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

1. CHEMICAL: Common name:

Iprodione.

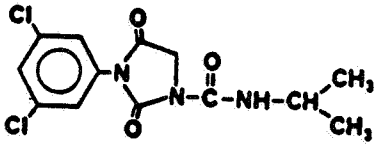
Chemical name:

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

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.

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.

DYNAMAC
CORPORATION

IPRODIONE ADDENDUM

Task 1: Review and Evaluation of Individual Studies

March 24, 1989

Final Report

Contract No. 68-02-4250

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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

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 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 165-2

FORMULATION--06--WETTABLE POWDER (WP)

STUDY ID 40881801
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.

DIRECT REVIEW TIME = 10

REVIEWED BY: L. Binari 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: P. Datta
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

P.D. Datta 7/7/87

SIGNATURE:

CONCLUSIONS:

Field Accumulation - Rotational Crops

1. This study cannot be used to fulfill data requirements at this time.

2. This study is unacceptable because soil data were inadequate; the application rate was not reported and the extent of pesticide uptake by the rotational crops in relation to the concentration of pesticide in the soil could not be determined. In addition, this study would not fulfill EPA Data Requirements for Registering Pesticides because residues in the crops were identified as "total residue found" rather than as specific compounds, and frozen storage stability data were not provided.

3. In order for this study to fulfill the accumulation in field-grown rotational crops data requirement, data must be provided on: the concentration of iprodione and its major degradates in the soil at the time of application, and at the planting and harvest of each crop; the concentration of specific compounds rather than "total residues" in each crop; and the frozen storage stability of iprodione and its metabolites in each crop.

METHODOLOGY:

California Site

One unvegetated field plot (32 x 5 feet) of loamy sand soil (81% sand, 7% silt, 12% clay, 0.5% organic matter, pH 5.6 CEC 2.7 meq/100 g) located in Hughson, California, was sprayed at 7 day intervals with iprodione (Rovral, 50% WP, Rhone-Poulenc) at 1.0 lb ai/A/application for 10 weeks (10 lb ai/A total) beginning 07/26/85. A second plot (32 x 144 feet) was treated in a similar fashion beginning 02/10/86; a third plot (32 x 36 feet) was treated beginning 07/14/86. At 28 days following the final application of iprodione, the treated plots were planted to various rotational crops (cabbage, mustard, radishes, sugar beets, peppers, tomatoes, peas, soybeans, field corn, sweet corn, sorghum, wheat, clover, and cotton); the crop species planted in each plot depended on the time of year the planting occurred. Crops were also planted in untreated soil to serve as a control. The following crops were harvested both when immature and at maturity: field corn, soybeans, and sorghum up to 121-122 days postplanting; cotton up to 193 days; peas up to 211 days; and clover up to 256 days. The following crops were harvested only at maturity: radishes at 88 days postplanting; sweet corn at 93 days; peppers at 105 days; tomatoes at 121 days; mustard at 124 days; cabbage at 147 days; wheat at 225 days; and sugar beets at 320 days. Samples were stored frozen until analysis.

Green/succulent plant samples were analyzed for iprodione, its isomer 1-(3,5-dichloroanilino)carbonyl-3-isopropylamino-2,4-dioxoimidazolidine (RP-30228), and the degradate 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP-32490) using Rhone-Poulenc Analytical Method No. 151. The samples were extracted twice with acetone:water (9:1); the extracts were filtered, combined, and concentrated. Nonoily extracts were diluted with 1% sodium sulfate solution, then partitioned twice with methylene chloride:ethyl acetate (9:1). The organic phases were drained through anhydrous sodium sulfate, combined, and concentrated. The concentrate was redissolved in ethyl acetate:toluene (3:1) and applied to a gel permeation column (Bio-Beads: S-X3, 200-400 mesh). Collected fractions were concentrated, dissolved in hexane:ethyl acetate (97:3), then applied to a Florisil column. Iprodione and its isomer were eluted with hexane:ethyl acetate (85:15), then RP-32490 was eluted with hexane:-ethyl acetate (1:1). The eluents were separately concentrated. The sample containing iprodione and its isomer was dissolved in hexane, then analyzed by GC with electron-capture detection (GC/EC). The sample containing RP-32490 was dissolved in benzene, then analyzed by GC/EC.

