12-5-85

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

DEC 5 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6F3305, (RCB #9). Iprodione (Rovral®) in or on Broccoli. Evaluation of Analytical Methods and Residue Data (Acc. #073874 and #073875).

FROM: W. T. Chin, Ph. D., Chemist
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: Henry Jacoby, PM #21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The petitioner, Rhone-Poulenc Inc., proposes a tolerance for the combined residues of the fungicide iprodione, [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer, RP-30228, 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite, RP-32490, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, in or on the raw agricultural commodity broccoli at 25 ppm.

Under 40 CFR 180.399(a), tolerances have been established for the combined residues of iprodione, its isomer RP-30228 and metabolite RP-32490 in or on several raw agricultural commodities at levels ranging from 0.05 in almond meat to 150 ppm in peanut hay.

Under 40 CFR 180.399(b), tolerances have been established for the combined residues of iprodione, its isomer RP-30228 and its metabolites RP-32490 and N-(3,5-dichloro-4-hydroxyphenyl)-ureidocarboxamide (all expressed as iprodione equivalents) in or on several animal commodities at levels ranging from 0.5 ppm in meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses and sheep to 3 ppm in liver and kidney of the preceding animals.

Food additive tolerances have also been established at levels ranging from 10 ppm in soapstock to 300 ppm in raisins.

No Registration Standard has been issued for iprodione.

CONCLUSIONS

1a. The nature of the residue in broccoli is adequately understood. The residues of concern consist of iprodione, its isomer RP-30228 and metabolite RP-32490.

1b. The nature of the residue in animals is adequately understood. The residues of concern consist of iprodione, its isomer RP-30228 and metabolites RP-32490 and N-(3,5-dichloro-4-hydroxyphenyl)-ureidocarboxamide.

2. Adequate analytical methodology is available for residue analysis and enforcement purposes.

3a. RCB concludes that the proposed tolerance of 25 ppm for the combined residues of iprodione, its isomer RP-30228 and its metabolite RP-32490 in or on broccoli is appropriate.

3b. Since no animal feed items would result from the proposed use, RCB classifies the proposed use in category 40 CFR 180.6(a)(3) with regard to secondary residues in meat, milk, poultry and eggs.

4. An International Residue Limit (IRL) Status sheet is attached. Canada, Mexico and Codex have not established any limits or tolerances for iprodione in or on broccoli. Therefore, there is no compatibility problem with respect to Codex.

RECOMMENDATION

TOX and EAB considerations permitting, RCB recommends for the establishment of the proposed tolerance for iprodione (combined residues of parent, its isomer RP-30228 and metabolite RP-32490) in or on broccoli at 25 ppm.

DETAILED CONSIDERATIONS

Manufacture and Formulation

The manufacturing process and a list of impurities in technical iprodione were submitted and reviewed by RCB in conjunction with PP#8G2087 (see A. Rathman's 3/2/79 memo). Technical iprodione is approximately 95% pure with none of the impurities comprising more [redacted] by weight. RCB does not expect a residue problem resulting from impurities in the technical material.

The formulation proposed for use on broccoli is Rovral® fungicide (EPA Reg. No. 359-685) which is a wettable powder containing 50% iprodione. All inerts are cleared for use under 40 CFR 180.1001.

Proposed Use

For controlling black leg disease, apply 2 lb Rovral® Fungicide (1 lb a.i.)/acre (1.0 oz/1,500 feet of row) immediately after thinning (2-4 leaf stage) as a directed spray to the base of the plant and the adjacent soil surface. If disease conditions persist or reoccur, a second application may be made up to the day of harvest. Apply in 40-200 gallons of spray solution per acre. Application should be made with a tractor mounted boom sprayer with 2 flat fan nozzles per row (one on either side) directed at the base of the plant and the adjacent soil surface. Position nozzles to insure thorough coverage of the lower portion of the stem. Do not drench.

Nature of the Residue

In Plants

No new plant metabolism studies are submitted in the subject petition. However, the petitioner has submitted previously metabolism studies on peanuts (PP#4G3037), lettuce (PP#3G2801), strawberries and wheat (PP#8G2078) and peaches (PP#2F2596); these studies have been reviewed by RCB. All the metabolism studies exhibited the same general pattern. RCB concludes that the nature of the residue in broccoli is adequately understood. The residues of concern in broccoli consist of iprodione, its isomer, RP-30228, 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite, RP-32490, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide.

In Animals

No new animal metabolism studies are submitted in the subject petition. However, metabolism studies with ^{14}C ring labeled iprodione have been carried out in cows and goats (PP#2F2728) and chickens (PP#3F2964). The residues of concern in animals consist of iprodione, its isomer RP-30228, and metabolites RP-32490 and N-(3,5-dichloro-4-hydroxyphenyl)-ureidocarboxamide. RCB concludes that the nature of the residue in animals is adequately understood.

Analytical Methodology

The analytical method used to generate the residue data submitted in the subject petition is the Rhone-Poulenc Analytical Method No. 151. This method was previously reviewed (see M. Kovacs's 10/25/82 memo, re: PP#2F2728) and has successfully undergone a method trial on kiwi fruit in conjunction with PP#3F2810 (see R. Perfetti's 3/21/83 memo).

In brief, broccoli samples are macerated, and residues are extracted with acidified acetone. After cleaning up the sample with gel permeation column chromatography and Florisil column chromatography, residues of iprodione, its isomer RP-30228 and metabolite RP32490 are determined by a gas chromatograph equipped with a ^{63}Ni electron capture detector. At fortification levels ranging from 1 to 40 ppm in control broccoli samples, recoveries ranged from 96.8% to 126.0% (ave. 110.4%) for iprodione, 72.1% to 111.6% (ave. 90.6%) for the isomer RP-30228 and 74.2% to 109.9% (ave. 95.6%) for the metabolite RP-32490. The claimed limit of detection of this method for these residues is 0.05 ppm.

RCB concludes that this method is adequate for residue analysis and enforcement purposes for iprodione in or on broccoli.

Residue Data

Eight studies using Rovral® Fungicide on broccoli crops grown in California (5), Texas (1), Michigan (1) and Oregon (1) were conducted. RCB considers the testing areas for generating residue data to be adequate. The Agricultural Statistics (1983) provides area production data for broccoli grown only in the states of Arizona, California, Oregon and Texas. Broccoli crops were treated with 2 applications; some at 1X rate and others at 2X rate in 1984. The first application was made at thinning and the second application was made on the same day of harvest (0-day PHI). These studies represent fall, winter and summer broccoli crops. Random whole plants were harvested, shipped in dry ice boxes, stored in a freezer at 0°F and analyzed in April, 1985. Storage stability residue data generated on strawberries, grapes, peaches and cherries (PP#8G2087) indicate that iprodione residues are stable in fruit samples stored under frozen conditions for about 1 year; thus, RCB concludes that residues in or on the treated broccoli samples discussed in the subject petition should have been relatively stable.

The residue data (corrected for method recoveries) are summarized in Table 1 below.

Table 1. Residue Data of Broccoli Field Studies

Location	Total lb a.i./A	PHI (day)	Residue Range (ppm) RP-26019	RP-30228	RP-32490
CA, MI. OR, TX	0.0	0	<0.05 - 0.23	<0.05 (all)	<0.05 (all)
CA, MI, OR, TX	2x1.0 (1X)	0	4.08 - 22.09	<0.05 - 0.31	<0.05 - 0.25
CA, MI, OR, TX	2x2.0 (2X)	0	6.84 - 41.28	<0.05 - 0.85	<0.05 - 0.31

The residue data shown in Table 1 indicate that at 2 applications, 1X rate and 0-day PHI, the combined maximum residues of iprodione, its isomer RP-30228 and metabolite RP-32490 is 22.65 ppm which does not exceed the proposed tolerance of 25 ppm. Confirmative results are indicated by the 2X rate tests.

RCB concludes that the proposed tolerance of 25 ppm for the combined residues of iprodione, its isomer RP-30228, and its metabolite RP-32490 in or on broccoli is appropriate.

Meat, Milk, Poultry and Eggs

Since no animal feed items would result from the proposed use, RCB does not expect a significant contribution of secondary residues in meat, milk, poultry and eggs as a result of the proposed use. RCB classifies the proposed use in category 40 CFR 180.6(a)(3) with regard to secondary residues in meat, milk, poultry and eggs.

Other Considerations

An International Residue Limit (IRL) Status sheet is attached. Canada, Mexico and Codex have not established any limits or tolerances for iprodione in or on broccoli. Therefore, there is no compatibility problem with respect to Codex.

Attachment: Codex Sheet

cc: R.F., Circu., W.T.Chin, EAB, PP#6F3305, EEB, PMSD-ISB, FDA
RDI: J.H.Onley(12/2/85), R.D.Schmitt(12/2/85)
TS-769: RCB: CM#2, RM812,557-7484, W.T.Chin,wc(12/3/85)

F.A. 10/16/85

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL IPRODIONE

PETITION NO. PP6F3305

CCPR NO. 111

Reviewer: W. T. Chin

Codex Status

Proposed U.S. Tolerances

[ ] No Codex Proposal Step 6 or above

Residue (if Step 9):

Iprodione

Residue: Iprodione, its isomer [3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide + its metabolite, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide

Crop(s)	Limit (mg/kg)
none	(on broccoli)

Crop(s)	Tol. (ppm)
Broccoli	25 ppm

CANADIAN LIMIT

Residue: Iprodione plus metabolites 3-isopropyl-N-(3,5-dichlorophenyl)-2,4-dioxoimadazolidine-1-carboxamide and 1/

Crop	Limit (ppm)
none (on broccoli)	

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm
none	

NOTES:

1/ 3-(3,5-dichlorophenyl)-2,4-dioxoimadazolidine-1-carboxamide