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

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SUBJECT: PP#9G2204. BAS 352F (RONILAN®) on lettuce and stone fruits. Amendment of 7/2/81

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

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This amendment (7/2/81) is in response to our last review (memo of Dr. B. Davis, 4/14/80) in which we concluded that all but two of the deficiencies cited in our initial review (memo of Dr. B. Davis, 5/1/79) were resolved. The two deficiencies involved the need for clearance of the inert ingredient [redacted] and for additional residue data for cherries, nectarines and plums.

In addition, our review stated that the revised label contained an error for treatment of brown fruit rot under "High Disease Pressure" for stone fruit. The label should read, "2 lbs product per acre" and delete "1 1/2 lbs product per acre".

In response the petitioner has submitted the following:

(a) A revised Section F in which the proposed tolerances are reduced for cherries from 5 ppm to 4 ppm, for peaches from 25 ppm to 4 ppm, and for lettuce (head) from 10 ppm to 5 ppm.

This is in response to TOX's request (memo of R. Coberly, 5/6/81) that the temporary tolerance be adjusted so that the cumulative TMRC does not exceed 100% of the PADI.

The previously proposed tolerances of 25 ppm for apricots and 3 ppm for nectarines have also been deleted because of insufficient residue data.

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(b) "A revised Section B in which the PHI for lettuce is decreased from the previously proposed 30 days to 14 days and the PHI's for cherries, peaches and plums increased from the previous zero days to 3 days.

(c) Additional residue data for cherries, plums, and peaches.

(d) Additional recovery data for cherries, plums, peaches, and lettuce.

Formulation

The petitioner has informed us that the inert ingredient [redacted] This has been cleared under Section 180.1001 [redacted] Therefore, we consider this deficiency resolved.

Residue Data

Cherries

Additional residue data were submitted from one location each in the states of Oregon, California, Michigan and two in New York. The treatment rate varied from 0.75 to 3 lbs a.i./A, with from one to six applications. In the Michigan study, residues of 12.4 ppm were found following 5 applications at 0.75 lb act/A (0.75X the maximum proposed rate) and a 0 day PHI. In the summary, the rate in this study is erroneously reported to be 3 lb ai/A. The other studies show a wide range of residue levels ranging from 0.87 ppm at zero day PHI (California) to 14.8 ppm also at zero day PHI (Geneva, N.Y.) both reflecting 3 applications at a treatment rate of 0.75 lb a.i./A. Another sample from the Geneva, N.Y. study, also with a treatment rate of 0.75 lb a.i./A, with five applications and a zero day PHI contained a residues level of 11.2 ppm. In the California study analyses of samples taken at 3, 7 and 13 days showed residues declined relatively slowly with a half-life of approximately 24 days.

Based on the high initial residues and the relatively slow decline rate, we conclude that residues will exceed the proposed tolerance of 4 ppm at a three day PHI. A tolerance of 25 ppm would be more appropriate. If a 14 day PHI were proposed, we would consider a 10 ppm tolerance to be adequate.

Plums

In a previous study from California, plum samples at 0, 3 and 8 day PHI's contained residues of 0.87, 0.86 ppm, and 0.77 ppm, respectively, following three treatments at 1 lb ai/A in 200 gal/A. A fourth sample, with similar treatment, contained residues of 0.56 ppm at a 15 day PHI.

The current amendment contains two additional studies. One study reflected three applications of 0.75 ai/A in 400 gal water and a 16 day PHI and the second, nine applications of 0.75 ai/A in 300 gals water and a zero day PHI. The resulting residues were 0.40 ppm and 2.0 ppm, respectively.

Based on this limited data, we conclude that the residues resulting from the proposed use of RONILAN® on plums will exceed the proposed temporary tolerance of 1 ppm. Additional residue data are needed to determine the appropriate tolerance with a 3 day PHI. A temporary tolerance of 2 ppm for residues of BAS-352F and its 3,s-dichloroaniline moeity would be appropriate if a 14-day PHI were proposed. In the absence of data for dried prunes, use should be limited to plums and fresh prunes.

Peaches

Two new residue studies, one each from Michigan and California were submitted. One involved three applications of 0.75 lb a.i./A and a 7 day PHI and the other, nine applications of 0.75 a.i./A and a 0 day PHI. The resulting residues were 1.05 ppm and 3.44 ppm, respectively.

In the previously submitted data, however, residue levels at 0 and 1 day PHI's at the maximum proposed rate of 1 lb a.i./A for 3 samples ranged from 16.4 to 27.5 ppm. A graph of all the available residue data extending to a PHI of 20 days points out that the decline of residues on the treated peaches is relatively slow with a half-life of 8-9 days. Based on this decline curve and the high initial residues, we conclude that residues will exceed the proposed tolerance of 4 ppm at a three day PHI.

We reiterate that a tolerance of 25 ppm for residues of BAS 352-F and its 3,5-dichloroaniline containing metabolites in/on peaches would be more appropriate. If a 14 day PHI were proposed, we would consider a tolerance of 10 ppm to be adequate.

Lettuce

Data from four additional studies on lettuce (two from Texas and are each from New York and Ohio) are now submitted.

In one Texas study, residues in 8 samples taken 21 days after the second of two applications at the maximum proposed rate of 1 lb act/A ranged from 0.49 to 1.19 ppm. In the second Texas study, lettuce contained 0.74 ppm following 2 applications at 0.75 lb act/A and a 15 day PHI.

