2-3-81 QUICK

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 3 1981

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP#0E2414 - ROVRAL; Petition for tolerance of 7 ppm in Kiwi fruit imported. CASWELL#470A

FROM: Alex Arce
Toxicology Branch, HED (TS-769)

TO: Eugene Wilson, PM#21
Registration Division (TS-767)

THRU: William Burnam, Acting Chief
Toxicology Branch, HED (TS-769)

Reference Numbers: Reg/EUP No. 359-EUP-58; PP#8G2087

Product Name: ROVRAL®

Caswell Number: 470A

Chemical Name of the isomer of Iprodione, (R.P. 30228): 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide. Caswell No. 568D

Applicant: Rhodia, Inc.
P.O. Box 125
Monmouth Junction, N.J. 08852

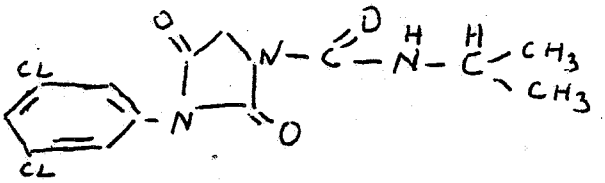
Chemical and Physical Properties:

Iprodione

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

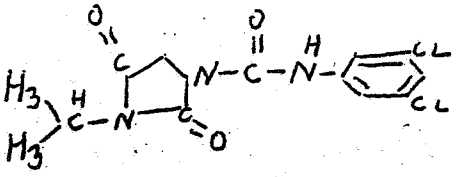
Common and Proprietary Names: Iprodione, Anfor, BSI, Glycophene, R.P. 26019, Chipco®, ROVRAL®

Chemical Structure:



Iprodione, R.P. 26019
Caswell No. 470A

Chemical structure of the isomer of Iprodione:



R.P. 30228
Caswell No. 568D

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

Pesticide Class: Fungicide vs. Septoria, Botrytis spp., Monilia spp., Sclerotinia, Tilletia spp. wheat smut, Fusarium roseum, Alternaria spp.

Mol. Wgt. - 330.17g Density - 1.4 g/cc M.P. 136°C

Vapor Press - $<1 \times 10^{-5}$ mm Hg @ 20°C

Soluble In: water, ethanol, acetone, methyl chloride

Physical State: nonhydroscopic powder, off white to cream colored, ordorless and stable.

Statement of Formula:

Ingredient	Percent
3-(3,5-dichlorophenyl)-N-(1-methyl)2,4-dioxo-1-imidazolidine carboxamide	53.16 active
[redacted]	

INERT INGREDIENT INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Identity	Percent
[redacted]	

Background

A previous temporary tolerance request of 20 ppm on stone fruits (apricots, sour and sweet cherries, nectarines, peaches, plums and prunes) was toxicologically supported (J.E. Preston October 31, 1978).

Data Gap: A 6-Month Dog Feeding Study

Recommendation

Based upon available toxicity data and calculations demonstrating that the proposed tolerance for residues of Iprodione on Kiwi fruit (7 ppm) result in only a 0.842% increase in the TMRC (only a 0.175% increase in the PADI), RCB considerations permitting, Toxicology Branch has no additional objections to this proposed tolerance.

The petitioner should be informed that a data gap exists for a 6-month dog feeding study.

Attachments

a) Summary of Toxicity Data Bank from our files.

b) Toxicology calculations of % PADI and TMRC increment.

This chemical is not on the RPAR list.

There are no existing regulatory actions against this chemical.

Calculation

The tolerances are based upon a 3-month dog feeding study with a NOEL of 2400 ppm or 60 mg/kg, using a safety factor of 2000.

The PADI = 0.0300 mg/kg/day

The MPI = 1.8000 mg/day for a 60 kg person

Prior to this action, the total % of the ADI utilized was 20.78%. This action will utilize an additional 0.175% of the ADI, raising the total to 20.96%.

The new TMRC = 0.3772 mg/day/1.5 kg food

The proposed tolerance on Kiwi fruit increases the TMRC 0.842%

$$\frac{0.00315 \times 100}{1.8000} = 0.175\% \text{ ADI}$$

$$\frac{0.00315 \times 100}{0.3740} = 0.842 \text{ TMRC increment}$$

The 3-month dog feeding study has been used temporarily as the basis for the PADI because of a data gap for a 6-month dog feeding study.

TS-769:th:LCHITLIK:10-15-80:TOX/HED