1-28-81

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

JAN 28 1981

MEMORANDUM

PP# OE2414 Iprodione on kiwi fruit. Evaluation of analytical methods and residue data.

FROM: R. B. Perfetti, Ph.D, Chemist
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TO: H. Jacoby, Product Manager No. 21
Registration Division (TS-767)
and
Toxicology Branch (TS-769)
Hazard Evaluation Division

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

Rhone Poulenc Inc. proposes the establishment of a tolerance for combined residues of the fungicide iprodione (3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolites 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide in or on kiwi fruit at 7 ppm.

Temporary tolerances for iprodione have been established previously at 20 ppm on various stone fruits and at 0.05 ppm on almonds. This is the first permanent tolerance request for iprodione. No other iprodione petitions are pending.

Conclusions

1. The nature of the residue in kiwi fruit is adequately delineated.

2. Pending successful completion of the initiated method trial an adequate analytical method is available for enforcement purposes. (Note to PM: No tolerances for iprodione can be established for kiwi fruit until the method trial is successfully completed.)

3. Since only a very limited amount of residue data were submitted in the petition, it is our judgment that a more appropriate tolerance level for residues of iprodione on kiwi fruit would be 10 ppm. This new tolerance proposal should be submitted in a revised Section F.

4. Since no feed items are involved in this petition, there will be no problem with secondary residues in meat, milk, poultry and eggs.

5. The International Tolerance Sheet is attached. There are no foreign tolerances for residues of iprodione on kiwi fruit.

Recommendations

TOX and EFB considerations permitting, we recommend that a tolerance be established for residues of iprodione and metabolites on kiwi fruit, provided the petitioner submits a revised Section F proposing a 10 ppm tolerance level and the already initiated method trial is completed successfully.

Detailed Considerations

Formulations

The formulation proposed for use in Rhone-Pouleuc's Rovral 50% wettable powder. This formulation is sold in New Zealand by May and Baker, a member of the Rhone-Pouleuc group of companies. Rovral contains 53% technical iprodione (EPA Reg. No. 359-684). The technical material is 95% pure. The impurities and manufacturing process are discussed in detail in our review of PP#8G2087 (A. Rathman). We expect no residue problems from the low level of impurities in the formulated product.

Inerts in the formulation include [redacted] All of these inerts are cleared under Section 180.1001.

Proposed Use

This iprodione formulation is to be applied to kiwi fruit grown in New Zealand at present. The kiwi fruit is to be treated with a 400 ppm spray at 10 to 14 day intervals during the period from early flowering to petal fall and at the 4 week period before harvest. No specific limit to number of applications or maximum amount of material to be applied is prescribed. A 3 day PHI is proposed.

Nature of the Residue

No metabolism study on kiwi fruit was submitted in this petition. A previously submitted study on strawberries and wheat using uniformly ring- ^{14}C-labeled iprodione was discussed in detail in our review of PP#8G2087. This study indicated that there is little migration of iprodione after foliar treatment, but that uptake via the root system after ground application does occur with subsequent translocation to aerial plant parts. The major identified portion of the residue after foliar treatment consisted of parent, 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide (RP30228) and to a lesser extent a de-isopropylated metabolite (RP32490). Plants analyzed after soil treatment showed that the majority of the radioactivity was in a bound form and this was not identified. The portion of the residue which was extractable was found to be parent, RP30228 and RP32409.

It is our judgment that these metabolism data can be translated to kiwi and the nature of the residue in kiwi fruit is adequately understood at this time.

Analytical Method

The method used to obtain residue data utilized glc and a ^{63}Ni electron - capture detector. Briefly, the method involves extraction with acetone, addition of pH 7 buffer, removal of the acetone and partitioning into dichloromethane. The dichloromethane is removed and the residue is then taken up in toluene. The samples are then cleaned-up and separated on a Florisil column. One fraction of the eluate contains iprodione and 30228 R.P. and a second fraction contains 32490 R.P. These fractions are then taken to dryness, redissolved in toluene and analyzed via glc as above using one column for iprodione and 32490 R.P. and a different column for 30228 R.P. Different conditions are also used on the column quantitating parent and 32490 R.P.

Validation data submitted reflected fortification of earlier iprodione, 30228 R.P. or 32490 R.P. at 0.05, 0.1, 0.5, 1.0, 5.0 and 10 ppm. Recoveries of iprodione ranged from 70 to 105%. Isomer 30228 R.P. showed recoveries of 59 to 94% and recoveries of 32490 R.P. ranged from 60 to 93%. Control values for all compounds ranged from 0.005 to 0.016 ppm. Sample chromatograms were submitted.

A method trial for iprodione and metabolites in kiwi fruit has been initiated, and pending successful completion of this trial we consider that an adequate analytical method is available for enforcement purposes. A TLC procedure is available for confirmatory purposes. (Note to P.M.: No tolerances for the compound on kiwi fruit can be established until the method trial is successfully completed.)

Residue Data

Residue data submitted reflected three trials carried out on kiwi grown in New Zealand. The studies involved 5 applications to kiwi fruit, 3 during flowering and 2 pre-harvest, of 2000 l of the 400 ppm spray (1500 gms active ingredient total). Samples were taken 0 to 23 days after the last application and combined residue of iprodione 30228 R.P. and 32490 R.B. ranged from 2.6 to 4.96 ppm after 0 to 4 days and from 0.23 to 2.86 ppm after 8 to 23 days.

The amount of residue data available is rather limited. However, it is our judgment that a more suitable tolerance level for iprodione residues on kiwi fruit would be 10 ppm. This new proposed tolerance should be submitted in a revised Section F. The petitioner should be informed.

Meat, Milk, Poultry and Eggs

No animal metabolism or feeding studies have been submitted to date. Since no feed items are involved in this petition, there will be no problem with respect to secondary residues in meat, milk, poultry and eggs.

Other Considerations

The International Tolerance Sheet is attached. There are no foreign tolerances for residues of iprodione on kiwi fruit.

Attachment

TS-769:RCB:R.Perfetti:gs:CM#2:RM.810:1/26/81
cc: RF, CIRC., PERFETTI, WATTS, FDA, TOX, EEB, EFB, PP#OE2414
RDI: Quick, 1/14/81

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione (Rovral) PETITION NO OE2414
3(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
CCPR NO. 111

Codex Status

Proposed U. S. Tolerances
See below.

| | No Codex Proposal
Step 6 or above

Residue (if Step 9): _____

Iprodione

Residue: Iprodione, 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and 3-(3,5-dichlorophenyl) -2,4-dioxo-1-imidazolidinecarboxamide

Crop(s)	Limit (mg/kg)
None on these commodities.	

Crop(s)	Tol. (ppm)
kiwi fruit	7

CANADIAN LIMIT

Residue: None

Crop	Limit (ppm)
None	

MEXICAN TOLERANCIA

Residue: None

Crop	Tolerancia (ppm)
None	

Notes: