PP#4F1502 File

7-22-74

PP#4E1502. Chlorothalonil on Green and Bulb onions.
Evaluation of Analytical Methods and Residue Data.

JUL 22 1974

Coordination Branch
and Toxicology Branch, RD

C.C. Compton on behalf of the IR-4 Technical Committee and the Agricultural Experimental Stations of New York and Michigan requests a tolerance of 5 ppm on green onions and 0.5 ppm on dry bulb onions for the fungicide chlorothalonil (Tetrachloro-isophthalonitrile; Daconil). and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile.

Tolerances for chlorothalonil have previously been established on many agricultural commodities at levels ranging from 0.1 to 15 ppm (180.275).

PP#2F1230 proposing tolerances on various raw agricultural commodities is currently in reject status.

Conclusions

1. The fate of Daconil on onions is adequately understood.

2. Adequate methods are available to enforce the proposed tolerance.

3a. The petitioner should clarify whether the tabulated data in Section D reflects combined residues of the parent and the 4-hydroxy metabolite or parent alone.

3b. The proposed 5 ppm tolerance on green onions is not adequate for the proposed use.

Correction for recovery results in residues in excess of 5 ppm following 4 applications. Since a higher tolerance cannot be supported toxicologically, we suggest restricting use to a maximum of 3 applications per season and increasing the PHI to 14 days.

3c. The proposed 0.5 ppm tolerance for bulb onions is adequate, contingent upon a satisfactory resolution of conclusion 3a. If metabolite residues are not included in the data in Section D, the adequacy of the proposed tolerance will have to be reevaluated.

4. This use can be placed in Category 3 of Section 180. 6(a) with respect to meat, milk, poultry and eggs.

5. The petitioner should request the manufacturer to submit a description of the manufacturing process used for Daconil. If the method of synthesis indicates that hexachlorobenzene (HCB) is a logical impurity, then the results of analysis for HCB in technical chlorothalonil should be submitted.

6. The identity of the inert ingredient, [redacted] in the 6F formulation should be submitted.

7. A label restriction limiting use to ground application is needed unless adequate data reflecting aerial application are available.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED
PRODUCT IMPURITY INFO NOT INCLUDED

Recommendation

We recommend that the proposed tolerances not be established for the reasons given in conclusions 3a, 3b, 3c, 5,6 and 7.

Detailed Considerations

Formulation

The formulations proposed for use on onions are Bravo 6F and Bravo W75. All inerts are cleared for this use except for [redacted] in the 6F formulation. Although we anticipate no residue problems from this low level of surfactant, the petitioner should identify the nature of this inert ingredient.

Technical Daconil is 95.6-98.5% pure. Impurities analyzed for in Technical Daconil include [redacted]

We do not have a description of the manufacturing process for Daconil. This should be obtained from the manufacturer prior to approval of this tolerance proposal. If the method of synthesizing chlorothalonil is such that hexachlorobenzene (HCB) is a logical manufacturing impurity, a specific analysis for HCB will be needed.

Proposed Use

Daconil is applied as needed at 7-10 day intervals. A 7-day PHI is specified. The application rates range from 1.125 to 2.25 lbs. a.i. per acre per application.

Nature of the Residue

The metabolism of chlorothalonil has most recently been discussed in connection with PP#2F1230, (W.S. Cox). No additional metabolism data have been submitted with this petition.

The parent compound and small amounts of the 4-hydroxy metabolite constitute the residue of concern in plants. This conclusion is based on $^{14}C$ studies on corn and tomatoes and cold studies on patatoes in which other possible metabolites were not detected. The 4-hydroxy metabolite is the principal component of the residue in soils (70%), but on plants the 4-hydroxy metabolite constitutes at most 10% of the residue.

Foliar deposits of chlorothalonil do not translocate and there is no uptake from roots to aerial plant parts.

Analytical Methods

The data submitted in this petition were obtained using an analytical procedure submitted in appendix II to the amended Section D of PP#9F0743.

The method consists of acidified-acetone solution extraction, separation of the parent from the 4-hydroxy metabolite on a florisil column, conversion of the 4-hydroxy metabolite to the methyl ether using diazomethane and separate gas chromatographic detection of parent and metabolite using either a microcoulometric titration cell or an electron capture detector.

This method underwent a successful tryout (AMS) on peanuts (0.3 and 0.6 ppm) and broccoli (2.5 and 5.0ppm) for both the parent and the 4-hydroxy metabolite.

Crop blanks ranged up to 0.02 and 0.17 ppm for bulb and green onions, respectively. Recoveries ranged from 65-95% and 54 to 94% for green and bulb onions, respectively. Recoveries averaged 76% for bulb onions. The petitioner states that these recoveries refer to both the parent and 4-hydroxy metabolite although there is no indication in the tabulated data in section D as to whether the recovery calues refer to parent or metabolite.

Although recoveries for bulb onions are somewhat low, we consider the method suitable for enforcing the proposed tolerance.

Residue Data

The petitioner states in Section D that the levels of parent and the 4-hydroxy metabolite were determined. However, the tabulated data does not show separate values for the parent and metabolite. Even though the petitioner states that the 4-hydroxy metabolite is a minor component of the residue, we require clarification as to whether the tabulated data represent combined residues of the parent metabolite.

I have corrected the data in Section D for the average reported recoveries of 83% for green onions and 76% for bulb onions.

The petitioner does not indicate whether the data in Section D reflects ground or aerial application. Unless adequate aerial application data is available, use should be restricted to ground application only.

Residue from three field sites are presented in Section D. Zero day residues in samples from Middleton, N.Y. following 4 applications at 0.5 and 1X the maximum proposed rate were 7.9 and 19 ppm, respectively. No other data were reported for green onions from this field test.

One sample from Davis, California was analyzed. The sample was collected 7 days (the proposed PHI) after the last of 4 applications at 1X the proposed maximum rate. The residue level was 5.3 ppm after correction for recovery.

The third field test was carried out at Painsville, Ohio. Six samples reflecting 3 applications at 1X the maximum proposed rate showed residues ranging from 1.4 to 2.8 ppm 7 days (the proposed PHI) after the last application. Residues reflecting the above conditions ranged up to 10 ppm after 3 days and up to 19 ppm at 0 days.

The data above reflect a maximum of 4 applications at 1X the proposed rate. If an application is made every 7 days during the growing season as specified in Section B, up to 7 applications may be applied between germination and harvest.

Considering this fact and the limited amount of data submitted, we cannot conclude that a 5 ppm tolerance will be adequate for the proposed use. In fact, after correcting for recovery, the one sample from Davis, California showed a residue in excess of 5 ppm following 4 applications.

Toxicology has indicated (oral communication, C.H. Williams) that a higher tolerance cannot be supported. Although the data is limited, restricting use to a maximum of 3 applications per season and increasing the PHI to 14 days will provide assurance that the proposed tolerance is adequate.

Dry Bulb Onions

Residues on bulb onions were all reported as <0.2 ppm, with most values being <0.05 ppm. Data reflecting a maximum of 9 applications at 1X the proposed rate were presented. Although most of the data reflect a 14 day or longer PHI verses a proposed 7 day PHI, the data are satisfactory to assure us that residues will not exceed the proposed 0.5 ppm level.

Meat and Milk

Since onions are not an animal feed item, this use can be placed in Category 3 of Section 180.6(a).

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