11-28-84

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

NOV 28 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F3111, Iprodione on Onions. Evaluation of Analytical Method and Residue Data (Accession No. 072710).

FROM: E. T. Haeberer, Chemist E. T. Haeberer
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 onions at 0.5 ppm.

Permanent tolerances have been established for garlic at 0.1 ppm and apricots, cherries, nectarines, peaches, plums and prunes at 20 ppm (40 CFR 180.399). A Section 18 use of iprodione on onions and leeks in New Jersey was approved by RCB (memo May 6, 1982, 82-NJ-18, Edward Zager). Combined residues were estimated to not exceed 0.5 ppm at a 60 day PHI. A Section 18 request for use of iprodione on dry bulb onions in Washington state, September 1, 1984 to June 15, 1985, was approved by RCB pending TOX considerations (memo W. Anthony, 84-WA-12, August 9, 1984). Combined residues on dry bulb onions were estimated to not exceed 0.5 ppm.

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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-imidazolidine-carboxamide] and its metabolite[3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide].

2a. Adequate analytical methodology is available for enforcement of the proposed tolerance on dry bulb onions.

2b. We can draw no conclusions concerning the adequacy of the analytical methodology for enforcement of the proposed tolerance in green onions until validation data is submitted for green onions.

3. The label does not indicate whether the use is intended for green onions or dry bulb onions. The use directions also do not state whether application is for seeded onions or onions grown from sets. There is no PHI for the White Rot use. Our conclusions assume that both uses apply both to green onions and dry bulb onions and to onions grown from both seed and sets.

3a. We can draw no conclusions concerning the adequacy of the proposed tolerance for dry bulb onions until addition residue data reflecting adequate geographical representation is provided which reflects the proposed use at maximum levels on plants grown from onion sets.

3b. The petitioner has not proposed a PHI for furrow and spring spray usage. Section B should be amended to include a PHI for that use.

3c. We can draw no conclusions concerning the adequacy of the proposed tolerances on green onions. Additional data is needed reflecting foliar application at the maximum proposed use level on plants grown from seed. In addition, data is needed for both furrow and foliar application patterns, at maximum proposed use levels, on green onions grown from onion sets. PHI's should be proposed for both use patterns. The green onion data should reflect good geographical representation.

4. Since no feed items are involved, there is no reasonable expectation of secondary residues in meat, milk, poultry and eggs.

5. The International Residue Status sheet is attached. No tolerance for iprodione on onions is established in Mexico, A negligible residue tolerance of 0.1 ppm is established in Canada for iprodione, per se. There is a 0.1 ppm Codex tolerance for iprodione, per se. Metabolism studies on strawberries and wheat indicate that the isomer and metabolite increase with time and may comprise 50% or more of the residue. Since there is need to include the isomer and metabolite in the tolerance expression and the data supports a higher tolerance level, there is imcompatability with Codex.

Recommendation

We recommend against establishment of the proposed tolerance for the reasons cited in Conclusions 2b, 3a, 3b and 3c.

Detailed Considerations

Manufacture

See Confidential Appendix

Formulation

Iprodione formulated as Rovral® Fungicide (EPA Reg. No. 359-685) is a wettable powder containing 50% iprodione. All inerts are cleared under 40 CFR 180.1001.

Proposed Use

For the control of White Rot (Sclerotium cepivorum) in/on onions apply, with ground equipment, 1 lb ai/A in 15 to 20 gal/A in the furrow at planting. Position nozzles to treat seeds and soil that will fill the furrow, using a spray pressure of 15 to 20 psi. With fall planted onions, if conditions are favorable for disease development, apply a second directed spray to the base of the plants in the spring at the rate of 1.0 lb a.i/A in 40 to 75 gal/A.

For the control of Botrytis leaf blight (Botrytis squamosa) and Purple blotch (Alternaria porri) apply with ground equipment as a foliar spray at the rate of 0.75 lb a.i/A in 50 to 100 gal/A. Begin application as soon as conditions become favorable for disease and continue applications on a 7-day interval as long as conditions favor disease development, up to 10 applications/season. Do not apply within 7-days of harvest.

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 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 consist 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)].

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 of parent (RP-26019), isomer (RP-30228) and metabolite (RP-32490). Briefly, the sample is extracted with acetone, cleaned up by liquid-liquid partitioning and gel permeation chromatography. A florisil column is used for additional clean-up and separation of components. The parent (RP-26019) and its isomer (RP-30228)are eluted with 15% ethyl acetate/hexane. Metabolite RP-32490 is eluted with 50% ethyl acetate/hexane. These fractions are collected separately and evaporated to residue with rotary vacuum. After dilution to an appropriate concentration, they are determined by electron capture GC. GC column conditions are significantly different for the parent and isomer, and require two separate injections. The metabolite previously isolated, is determined separetely. The minimum detectable level for each component is 0.05 ppm.

A confirmatory TLC procedure is available. Samples prepared for GC analysis are spotted on silica gel TLC plates. The parent and isomer are developed with 10% ethyl acetate in benzene and the metabolite in 40% ethyl acetate in methylene chloride. Visualization is by a specific color reaction for aryl amines utilizing Bratton-Marshall reagent. The MDL for each component is 0.5 ug.