Dry plant samples, such as grain and hay, were analyzed by Rhone-Poulenc Analytical Method No. 162. Samples were homogenized, then extracted twice (the first time for 2.5 hours) with acetone:water (9:1). The extracts were filtered, combined, and concentrated; the combined extract was diluted with 1% sodium sulfate solution and adjusted to pH 3 with 5 N hydrochloric acid. With minor variations, the samples were prepared by methylene chloride:ethyl acetate partitioning, gel permeation chromatography, and Florisil column chromatography, and analyzed by GC/EC as described above.

The detection limit for iprodione, its isomer, and RP-32490 was 0.05 ppm. Reported recoveries from various crop substrates fortified with iprodione, its isomer, and RP-32490 are presented in Table 2.

To confirm the identities of iprodione, its isomer, and RP-32490, final concentrates were also analyzed by TLC on silica gel plates developed in benzene:ethyl acetate (9:1) for iprodione and its isomer or methylene chloride:ethyl acetate (6:4) for RP-32490. Reference compounds were cochromatographed with the samples. Following development, compounds were visualized by spraying with 1 N sodium hydroxide solution, drying at 100-110°C for 30 minutes, spraying with hydrochloric acid:methanol (1:1), air-drying, spraying with a 1% solution of sodium nitrite in water:methanol (8:2), air-drying, then spraying with a 1% solution of Bratton-Marshall reagent (N-1-naphthylethylenediamine dihydrochloride in 0.1 N hydrochloric acid).

At the California site, the depth to the water table was 85 feet and the field was described as level. During the entire study period (7/26/85-5/26/87), rainfall plus irrigation totaled ≈91 inches and air temperatures ranged from 21 to 105°F. Soil temperatures were not provided.

Mississippi Site

One unvegetated field plot (180 x 390 feet) of silt loam soil (31.8% sand, 58.1% silt, 10.1% clay, 0.95% organic matter, pH 6.05, CEC 10.6 meq/100 g) located at the Delta Research Farm in Mississippi (location not further specified) was treated at 7 day intervals with iprodione (Rovral, 50% WP, Rhone-Poulenc) at 1.0 lb ai/A/application for 10 weeks (10 lb ai/A total) beginning 01/30/86. A second plot (12 x 390 feet) was treated in a similar fashion beginning 05/15/86; a third plot (12 x 390 feet) was treated beginning 07/14/86. At 28-31 days following final application of iprodione, the treated plots were planted to various rotational crops (cabbage, mustard, radishes, sugar beets, bell peppers, tomatoes, cucumbers, summer squash, watermelons, black-eye peas, soybeans, field corn, sweet corn, sorghum, wheat, alfalfa, clover, and cotton); the crop species planted in each plot depended on the time of year the planting occurred. Crops were also planted in untreated soil to serve as a control. The following crops were harvested both when immature and at maturity: field corn, black-eye peas, and sorghum up to 126-128 days postplanting; soybeans up to 184 days; wheat up to 261 days; clover up to 272 days; and alfalfa up to 312 days. The following crops

were harvested only at maturity: cucumbers and summer squash at 52 days postplanting; radishes and mustard at 80 days; cabbage and sweet corn at 84-85 days; bell peppers at 90 days; tomatoes and watermelons at 111-112 days; cotton at 128 days; and sugar beets at 181 days. Samples were stored frozen until analysis, then prepared and analyzed as described above.

At the Mississippi site, the depth to the water table was 20 feet, and the slope of the field was 0%. During the entire study period (1/30/86-7/26/87), rainfall totaled ≈79 inches, air temperatures ranged from 19 to 104°F, and soil temperatures (depth unspecified) ranged from 36 to 100°F.

DATA SUMMARY:

Iprodione residues accumulated (≥0.05 ppm) in field-grown sorghum, sweet corn, field corn, soybean, wheat, peas, black-eye peas, radishes, cabbage, mustard greens, clover, and alfalfa planted 28-31 days after the soils received the last of ten 1 lb ai/A applications of iprodione (Table 1). Iprodione residues did not accumulate (≤0.05 ppm) in sugar beets, tomatoes, peppers, cucumbers, squash, watermelons, and cotton.

