

US EPA ARCHIVE DOCUMENT

Shaughnessy No.: 109801

Date Out of EFGWB: 4/2/90

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

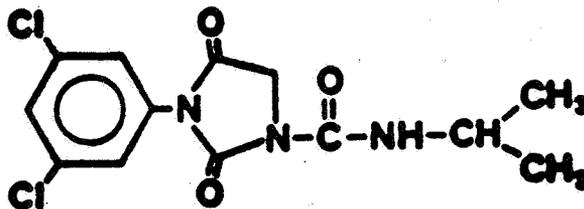
1. CHEMICAL:

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: C₁₃H₁₃Cl₂N₃O₃

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

6. APPROVED BY:

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

Signature: V. Nelson for ER
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 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 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:

<u>Guidelines Reference #</u>	<u>Data Requirements</u>	<u>Status of Studies</u>
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) -In fish	Data gap 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.

11. COMPLETION OF ONE-LINER:

No one-liner was completed; not applicable.

12. CBI INDEX:

Information submitted is not considered CBI.

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

	United States Environmental Protection Agency Office of Pesticide Programs Washington, DC 20460	Pack Number 49726 47780 EFED	Date Received 10-2-89 9/29/89
	Data Review Record Confidential Business Information - Does not contain National Security Information (E.O. 12065)		

1. Product Name Rowal 4F	Chemical Name Iprodione
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2. Identifying Number	3. Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
264-E4P-TI	252822	711	-	-

7. Reference No. 1	8. Date Rec'd (EPA) 8/3/89	9. Prod/Review Mgr/DCI Lewis / Stone	10. PM/RM Team No. 21	11. Date to HED/EFED/RD/BEAD 9/28/89	12. Proj Return Date 12/28/89	13. Date Returned to RD/SRRD
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Instructions

Company's response to Dr. Padma Dutta's review dated 7/1/89
 Attached is cover memo for review of cited preb rotation study.

This Section Applies to Review of Studies Only

14. Check Applicable Box <input type="checkbox"/> Adverse 6(a)(2) Data (405) <input type="checkbox"/> Generic Data (Reregistration)(660) <input type="checkbox"/> Special Review Data (870) <input type="checkbox"/> Product Specific Data (Reregistration)(655)	15. No. of Individual Studies Submitted
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16. Have any of the above studies (in whole or in part) been previously submitted for review? <input type="checkbox"/> Yes (Please identify the study(ies)) <input type="checkbox"/> No	17. Related Actions
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18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	SAC <input type="checkbox"/> PC	A. Policy Note No. 31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input type="checkbox"/> 1 = data in support of continued use of List 1 inert
		Toxicology/HFA	TOX/HFA <input type="checkbox"/> PL	
		Toxicology/IR	TOX/IR <input type="checkbox"/>	
		Dietary Exposure	DEB <input type="checkbox"/> EA	
EFED	X	Ecological Effects	NDE <input type="checkbox"/> AC	
		Environmental Fate & Groundwater	EEB <input type="checkbox"/> BA	
SRRD		Special Review	EFGWB <input type="checkbox"/>	
		Reregistration	SR <input type="checkbox"/>	
		Generic Chemical Support	RER <input type="checkbox"/>	
RD		Insecticide-Rodenticide	GSC <input type="checkbox"/>	
		Fungicide-Herbicide	IR <input type="checkbox"/>	
		Antimicrobial	FH <input type="checkbox"/>	
		Product Chemistry	AM <input type="checkbox"/>	
BEAD		Precautionary Labeling		
		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

<input type="checkbox"/> Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets)	<input type="checkbox"/> Label Attached
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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 method 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,

A handwritten signature in dark ink, appearing to read 'Nick Somma'.

Nick Somma
Registration Manager

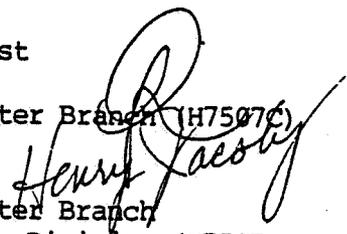
Shaughnessy No.: 109801

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.

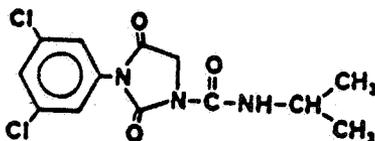
Chemical name:

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., Morristown Junction, NJ. (40881801)

5. REVIEWED BY:

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

Signature: _____

Padma Datta

Date: _____

7/8/89

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 deficiencies exist in this report:

Major deficiencies

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.