A successful method tryout was conducted in conjunction with PP#OE2414, Iprodione on Kiwifruit (memo May 28, 1981, R. Perfetti).

Check samples of onion bulbs contained no detectable residues. Bulbs fortified at 0.05 to 10.0 ppm had recoveries ranging from 68.0 to 128.9% for parent (RP-26019), 79.2 to 118.9% for its isomer (RP-30228), and 72.6 to 101.1% for the metabolite (RP-32490). No validation data was submitted for green onions, i.e. analysis of the whole plant, leaves and bulb. This data will be needed to determine the adequacy of the method for green onions.

We conclude that adequate analytical methodology is available for enforcement of the proposed tolerance on bulb onions. We can draw no conclusions concerning analytical methodology for green onions until the validation data discussed above is submitted.

Residue Data

Data submitted with this petition includes 12 studies on bulb onions previously submitted in conjunction with a Section 18 (84-WA-12, William Anthony, August 9, 1984) and 3 studies on green onions (scallions) previously submitted in conjunction with Section 18 (82-NJ-18, Edward Zager, May 6, 1982).

Two studies on bulb onions conducted in Oregon in 1982 consisted of furrow treatments of Rovral®, 50% wettable powder. A directed spray was made at the rate of 4 lb a.i./A (4X) at planting. Onion bulbs were harvested with PHI's of 113 and 146 days and analyzed for parent (RP-26019), isomer (RP-30228) and metabolite (RP-32490). All untreated check samples had no detectable residues. No residues were found in the onion bulbs of any of the treated samples. Recoveries of fortified checks (0.05 to 0.10 ppm) were 106 to 112% for RP-26019, 118.9% for RP-30228 and 95.7% for RP-32490.

Ten studies on bulb onions conducted in 1982 and 1983, consisted of post-emergence applications of Rovral®, 50% wettable powder at test plots located in New York(4) Oregon(2), California, Texas, Michigan and Illinois. There were 8 to 10 applications made at rates of 0.75 lb a.i./A (1X), 1.0 lb a.i./A (1.3X), and 2.0 lb a.i./A (2.7X). PHI's ranged from 0 to 21 days. Untreated check samples had no detectable residues. Parent residue only was found ranging from 0.06 to 0.17 ppm in the onion bulbs of treated samples with 0 PHI's. No residues were found in any onion bulbs after a 7 day PHI. Recoveries of fortified check samples (0.05 to 10.0 ppm) ranged from 68.0 to 124.0% for RP-26019, 84.6 to 100.0% for RP-30228 and 72.6 to 101.0% for RP-32490.

All of the above data was for dry bulb onions grown from seed. Additional residue data will be needed reflecting both use patterns at maximum application rates on bulb onions grown from sets. The same amount of active ingredient could be applied during a shorter time period and might lead to higher residue levels. In addition, a PHI should be proposed for the furrow and spring spray treatment which is compatible with the proposed use and the residue data.

We can draw no conclusions concerning the adequacy of the proposed tolerance on dry bulb onions. Additional data is needed reflecting the maximum proposed use on plants grown from sets.

The three studies on scallions conducted in New Jersey, 1979-1981, reflected the use pattern of furrow treatment and a single postemergence spray. The entire plant (leaves and bulb) was harvested and analyzed. Residues from 1 to 2 applications at 1 lb a.i./A ranged from 0.06 to 0.36 ppm parent (RP-26019), and no detectable residues (<0.05 ppm) of the isomer (RP-30228) and metabolite (RP-32490) at PHI's 61 to 65 days.

Based on the above data RCB has concluded that the residues of iprodione, its isomer and metabolite would not exceed 0.5 ppm on green onions from the described use with a 60 day PHI. A PHI for this use pattern was not included in Section B of this petition. The petitioner should revise Section B to include an appropriate PHI for this use.

No data was provided for the repeated application use on green onions, i.e. up to 10 applications of foliar spray, 0.75 lb a.i./A with a 7 day PHI. In addition studies did not include plants grown from sets as well as seeds. Plants grown from sets could receive the same amount of active ingredient in a shorter time frame and are likely to have higher residue levels.

We can draw no conclusions on the adequacy of the proposed residue tolerance for green onions from the data provided. Additional residue data will be needed which reflects the maximum proposed use for both patterns of application, includes residue data for plants grown from both seeds and sets, with appropriate PHI proposals for both use patterns.

Meat, Milk, Poultry and Eggs

No feed items are involved therefore we anticipate no secondary residues in meat, milk, poultry and eggs.

Other Considerations

The International Residue Status sheet is attached. No tolerance for iprodione on onions is established in Mexico. A negligible residue tolerance of 0.1 ppm is established in Canada for iprodione, per se. There is a 0.1 ppm Codex tolerance for iprodione, per se. Metabolism studies on strawberries and wheat indicate that the isomer and metabolite increase with time and may comprise 50% or more of the residue. Since there is need to include the isomer and metabolite in the tolerance expression, and the data supports a higher tolerance level, there is incompatability with Codex.

TS-769:RCB:E. Haeberer:vg:RM810:CM#2:77484:11/19/84
cc: RF, Circ., Haeberer, Thompson, FDA, TOX, EEB, EAB, PP#4F3111
cc: For CBI Appendix: PM 21, TOX, Haeberer, PP#4F3111
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