In the New York study, three samples received five treatments of 0.5 lb a.i./A with a nine day PHI and three samples received five treatments of 0.75 lb a.i./A also with a nine day PHI. Residues on the first three were 6.15, 6.38, and 10.7 ppm and on the latter three, 1.07, 12.5, and 13.2 ppm. In this study, controls contained apparent residues of 1.32-5.33 ppm (see Other Considerations).

In the Ohio study one sample which had been treated with three application of 1.0 a.i./A with a 14 day PHI contained residues of 1.32 ppm.

The previously submitted data consist of 2 dissipation studies and 2 other trials. In one of these trials, residues on untrimmed lettuce were 7.2 ppm following 3 applications at the maximum proposed rate of ~~1~~ lb act/A and a 30 day PHI. From a graph and a statistical analysis of all the available residue data we conclude that residues in/on lettuce resulting from proposed use will exceed the proposed temporary tolerance of 5 ppm. A temporary tolerance of 25 ppm would be more appropriate. Use should be limited to head lettuce as the time from transplanting or thinning to harvest for leaf lettuce is too short to allow 3 applications at 2 week intervals with a 14 day PHI. If a 28 day PHI were proposed, we would consider a temporary tolerance of 10 ppm to be appropriate. This use would be practical only for direct seeded head lettuce.

Other Considerations

Analytical Methodology

The assays for residues in lettuce, cherries, peaches, and plums were carried out using the methodology discussed in our original review.

Additional recoveries from spiked samples are now reported. The results are comparable to values obtained in the original petition.

Lettuce: Five samples were spiked with 0.05, 0.50, 1.0, 5, and 10 ppm of BAS 352F. Recoveries ranged from 81-108% (93%). Control values generally ranged from 0.1-0.3 ppm; however, in study WJS-79-UNY-66, control values of 1.32, 1.67 and 5.33 ppm were reported.

Peaches: Eight samples were spiked with 0.05, 0.50, 10.0, and 25.0 ppm of BAS 352F. Recoveries ranged from 62 to 109% (78%).

Plums: Four samples were spiked with 0.05, 0.20, 1.0 and 2.0 ppm. Recoveries ranged from 83 to 120% (95%).

We conclude that the proposed method is adequate for the purposes of enforcing temporary tolerances for stone fruits. However, in the absence of an adequate explanation for the high control values reported in study WJS-79-UNY-66 (Report No. PR-195, P. 17), we do not consider it adequate to enforce tolerances for lettuce.

(4d) Residues in/or lettuce are likely to exceed the proposed tolerance of 5 ppm at a 14 day PHI. A temporary tolerance of 25 ppm would be more appropriate. This use should be limited to head lettuce at the time from transplanting or thinning to harvest for leaf lettuce is too short to allow 3 applications at 2 week intervals with a 14 day PHI. If a 28 day PHI were proposed, we would consider a temporary tolerance of 10 ppm to be appropriate. This use would be practical only for direct seeded head lettuce.

(5) A label restriction against the grazing or feeding of cover crops grown in treated orchards to livestock is needed to preclude residues in meat and milk.

(6) The application rate of 1 1/2 lb product per acre for treatment of brown fruit rot when disease pressure is high has been corrected to read "2 lb product per acre" in the revised label of 7/1/81.

Recommendations

We recommend against the establishment of the proposed temporary tolerances for the reasons cited in Conclusions 3b, 4a, 4b, 4c, 4d and 5.

cc: R.F., Circu, Reviewer, FDA, TOX, EEB, EFB, (Robert Thompson Research Triangle Park, N.C.) PP# NO. 9G2204
RDI:Section Head:RJH:Date:3/10/81:RDS:Date:3/11/82
TS-769:RCB:Reviewer:WLAnthony:LDT:X77324:CM#2:RM:810:Date:3/12/82

Error on Revised Label

The revised label (2/1/80) contained an error in which the treatment of brown fruit rot should correspond to 2 lbs product/acre rather than 1 1/2 lbs product/acre as listed on label. This error has been resolved.

Grazing Restriction

For the use on stone fruits, a label restriction is needed against the grazing or feeding of cover crops grown in treated orchards to livestock.

Conclusions

(1) The dispersant surfactant [redacted] is exempt from a tolerance requirement [redacted]

(2) The residue of concern is BAS 352F and its metabolites containing the 3,5-dichloroaniline moeity.

(3a) The proposed analytical method is adequate to enforce temporary tolerances for stone fruits.

(3b) An explanation is needed for the high control values reported in study WJS-79-UNY-66 (Report No. PR-195, p. 17). In the absence of this explanation, we do not consider the proposed method adequate to enforce temporary tolerances for lettuce.

(4a) Residues in/on cherries are likely to exceed the proposed temporary tolerance of 4 ppm at a 3 day PHI. A tolerance of 25 ppm would be more appropriate. If a 14 day PHI were proposed, we would consider a temporary tolerance of 10 ppm to be appropriate.

(4b) Residues in/on plums are likely to exceed the proposed tolerance with a 3 day PHI. If a 14 day PHI were proposed, we would consider a temporary tolerance of 2 ppm to be appropriate. In the absence of data for dried prunes, use should be limited to plums and fresh prunes.

(4c) Residues in/on peaches resulting from the proposed use will exceed the proposed temporary tolerance of 4 ppm. A 25 ppm tolerance would be more appropriate. If a 14 day PHI were proposed, we would consider a temporary tolerance of 10 ppm to be appropriate.

INERT INGREDIENT INFORMATION IS NOT INCLUDED