5-17-85

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

MAY 17 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA ACCESSION NUMBER 073288. [RCB # 615].
PP5E3214: Iprodione in or on Small Berries.
Evaluation of Analytical Method and Residue Data.

TO: H. Jacoby, PM 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

FROM: R. W. Cook, Chemist RWCook
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Agrochemical Division, Rhone-Poulenc Inc. proposes tolerances for combined residues of the fungicide iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], 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-imidazolidinecarboxamide in or on the raw agricultural commodities raspberries, boysenberries, blueberries, and currants at 15 ppm. The petitioner reports that this petition was submitted at the request of the Government of New Zealand.

Note: Established tolerances are "(expressed as iprodione equivalents)". We presume the petitioner intended to express the residues as above, but a revised Section F including this expression is needed.

Tolerances for combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione] and 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-imidazolidinecarboxamide (expressed as iprodione equivalents) have been established under 40 CFR 180.399(a) in or on the raw agricultural commodities:

- kiwifruit (10 ppm);
- apricots, cherries, nectarines, peaches, plums, prunes (20 ppm);

1/7

° almond nutmeats (0.05 ppm), almond hulls (0.25 ppm);
° in grapes (60 ppm);

A SLN Registration for iprodione in Oregon caneberries has been recommended recently (85-OR-04, S. Malak, 5/14/85).

Representatives of Crop Group XIII, Small Fruits and Berries, are black berry or other Rubus species, blueberry, cranberry, grape and strawberry.

Conclusions:

1a. The residues of concern in plants are 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione, RP-26019], 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide [RP-30228], and 3-(3,5-dichlorophenyl)--2,4-dioxo-1--imidazolidinecarboxamide [RP-32490].

2a. There is a method in PAM II for enforcing iprodione tolerances in crops.

2b. Since validation data (crop blank and recovery data) are lacking, we cannot conclude that the analytical method(s) used in analyzing the berry residue data is adequate for residue analysis.

3. We cannot conclude that the formulation inerts are cleared under 40 CFR 180.1001. Clearance under 40 CFR 180.1001 (c) is necessary for a favorable opinion. The petitioner should request his supplier(s) of these inerts to provide information to EPA, on a confidential basis, verifying that the tradenamed products do not contain other, non-disclosed, uncleared inert ingredient(s).

4. We are unable to draw any conclusions regarding the proposed tolerance levels, since the residue data are deficient:

a) No information on the method of application (broadcast, backpack, aerial, ground, etc) is provided.
b) The year in which the the residue trials took place should be provided.
c) There are no storage stability data or information on the conditions of storage during the period of time between harvest and analysis.
d) There are no crop blank values or recovery data available.
e) No residue data for metabolites are submitted.
f) We do not know if the reported values are corrected for crop blank values and or recovery factors.
g) There is no information which assures us that the submitted analytical method was used by both May & Baker and by the Governmen of New Zealand.
h) There is no information regarding possible presence of the metabolite in small berries. We need some data demonstrating the expected level of the metabolite on these commodities.

5. A revised Section F including the term "(expressed as iprodione equivalents)" is needed.

6. Because the small berries are not considered as livestock or poultry feed, there will be no problem of secondary residues in meat, milk, poultry, and eggs.

7. There are Codex, Canadian, or Mexican tolerances for residues for iprodione in or on raspberries. boysenberries, blueberries, and currants. Therefore, we anticipate compatibility problems. We are not in a position to recommend any changes which could alleviate possible compatibility problems.

Recommendations:

We recommend against the establishment of the proposed tolerances, for the reasons cited in Conclusions 2, 3, 4a through 4h.

For a favorable recommendation, the petitioner should be advised that the following information is needed.

1. Validation data (crop blank and recovery data) for the analytical method(s) used in gathering residue data.

2. The formulation inerts must be cleared under 40 CFR 180.1001. The petitioner should request his supplier(s) of these inerts to provide information to EPA, on a confidential basis, verifying that the tradenamed products do not contain other, non-disclosed, uncleared inert ingredient(s).

