

Shaughnessy No.: 109801

Date Out of EAB: DEC - 4 1987

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

From: Therese M. Dougherty, Chief
Environmental Chemistry Review Section 1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769-C)

TK

Attached, please find the EAB review of...

Reg./File # : 359-685

Chemical Name: Iprodione

Type Product : Fungicide

Product Name : Rovral Fungicide

Company Name : Rhone-Poulenc, Inc.

Purpose : Review request to add potatoes to label.

Date Received: 8/18/87

Action Code: 335

Date Completed: DEC - 4 1987

EAB #(s): 70900

Monitoring study requested:

Total Reviewing Time: 0.8 day

Monitoring study voluntarily:

Deferrals to: Ecological Effects Branch
 Residue Chemistry Branch
 Toxicology Branch

1. CHEMICAL: Common name:

Iprodione

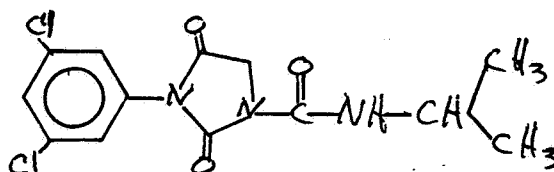
Chemical name:

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

Trade name(s):

Rovral, RP 26019, Glycophene

Structure:



Formulations:

50% WP

Physical/Chemical properties:

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

Molecular weight: 329.9

Physical state: White, odorless, nonhygroscopic crystals.

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

2. TEST MATERIAL: N/A

Not applicable. No data were submitted.

3. STUDY/ACTION TYPE:

The registrant is requesting an amendment to the Rovral label to include use on potatoes to control early blight and white mold.

4. STUDY IDENTIFICATION:

Not applicable. No data were submitted.

5. REVIEWED BY:

Herbert L. Manning
Microbiologist
EAB/HED/OPP

Signature: Herbert L. Manning
Date: DEC - 4 1987

6. APPROVED BY:

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

Signature: Therese M. Dougherty

Date: DEC - 4 1987

7. CONCLUSIONS:

EAB has reviewed the data in our file regarding the request to add potatoes to the label and finds that most of the data requirements for a terrestrial crop use (e.g. potatoes) have been satisfied. See RECOMMENDATIONS for required studies.

8. RECOMMENDATION:

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

<u>Data Requirement</u>	<u>Status in File</u>
● Hydrolysis.....	Accepted.
● Photodegradation (water).....	Accepted.
● Photodegradation (soil).....	Accepted.
● Aerobic and anaerobic soil metabolism...	Accepted.
● Leaching (soil column).....	While the study results were acceptable, the conclusion was that there is some potential for leaching by parent and degradates to groundwater from finer textured soils.
● Field soil dissipation.....	Accepted.
● Fish accumulation.....	Accepted.
● Confined rotational crop.....	Data gap. Application rate should be the maximum rate proposed for potatoes. Crops rotated should be representative of leafy vegetables, root crops, and small grains, e.g., lettuce, beets, or wheat, respectively.
● <u>Potential to leach to groundwater:</u>	In assessing the potential of a pesticide to leach, certain studies are considered, namely, hydrolysis, photolysis, aerobic soil/field dissipation, K_d , and solubility in water. For iprodione, hydrolysis $t_{1/2}$ is <u>ca.</u> 20 days (pH 6); it is stable at pH 3 and $t_{1/2}$ is one day at pH 9. Photolysis $t_{1/2}$ is <one week. Persistence ($t_{1/2}$) of parent in a field dissipation study ranged from one to 12 weeks. Iprodione is very insoluble in water (13 ppm). While

iprodione and its major degradate, RP-30228, is fairly persistent (one to 12 weeks) in soil and column leaching may occur with finer textured soils, based on the other known parameters the evidence indicates that iprodione would have a low potential to leach to groundwater.

Therefore, the study that is required for registration of potatoes is:
Confined rotational crop

EAB could concur with granting conditional registration of iprodione on potatoes with the provision that labeling restrictions noted below for rotational crops are observed and a confined crop rotation study is initiated and submitted.

The specimen label (proposed) submitted by the registrant states the following:

NOTE TO USER: The following crops may be rotated after harvest:

Garlic, Dry Bulb Onions, ^{Head Lettuce} Leafy Vegetables, and Peanuts. 7

The following crops may be rotated the year following treatment: Root Crops, Cereal Grains, Soybeans, and Tomatoes.

EAB has no rotational crop data for any of the crops listed. However, it was communicated to us by Residue Chemistry Branch that the crops shown as being rotated after harvest (garlic, dry bulb onions, head lettuce, and peanuts) have established tolerances, which would allow them to be rotated after harvest without the need for rotational crop studies.

Therefore, the registrant's request to add dry bulb onions and peanuts to their label as crops that can be rotated after harvest is supported by the tolerances that have been established. This support also includes garlic, which also has an established tolerance. However, the "crop" listed as Leafy Vegetables should be replaced by Head Lettuce, since only this leafy vegetable has an established tolerance. Other leafy vegetables that did not have a tolerance would require a confined rotational crop study.

The second line in the NOTE TO USER statement refers to rotating root crops, cereal grains, soybeans, and tomatoes one year after treatment. We cannot support these rotations. We have no rotational crop data on these crop groupings/crops, therefore, radiolabeled, confined rotational crop studies are required for them.

9. BACKGROUND:

A. Introduction

The registrant is requesting the addition of potatoes to the Rovral label. A specimen label was submitted and some questions on rotational crop statements on it were addressed above (see RECOMMENDATION).

B. Directions for Use

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

11. COMPLETION OF ONE-LINER:

Not applicable.

12. CONFIDENTIAL APPENDIX:

There is no CBI.

AIN 5721-93

Exprodione EF Reviews

Page is not included in this copy.

Pages 6 through 13 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.