In rotational crops that were planted in loamy sand (California) or silt loam (Mississippi) soils 28-31 days after the plots received the last of ten applications of iprodione (Rovral, 50% WP) at 1.0 lb ai/A per application, total iprodione residues [including iprodione, its isomer 1-(3,5-dichloroanilino)carbonyl-3-isopropylamino-2,4-dioxoimidazolidine (RP 30228), and 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP 32490)] were ≥0.05 ppm in:

sorghum forage at 0.11 ppm (CA only), but not silage, grain, or fodder;

sweet corn forage at <0.05 and 0.05 ppm, but not ears with husk;

field corn fodder at 0.06 and 0.52 ppm, but not silage or grain;

soybean trash at <0.05 and 0.07 ppm, but not forage or seed;

wheat forage at 0.05 ppm (MS only) and straw at <0.05 and 0.15 ppm, but not grain;

pea vines at 0.55 ppm and dry pea seeds and straw at ≤0.06 ppm, but not succulent seeds and pods (peas grown in CA only);

black-eye pea straw at 0.05 ppm, but not seed, pods, vines, or dry seed (black-eye peas grown in MS only);

radish tops at 0.05 and 3.7 ppm, and radish roots at 0.06 and 0.77 ppm (the higher values were from CA);

cabbage wrapper leaves at <Ø.Ø5 and 1.Ø ppm, but not heads;

mustard leaves at Ø.17 and Ø.36 ppm;

clover hay at <Ø.Ø5 to Ø.29 ppm); and

alfalfa hay at Ø.Ø9-Ø.1Ø ppm, but not forage and seed (alfalfa grown in MS only).

Residues were not detected (<Ø.Ø5 ppm) in sugar beets (tops and roots), tomatoes (fruit), peppers (fruit), cucumbers (fruit), summer squash (fruit), watermelons (fruit), and cotton (forage and seed).

No soil data were provided.

COMMENTS:

1. No soil data were provided with the study; the study protocol provided with the original document gave the impression that soil samples were not collected. Without soil data, the application rate could not be confirmed and the extent of pesticide uptake by the rotational crops in relation to the concentration of pesticide in the soil could not be determined.

2. Although the analytical methods were specific for iprodione, its isomer, and the degradate RP-32490, the data were reported as "total residues found" rather than specific compounds. The study authors did not explain why the residue concentrations were totaled.

3. Freezer storage stability data were not provided for the various plant tissues.

4. Iprodione residues were $\leq$ Ø.Ø5 ppm in the control crop samples for sorghum, field corn, soybeans, wheat, peas, mustard greens, and alfalfa. In several cases (especially mustard greens), the concentration of iprodione residues was greater in the control crops than in the crops planted in treated soil.

5. Immature samples taken for all crops were inadequate.

6. Several pages (6, 8, 1Ø, 12, 14, 16, and 18) were missing from Rhone-Poulenc Analytical Method No. 162; however, the method appeared sufficiently similar to Analytical Method No. 151, which was also supplied, to permit review. A complete Analytical Method No. 162 should be submitted.

7. In Analytical Method No. 162, the initial extract was acidified to pH 3 following the addition of the 1% sodium sulfate solution to prevent conversion of iprodione to its isomer. This step was not mentioned in Analytical Method No. 151.

8. It was not specified how the field plots were prepared prior to treatment. The location of the treated and control plots in relation to each other was not specified.

9. At the California site, it was reported that alfalfa and wheat were planted on 10/25/85, alfalfa was planted on 5/12/86, and cotton was planted on 10/13/86; however, no data on these specific plantings were reported.

10. At the California site, sugar beets were allowed 320 days to reach maturity, which is excessive compared to normal practices.

11. At the Mississippi site, additional pesticides (Cygon, D-264 EC 500, Bravo 500, Sevin 4L, Dithane M-45, Roundup, Terrachlor, Super X, Lexane 750F, Karmex 80W, Dacthal 75W, and Pydrin 2.4 EC) were applied to the crops during the field tests.

12. At the Mississippi site, it was reported that the high application rate of iprodione caused crop injury (stunted growth and retarded maturation) as compared to the controls. In some cases, synergistic injury responses with the additional pesticides were noted.

13. Analytical Method No. 151 included a procedure for analyzing oily crop residues. The method defined oily crop residues as nut meats; since the rotational crops did not include nut crops, this section of the methodology was not summarized.

FIN 5721-93

Iprodione EF Reviews

Page_____ is not included in this copy.

Pages 14 through 26 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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