3. The following deficiencies should be addressed:
a) No information on the method of application (broadcast, backpack, aerial, ground, etc) is provided.
b) The year in which the the residue trials took place should be provided.
c) There are no storage stability data or information on the conditions of storage during the period of time between harvest and analysis.
d) There are no crop blank values or recovery data available. (Same as Recommendation #1 above)
e) No residue data for metabolites are submitted.
f) We do not know if the reported values are corrected for crop blank values and or recovery factors.
g) There is no information which assures us that the submitted analytical method was used by both May & Baker and by the Governmen of New Zealand.
h) There is no information regarding possible presence of the metabolite in small berries. We need some data demonstrating the expected level of the metabolites on these commodities.

4. A revised Section F including the term "(expressed as iprodione equivalents)" is needed.

DETAILED CONSIDERATIONS:

Formulation:

The formulation proposed for use is formulated from Iprodione, EPA Reg. No. 359-684. It is a wettable powder formulation containing 50% iprodione. We have previously concluded residue problems are not anticipated from manufacturing impurities.

On the basis of the information provided, we cannot conclude that the formulation inerts are cleared under 40 CFR 180.1001. The petitioner should request his supplier(s) of these inerts to provide information to EPA, on a confidential basis, verifying that the tradenamed products do not contain other, non-disclosed, uncleared inert ingredient(s).

The New Zealand government has a pesticide registration mechanism.

Directions for Use:

'Rovral' is a fungicide containing 500 g/kg iprodione in the form of a wettable powder. For botrytis on berryfruit, use 100 g/100 liters of water for high volume spraying to the point of runoff. Rates should be increased for concentrate spraying. Do not use less than 75 g. 'Rovral'/100 liters. Use at 10-14 day intervals commencing at early flower. Use the closer spray interval whilst conditions favour disease. There is a 1 day withholding period.

This use appears on a registered New Zealand label.

Nature of the Residue:

Plants:

Plant metabolism studies have been reported on strawberries and wheat (A. Rathman, 3/2/79, PP8G2087), peaches (R. Perfetti, 5/13/84, PP2F2596), lettuce (N. Dodd, 4/11/83, PP3G2801), and peanuts (N. Dodd, 5/31/84, PP4G3037). In ^{14}C-iprodione plant metabolism studies in strawberries, wheat, peaches, and peanuts, the primary residue from foliar application was the parent compound iprodione and smaller amounts of its isomer RP-30228. Soil applications resulted in these two compounds plus small amounts of the metabolite RP-32490.

We reiterate our conclusion that the residues of concern in peanuts and other plants are iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide]; 3-(1-methylethyl)-N(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP-30228]; and 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP-32490].

Animals:

Since there are no significant animal feed items involved in subject petition, the metabolism in animals is not of interest.

Analytical Methods:

The analytical method for iprodione, marked "CONFIDENTIAL", is entitled "Determination of iprodione residues in crops in high water content" (SOP/MR/030/02, dated 30 Jun 1982). The method determines parent compound RP26019 only. The method is claimed to be suitable for the analysis of iprodione in blackcurrant and juice, cabbage (chinese, green, red, and white), carrots, cucumbers, gooseberries, grapes, kiwifruit, lettuce, onions, peaches, peppers, raspberries, strawberries, and tomatoes.

In principle, iprodione residues in frozen, crushed and blended, plant tissues are extracted twice into acetone. After addition of buffer (pH 7, 10 ml.), the sample is evaporated until only an aqueous solution remains. The iprodione is partitioned three times from the aqueous solution into dichloromethane, which is dried through anhydrous sodium sulfate. The iprodione residue is taken up into toluene after rotary evaporation of the dichloromethane. The toluene solution is cleaned up on Florisil Sep-Pak using 5% v/v ethyl acetate in toluene prior to analysis for iprodione residues (parent only) by GLC with ^{63}Ni electron capture detection.

Since there are no control sample (crop blank) or recovery data from spiked samples, we are unable to draw any conclusions about the validity of the analytical method, or the sensitivity of the method for iprodione residues.

