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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F2840 Iprodione on Lettuce. Evaluation of analytical method and residue data.

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

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

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 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 and/or on the raw agricultural commodity lettuce at 7.0 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 (both at 20 ppm). We have recently recommended for a temporary tolerance on lettuce (PP#3G2801). Almond, meat and milk tolerances are pending (PP#3F2728).

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Condlusions

- 1a. 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].
- 1b. Since no feed items are involved here a discussion of animal metabolism is irrelevant.
2. Adequate analytical methodology is available for enforcement.
3. We cannot draw a conclusion as to an appropriate tolerance for the following reasons:
 - (1) Too few of the residue experiments represent the maximum proposed use and minimum PHI;
 - (2) The submitted residue data include separate values for trimmed lettuce heads and for wrapper leaves. Unless we know the weight proportion of the leaves we cannot calculate a tolerance for the whole head. In gathering residue data, lettuce should not be trimmed except for leaves that are obviously wilted or decayed.

Additional residue data are needed.

4. The petitioner has proposed a tolerance for lettuce but the submitted data are for head lettuce. If use is intended only for head lettuce then this should be indicated in the directions and a tolerance should be proposed for head lettuce. If use on other types of lettuce (leaf lettuce, for example) is desired then representative residue data will be needed.
5. Since no feed items are involved there will be no problems of secondary residues in meat, milk, poultry, and eggs.
6. An International Residue Limit Status sheet is attached. The Codex MRL for iprodione on lettuce is 10 ppm. 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 expression.

Recommendation

We recommend against the proposed tolerance. For further consideration we require additional residue data that represents the maximum proposed use and the minimum PHI. These residue experiments should represent the major lettuce growing areas and should include tests from the Imperial Valley of California, especially for winter lettuce. Also, see conclusion 4.

The label should not restrict usage in certain geographical areas because there is a lack of residue data in those areas. The lettuce sampled for residues should not be trimmed; only obviously decayed or wilted leaves should be removed.

Detailed Considerations

Formulation

The formulation proposed for use on lettuce 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, none of which comprise more than [redacted] the technical material.

Proposed Use

For control of lettuce drop in California, Rovral is to be applied at the rate of 1.5-2.0 lb (0.75-1.0 lb. a.i.)/A at the 3-leaf stage of growth.

In other states, for control of bottom rot and lettuce drop, Rovral is to be applied at the rate of 1.5-2.0 lb (0.75-1.0 lb. a.i.)/A at the three-leaf stage and again, 10 days later. If conditions favor disease development a third application should be made 10 days after the second. No application should be made within 14 days of harvest.

The label includes a restriction against use on winter grown lettuce in Arizona and the Imperial Valley of California because no representative residue data are available. Such a label restriction is acceptable only if the pest controlled is not a problem in the excluded area.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Nature of the Residue

Radiolabel metabolism studies have been carried out on strawberries and wheat (PP#8G2087, memo of 3/2/79 A. Rathman), peaches (PP#2F2596, memo of 5/13/82, R. Perfetti), and on lettuce (PP#3G2801, memo of 4/11/83, N. Dodd). For these plants a similar metabolic pathway for iprodione has been established. The residue of concern consists of parent, its isomer [3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, RP 30228] and a des-isopropyl metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, RP 32490].

We have considered whether, for compatibility with Codex, the U.S. tolerance should be expressed in terms of parent compound only. We have reviewed metabolism and residue data for parent compound, its isomer and its metabolite on stone fruits, strawberries and wheat. 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. Note: The data for lettuce do not reflect the proposed use (see below) and we cannot draw a conclusion as to what portion of the lettuce residue that the isomer and metabolite will comprise.

Analytical Method

The method used to determine residues in lettuce is Rhone-Poulence Analytical Method No. 151. This method is described in earlier reviews and has undergone a successful method tryout on kiwifruit. Validation data for lettuce were reported in our review of PP#3G2801 (memo of 4/11/83, N. Dodd). Recoveries of parent and the two metabolites ranged from 61-140% at fortifications of 0.1-10 ppm. No interferences were noted from eleven other pesticides. A confirmatory TLC method is available. We conclude that adequate analytical methods are available for enforcement of the proposed tolerance.

Residue Data

Residue experiments were carried out in New York, New Jersey, Wisconsin, Florida, and California. In most experiments both lettuce heads and wrapper leaves were examined for residue. For lettuce heads the maximum combined residue for parent, isomer and metabolite as a result of 1-3 applications of 1.0-2.0 lb a.i./A and PHI's of 9 to 61 days was

0.17 ppm. Not suprisingly, much higher residues were found in lettuce leaves, up to 62 ppm (combined residues) on the day of the last of 3 applications of 2.0 lb ai/A. The highest residue found in leaves at PHI's of 14 days or longer was 5.89, found 33 days after one application of 1.0 lb a.i./A. We cannot arrive at a tolerance level for the following reasons:

1. Too few of the data reflect the maximum proposed rate and the minimum PHI.
2. The lettuce sampled for residue should include all wrapper leaves except those obviously wilted or decayed; the submitted data include values for heads and wrapper leaves, but unless we know the relative weights, we cannot calculate the residue in the whole head (i.e., including wrapper leaves.)
3. The petitioner has proposed a tolerance for lettuce but the submitted data are, apparently, for head lettuce. If use for leaf lettuce is intended then representative data will be needed. If use is to be limited to head lettuce then Section B should be revised to limit this use to head lettuce and Section F should be revised to propose a tolerance for head lettuce. Also, when reporting data, the type of lettuce, head or leaf, should be indicated. We are familiar with many, but not all, of the varieties of lettuce that were used in the residue experiments.
4. There are no residue data for winter lettuce grown in California, Arizona, or Texas. Such data should be submitted. We do not accept label restrictions that are based on lack of residue data (see proposed use).

In summary the petitioner should conduct additional residue experiments that are reflective of the maximum proposed use and the minimum PHI. The type of lettuce, head or leaf, should be specified. If use is intended for head lettuce only, a tolerance should be proposed for head lettuce, and the directions should stipulate head lettuce. Also the data should be geographically representative of the major lettuce growing areas.

Meat, Milk, Poultry, and Eggs

Since lettuce is not of importance as a feed item we expect no problem of secondary residue in meat, milk, poultry and eggs.

Other Considerations

The Codex MRL for iprodione on lettuce is 10 ppm but is regulated in terms of parent only. We have considered the compatibility of the U.S. Tolerance with the Codex MRL. (see Nature of the Residue, above).

cc: R.F.
Circu
Reviewer
Subject S.F.

Amended use File

RDI:Section Head-RJH:Date- :RDS:Date-
TS-769:RCB-24:Reviewer-K.Arne:efs:Rm810:CM#2:6/24/83:DCR-11059
REVISED-6/29/83:DCR-11646:RCB-24:efs

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione

PETITION NO. 3F2840

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)

lettuce 10

CANADIAN LIMIT

Residue: _____

Crop Limit (ppm)

none (on lettuce)

Proposed U.S. Tolerances

Parent plus isomer (3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide plus metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide.

Residue: _____

Crop(s) Tol. (ppm)

lettuce 7

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) and whether numerical compatibility is feasible.

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