7-1-83

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

JUL 1 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F2841 Iprodione on Garlic. Evaluation of Analytical Method and Residue Data.

FROM: K.H. Arne, Ph.D., Chemist
Residue Chemistry Branch,
Hazard Evaluation Division (TS-769)

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

TO: Henry Jacoby, PM Team No. 21
Registration Division, (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

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 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and its metabolite 3-(3,5-dichlorophenyl-2,4-dioxo-1-imidazolidinecarboxamide on garlic at 0.1 ppm.

Permanent tolerances have been established for kiwifruit (10 ppm) and on cherries, peaches, and nectarines (all at 20 ppm). Temporary tolerances have been established for almonds (0.05 ppm) and apricots and plums (20 ppm). We have recently recommended for a temporary tolerance on lettuce (PP#3G2801; a permanent lettuce tolerance is proposed in PP#3F2840). Tolerances are pending for almonds, meat and milk (PP#3F2728).

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Conclusions

1. The nature of the residue in plants is adequately understood. The residue of concern consists of parent, 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].

2. Adequate analytical methods are available for enforcement.

3. The proposed tolerance on garlic will not be exceeded as a result of the proposed use.

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

5. An International Residue Limit Status sheet is attached. The Codex MRL for iprodione on garlic is 0.1 ppm but only parent is regulated. We have considered whether the U.S. expression of a tolerance can be made compatible with that of Codex. Because the amount of isomer and metabolite on crops increases with time and comprises up to 50% or more of the total residue, we believe these residues should remain in the tolerance.

Recommendation

Toxicological and EAB considerations permitting, we recommend for the proposed tolerance of 0.1 ppm in or on garlic.

Detailed Considerations

Formulation

The formulation proposed for use on garlic is Rovral, a wettable powder that contains 50% iprodione. All inerts in the formulation are cleared under Section 180.1001.

The manufacturing process for iprodione was reviewed in conjunction with PP#8G2087 (memo of 3/2/79, A. Rathman). The technical material is about 95% pure. We expect no residue problems from the impurities in the technical material none of which comprise [redacted]

Proposed Use

For control of white rot (Sclerotium cepivorum) Rovral is to be applied in the furrow at planting at the rate of 4 lb (2 lb. a.i.)/A.

Nature of the Residue

Radiolabel metabolism studies have been carried out on strawberries and wheat (PP#8G2087, see memo of 3/2/79, A. Rathman), peaches (PP#2F2596, memo of 5/13/82, R. Perfetti), and lettuce (PP#3G2801, memo of 4/11/83, N. Dodd). Based on the similarity of metabolic pathways shown in these studies we have concluded that the nature of the residue in plants is adequately understood and that the residue of concern consists of parent, its isomer [3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP30228)] and a des-isopropyl metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP32490)]. We have considered whether, for compatability with Codex, the U.S. tolerance should be expressed in terms of parent compound only. We have reviewed metabolism data and residue for parent compound, its isomer and its metabolite on stone fruits, strawberries and wheat. (We did not consider garlic because no residues of any of the regulated residues were detected in garlic). On the stone fruits, the parent compound comprised about 90% of the residue. On strawberries and wheat, the data show that the level of isomer and metabolite increase with time and may comprise 50% or more of the total residue. Therefore, we believe that the isomer and the metabolite should be included in the tolerance.

Since no animal feed items are involved with this use, animal metabolism will not be discussed here.

Analytical method

Rhone-Poulenc Analytical Method No. 151 was used to determine residues in garlic. Briefly, the sample is extracted with acetone, cleaned up by liquid-liquid partitioning and column chromatography and quantified by gas-liquid chromatography using an electron capture detector.

Using this method recoveries from garlic bulbs, fortified at 0.05-0.2 ppm, ranged from 72 to 109% for parent; from 77 to 99% for RP-30228, and from 71 to 114% for RP-32490. Similar recoveries were obtained from dried flakes. No residues were detected (<0.05 ppm) in controls. Two (of 5) control samples gave interfering peaks in the GLC of RP-30228, the isomer of iprodione. Since residues of parent would be determined even if residues of this isomer were not, and because residues are not expected from this use, we do not consider these interfering peaks to be of significance (Note: garlic samples often have interference problems.) We

conclude that adequate analytical methodology is available for enforcement purposes.

Residue data

Residue experiments were carried out in California. Garlic is grown is other parts of the country, for example, Texas and Louisiana, but since the great majority (>90%) is grown in California and since no residues were detected we consider the data adequately representative.

Garlic furrows were treated, at planting, with either 2 (1x rate) or 4 (2x rate) lb a.i./A. Samples were collected for analysis at PHI's of 204-263 days. No residues (<0.05 ppm) of parent, its isomer, or its des isopropyl metabolite were detected in any samples. Neither were residues detected in garlic flakes that had been processed from treated (1x or 2x rate) cloves that were harvested 211 days after application.

Based on these data we conclude that the proposed tolerance will not be exceeded as a result of the proposed use.

Meat, Milk, Poultry, and Eggs

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

Other Considerations

The proposed tolerance is numerically equivalent to the Codex MRL for iprodione on garlic. We have considered the compatibility of the U.S. tolerance with the Codex MRL above (See Nature of the Residue).

cc: R.F.
Circu
Reviewer
TOX
EEB
EAB
Petition No. 3F2841
FDA, Robert Thompson

RDI:Section Head-RSQ:Date-6/21/83:RDS:Date-6/21/83
TS-769:RCB-24:Reviewer-ka:jad:Rm810:CM#2:6/28/83:DCR-11058
REVISED-6/29/83:DCR-11645:efs

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione PETITION NO. 3F2841

CCPR NO. [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide]

Codex Status

/_____/ No Codex Proposal
Step 6 or above

Residue (if Step 9):

Iprodione only[1/]

Crop(s)	Limit (mg/kg)
garlic	0.1

Proposed U.S. Tolerances

Parent plus isomer (3-(1-methyethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide plus metabolite 3-(3,5-dichlorphenyl)-2,4-dioxo-1-imdazolidinecarboxamide.

Residue:

Crop(s)	Tol. (ppm)
garlic	0.1

CANADIAN LIMIT

Residue:

Crop	Limit (ppm)
none	(on garlic)

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm
none	

NOTES: [1/] Consideration needs to be given as to whether the U.S. definition of residue can be made compatible with Codex (Deferral to Tox suggested).

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