There is a method in PAM II for enforcing iprodione tolerances in crops. A successful trial of the PAM II method was conducted on kiwifruit in conjunction with PP3F2810 (R. Perfetti, 3/21/83).

Residue Data:

All residue data are for the parent compound only, with no information available for the isomer or the metabolite. The available residue data in support of the proposed uses is derived from several sources:

1) May & Baker Ltd (a subsidary of Rhone-Poulenc, Inc., performed field residue trials on grapes and strawberries in New Zealand;

2) New Zealand government agencies performed residue trials on other small fruits and berries.

3) FAO/WHO JMPR Pesticide residues in food: 1977 evaluations, pages 316-7, iprodione, Table 6, supervised trials: residues in berry fruit and currants.

4) RP report RP/RD/CNG No. 19177E: 26019RP - residues in grapes, must, wine and spirits, Tables A & B. [Note: We are unable to find this document].

The residue data are deficient in numerous regards:

a) No information on the method of application (broadcast, backpack, aerial, ground, etc).
b) The year in which the the residue trials took place should be provided.
c) There are no storage stability data or information on the conditions of storage during the period of time between harvest and analysis.
d) There are no crop blank values or recovery data available.
e) No residue data for metabolites are submitted.
f) We do not know if the reported values are corrected for crop blank values and or recovery factors.
g) There is no information which assures us that the submitted analytical method was used by both May & Baker and by the Government of New Zealand.
h) There is no information regarding possible presence of the metabolite in small berries. We need some data demonstrating the expected level of the metabolite on these commodities.

On the basis of the information available to us, we are unable to draw any conclusions on the adequacy of the proposed tolerance level of 15 ppm in small berries from New Zealand. However, if we were able to conclude that the submitted residue data are valid, we would then be able to state that residues of the parent compound iprodione per se are not likely to exceed 15 ppm.

Residues in Meat, Milk, Poultry, and Eggs:

Since the small berries are not considered a feed item in the livestock or poultry diet, there will be no problem of secondary residues in meat, milk, poultry, and eggs.

OTHER CONSIDERATIONS:

International Tolerances:

There are Codex, Canadian, or Mexican tolerances for residues of iprodione in or on raspberries. boysenberries, blueberries, and currants. Therefore, we anticipate compatibility problems. A Codex sheet was attached to our previous review.

The petitioner reports the following International tolerances:

	New Zealand	W. Germany	FAO/WHO JMPR
Raspberries	10		5
Currants	10		5
Strawberries	10	15	7
Grapes	10	10	10

cc: R.F., Circu, R. W. Cook, FDA, PP5E3214, TOX, EEB, EAB, PMSD/ISB, Robert E. Thompson.
TS-769:RCB:Reviewer:RWCook:Date:5/15/85:CM#2:RM:810:557-7377
RDI:Section Head:RSQuick:Date:5/16/85:RDSchmitt:Date:5/16/85

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione
[Rovral®]

CCPR NO. 111

Codex Status

|__| No Codex Proposal Step 6 or above

Residue (if Step 9):
Iprodione

Crop(s)	Limit (mg/kg)
Raspberries	5
Black currants	5

CANADIAN LIMIT

Residue: Iprodione including metabolites 3-isopropyl-N-(3,5-dichlorophenyl)-2,4-dioxo-imidazolidine-1-carboxamide and 3-(3,5-dichlorophenyl)-2,4-dioxo-imidazolidine-1-carboxamide.

Crop	Limit (ppm)
None on above commodities.	

Comments:

PETITION NO. 5E3214
Nelson 2/14/85
F. I. 2/14/85
R. W. Cook
4/29/85
Proposed U.S. Tolerances

Confirmed 4/30/85 FI

40 CFR 1 80.399(a)

Residue:
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-imidazolidinecarboxamide

Crop(s)	Tol. (ppm)
Raspberry	15.
Boysenberry	15.
Blueberry	15.
Currants	15.

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm)
None	