUP) be granted prior to submission/review of previously requested Confined Rotational Crops Study.

4. STUDY IDENTIFICATION:

Letter of Nick Somma (Registration Manager -- RHÔNE-POULENC Agricultural Company -- Requesting EUP grant without submission of studies), and Cover Memo (12-Liner) of Review #90268 dated 7/10/1989 on Field-Rotational Crops Study. Copies of both documents, the letter and the cover memo, are attached to this review.

5. REVIEWED BY:

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

Signature: María Isabel Rodríguez
Date: 12/7/89

25

Attachment #2

6. APPROVED BY:

Emil Regelman
Supervisory Chemist, Review Section #2
OPP/EFED/EFWGB

Signature: N Nelson for E
Date: 12/27/89

7. CONCLUSIONS:

EFGWB can not concur with RHÔNE-POULENC Agricultural Company's request for an EUP prior to submission/review of previously requested Confined Rotational Crops Study. The general use-pattern for ROVRAL 4F is Terrestrial Food Crop and this study is an Environmental-fate data-requirement (40 CFR, Part 158.290) for an EUP for this use-pattern. Therefore, it is a data gap.

8. RECOMMENDATIONS:

The following information should be given to the registrant (RHÔNE-POULENC Agricultural Company):

a. The Confined-Rotational Crops Study (Guidelines Reference #165-1) is a data-requirement for a Terrestrial Food Crop use EUP Application which would include aerial spraying of ROVRAL 4F on beans, potatoes, and dry bulb onions. At this moment, this study is a data gap: without this data EFGWB can not make any assessment of the nature and/or level of residues in rotated crops.

b. Since beans, potatoes, and dry bulb onions are commodities covered by established tolerances, a label restriction has to be added in which only those crops already on the label can be rotated.

9. BACKGROUND:

During the years 1983 to 1987, several (7) reviewers from EFGWB had requested from the registrant, RHÔNE-POULENC Agricultural Company, rotational crops data in 13 different environmental-fate data reviews and Radiolabeled, Confined Rotational Crop Studies for root crops, small grains, and leafy vegetables in order to establish the need for a rotational crop statement or rotational crop tolerances covering the use of Iprodione for Terrestrial Food Crops.

On 11/21/1988, the registrant submitted a study to fulfill the data-requirements for Field-Rotational Crops (Guidelines Reference #165-2) (MRID # 40881801), and the study was not accepted to fulfill the data requirements. EFGWB did not concurred with the EUP Application for aerial spraying of ROVRAL 4F on beans, potatoes, and dry bulb onions pending submission of a Confined-Rotational Crops Study (Guidelines Reference #165-1) (Refer to Review #90324 dated 7/12/1989 for details).

The registrant is now requesting that an EUP for aerial spraying of ROVRAL 4F on beans, potatoes, and dry bulb onions be granted prior to submission/review of previously requested Confined-Rotational Crops Study. The general use-pattern for ROVRAL 4F is Terrestrial Food Crop and the Environmental-fate data-

requirements (40 CFR, Part 158.290) for an EUP for this use-pattern are the following:

Guidelines Reference #	Data Requirements	Status of Studies
161-1	-Degradation studies-lab -Hydrolysis	Fulfilled
162-1	-Metabolism studies-lab -Aerobic soil	Fulfilled
163-1	-Mobility studies -Leaching and adsorption/desorption	Fulfilled
165-1	-Accumulation studies	
	-Rotational Crops (Confined)	Data gap
	-In fish	Fulfilled

The registrant is arguing that tolerances and registrations have already been obtained on these crops, that ground application to these crops has already been allowed and, that some states have granted 24(c) registrations for aerial application on these crops. Tolerances established under 40 CFR, Part 180.399 for the combined residues of Iprodione, its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide in or on the following raw agricultural commodities are as follows:

Commodities	ppm
Beans, dried, vine hay	90.0
Beans, dry	2.0
Beans, folage	90.0
Beans, succulent	2.0
Onions, dry bulb	0.5
Potatoes	0.5*

---

* Expiration date was June 8, 1989 but Product Manager (RD) communicated that tolerance is still in effect.

The registrant did not mention which states granted the 24(c) registrations and no evidence could be found on EFGWB files.

10. DISCUSSION OF INDIVIDUAL STUDIES:

No studies were submitted; not applicable.

Attachment #2

11. COMPLETION OF ONE-LINER:

No one-liner was completed; not applicable.

12. CBI INDEX:

Information submitted is not considered CBI.

Attachment #2

RHÔNE-POULENC

RHÔNE-POULENC AG COMPANY

August 29, 1989

Susan Lewis
Acting Product Manager (21)
Office of Pesticide Programs
Environmental Protection Agency
Crystal Mall, Building 2
Arlington, Virginia 22202

Dear Ms. Lewis:

SUBJECT> Iprodione Experimental Use Permit (264-EUP-TI)
Your Letter of August 23, 1989

In subject letter it stated that EFGWB concluded that the EUP Application for aerial spraying of Rovral on beans, potatoes, and dry bulb onions was denied pending submission of a confined crop rotational study. We are in the process of preparing this study for submission. However, we believe that the EUP can be granted without waiting for study submission and subsequent review.

Tolerances and registrations have already been obtained on these crops. The purpose of the EUP is only to obtain aerial residue data so that this metod of application can be added to our label. Ground application to these crops is already allowed and some states have granted 24(c) registrations for aerial application on these crops. Previously submitted residue trials on other crops has shown that there is no increase in residue when Rovral is applied by air as compared to ground.

Rhone-Poulenc has also submitted an iprodione field rotational crop study that can be used to support this EUP Application. The study was assigned MRID Number 40881801.

Rhone-Poulenc requests that the above information be given to EFGWB and that they reconsider their denial of the EUP.

If any further information is needed, please let me know.

Sincerely,

Nick Somma
Registration Manager

29

Attachment #2

Shaughnessy No.: 109801

Date Out of EFGWB: JUL 10 1989

To: Susan Lewis
Acting Product Manager #21
Fungicide-Herbicide Branch
Registration Division (H7505C)

From: Emil Regelman, Supervisory Chemist
Chemistry Review Section #2
Environmental Fate and Ground Water Branch (H7507C)

Thru: Henry Jacoby, Acting Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Evaluation Division (H7507C)

Attached, please find the EFGWB review of . . .

Reg./File # : 264-453

Common Name : Iprodione

Type Product : Fungicide

Product Name : Rovral, RP 26019, Glycophene

Company Name : Rhone-Poulenc, Inc.

Purpose : Evaluation of an accumulation in field-grown rotational crops experiment

Date Received: 11/10/88 Action Code: 305

Date Completed: 7/7/89 EFGWB # (s): 90268

Total Reviewing time: 3.5 days

Deferrals to:

_____ Ecological Effects Branch, EFED

_____ Science Integration and Policy Staff, EFED

_____ Non-Dietary Exposure Branch, HED

_____ Dietary Exposure Branch, HED

_____ Toxicology Branch FHA Support, HED

Attachment #2

1. CHEMICAL: Common name:

Iprodione.

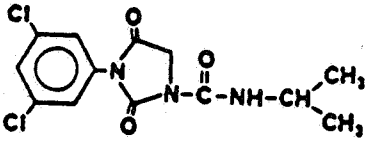
Chemical name:

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

Trade name(s):

Rovral, 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.

2. TEST MATERIAL:

Rovral 50% WP.

3. STUDY/ACTION TYPE:

Evaluation of a study to support the accumulation in rotated field crops data requirement. The registrant wishes to amend the label to allow a greater variety of crops to be rotated after iprodione application.

4. STUDY IDENTIFICATION:

Gemma, A. and O. Gillings. 1988. Residues of iprodione and its metabolites in/on field-grown rotational crops. Performed and submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ. (40881801)

5. REVIEWED BY:

Padma Datta. Ph.D.
Chemist
Chemistry Review Section #2
EFGWB/EFED/OPP

Signature: PRDatta

Date: 7/3/89

Attachment #2

6. APPROVED BY:

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

Signature: _____

Date: JUL 13 1989

7. CONCLUSIONS:

EFGWB cannot accept this study to fulfill the data requirement for the field accumulation studies on rotational crops (165-2) because of the following reasons:

A. The uptake of iprodione and its major degradates from soil residues was evident from the submitted residues data in the field-grown rotated crops one month (28-31 days) after the last application of iprodione. The data were inadequate to establish any rotational interval.

B. In addition, the following major and minor deficiences exist in this report:

Major deficiences

1) The concentration of iprodione and its major degradate(s) in the soil at the times of application, at planting, and at harvest of each rotational crop were not reported; therefore, the extent of uptake of iprodione and its degradate(s) by the rotational crops could not be determined;

2) Residues in the crops were reported as "total residue found" rather than as specific compounds; and,

3) Freezer storage stability data were not provided for the various plant tissues sampled in the study; no other data on freezer storage stability is available.

Minor deficiencies

1) Immature samples taken for all crops were inadequate;

2) A complete copy of the Analytical Method used (#162) was not provided,

3) Preparation of the field plots prior to treatment was not specified; and,

4) locations of the treated and controls plots in relation to each other were not specified.

(For details, see the attached DER on the individual study of iprodione).

8. RECOMMENDATIONS:

RD should inform the registrant (Rhone-Poulenc Inc.) :

1. To provide (a) the radiolabeled, confined rotational crops study (165-1) requested by our branch since 1983; and, (b) all additional data/ information to remedy the discrepancies cited in the Conclusions Section.

32

Attachment #2

8. RECOMMENDATIONS (Cont'd):

2. To postpone conducting of field-grown rotational crops study (165-2) until EFGWB evaluates the radiolabeled, confined rotational crops study (165-1) which the registrant intends to submit shortly.

9. BACKGROUND:

During 1983 to 1987, 7 reviewers of EFGWB (formerly EAB) requested: (1) rotational crops data in 13 different environmental fate data reviews and (2) that the registrant provide a radiolabeled, confined rotational crop studies for leafy vegetables, root crops and small grains to support registration of iprodione for terrestrial food crops. (For details, refer to EAB's reviews #103,1/28/83; #71005, 12/17/87; and, #80036, 12/31/87).

On 11/21/88, Rhone-Poulenc submitted a study to fulfill the data requirements, for field rotational crops (165-2) with a request to amend the label to allow a greater variety of crops to be rotated after the final iprodione treatment.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

See attached individual DER.

11. COMPLETION OF ONE-LINER:

See attached one liner.

12. CBI APPENDIX:

N/A.

ATTACHMENT #3

Information obtained from the study.

AIN 5721-93

Iprodione EF Reviews

Page_____ is not included in this copy.

Pages 35 through 64 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.
