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

OCT 25 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#1F3995 (CBTS #13774; Barcode #D203653). Fenbuconazole on Pecans. Amendment dated 5/3/94. (No MRID #).

FROM: Nancy Dodd, Chemist *Nancy Dodd*
Tolerance Petition Section II
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Health Effects Division (7509C)

THROUGH: Richard Loranger, Ph.D., Acting Chief *R. Loranger*
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TO: Cynthia Giles-Parker, PM #22
Herbicide-Fungicide Branch
Registration Division (7505C)

and

Albin Kocialski, Section Head
Registration Section
Chemical Coordination Branch
Health Effects Division (7509C)

Rohm and Haas Company has responded to a fenbuconazole review of PP#1F3995 on pecans (N. Dodd, 4/5/94; CBTS #12883, Barcode #D197093). This amendment contains a letter dated 5/3/94, a revised Section F for pecans, and an amended Section B/label for pecans, and Confidential Statement of Formula dated 5/3/94 for fenbuconazole technical.

CONCLUSIONS

1. CBTS agreed in a phone conversation on 5/3/94 (N. Dodd, 5/5/94) that the company could add a statement on the label which refers to directions on the manufacturers' labels instead of indicating the amount of the surfactant or spray oil (v/v) to be added to the spray solution on the label. Referring to directions on the manufacturers' labels would be appropriate because each product contains such directions and because Rohm and Haas cannot determine vol/vol without knowing the concentration of each product.



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2. The petitioner now refers to "EPA-registered" adjuvants. Since EPA does not "register" adjuvants, this terminology is not appropriate and should be removed from the labels. EPA will accept reference to "EPA approved" adjuvants. Revised labels reflecting the appropriate terminology must be submitted.

3. A revised Section F which proposes a tolerance of 0.1 ppm for residues of fenbuconazole, RH-9129, and RH-9130 on pecans has been submitted.

4. A satisfactory EPA method validation for fenbuconazole (RH-7592), RH-9129, and RH-9130 on pecans has been conducted by EPA's Analytical Chemistry Branch. Although satisfactory recoveries were obtained, the method must be revised to account for ACB's comments. (See concurrent memo by N. Dodd.)

5. Since a satisfactory method validation for fenbuconazole (RH-7592), RH-9129, and RH-9130 on pecans has been conducted by EPA's Analytical Chemistry Branch, CBTS can conclude that residues resulting from the proposed use will not exceed 0.1 ppm on pecans.

6. A revised Section B/label has been submitted which contains the requested statement, " Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock. "

RECOMMENDATIONS

CBTS recommends against the proposed tolerance for fenbuconazole on pecans for the reason given in Conclusions #2 and #4 above.

Registration Division will determine whether the inerts in the formulation Indar® 2F Agricultural Fungicide are cleared under 40 CFR 180.1001.

DETAILED CONSIDERATIONS

Deficiencies from the review of PP#1F3995 dated 4/5/94 (N. Dodd) are repeated below, followed by the petitioner's responses and CBTS's conclusions. (The deficiencies are numbered as in the 4/5/94 review.)

Deficiency #3

The amount of the surfactant or spray oil (v/v) to be added to the spray solution was not added to the label. The petitioner should submit a revised Section B/label which indicates the amount of the surfactant or spray oil (v/v) to be added to the spray solution.

Petitioner's Response to Deficiency #3

A revised Section B/label for pecans is submitted. The label is revised in accordance with the agreement reached with EPA in a phone conversation on 5/3/94. The following statement has been added under "General Information": "A wetting agent such as LATRON B-1956, LATRON CS-7 or other EPA-registered spray adjuvant should be added to spray solutions according to manufacturers' use instructions to achieve optimum disease control." The following statement has been added under "Compatibility": "Follow the manufacturer's instructions for any registered adjuvant to achieve proper spray concentrations.

CBTS's Conclusion #3

Deficiency #3 is resolved by submission of the revised Section B/label. CBTS agreed in a phone conversation on 5/3/94 (N.Dodd, 5/5/94) that the company could add a statement on the label which refers to directions on the manufacturers' labels instead of indicating the amount of the surfactant or spray oil (v/v) to be added to the spray solution on the label. Referring to directions on the manufacturers' labels would be appropriate because each product contains such directions and because Rohm and Haas cannot determine vol/vol without knowing the concentration of each product.

The petitioner now refers to "EPA-registered" adjuvants. Since EPA does not "register" adjuvants, this terminology is not appropriate and should be removed from the labels. EPA will accept reference to "EPA approved" adjuvants. Revised labels reflecting the appropriate terminology must be submitted.

Deficiency #4

Since the residues of concern for this use on pecans have been determined to be fenbuconazole, RH-9129, and RH-9130, a revised Section F with RH-6467 deleted should be submitted.

Petitioner's Response to Deficiency #4

A revised Section F which proposes a tolerance of 0.1 ppm for residues of fenbuconazole, RH-9129, and RH-9130 on pecans has been submitted.

CBTS's Conclusion #4

Deficiency #4 is resolved by submission of the revised Section F.

Deficiency #6

An EPA analytical method validation is needed. A method validation for RH-7592, RH-9129, and RH-9130 on pecans has been requested in a memo dated 3/23/94 from N. Dodd (CBTS) to Don Marlow (ACB/BEAD/EPA).

Petitioner's Response to Deficiency #6

This is an EPA issue which is not under the control of Rohm and Haas.

CBTS's Conclusion #6

Deficiency #6 is tentatively resolved. A satisfactory EPA method validation for fenbuconazole (RH-7592), RH-9129, and RH-9130 on pecans has been conducted by EPA's Analytical Chemistry Branch. Although acceptable recoveries were obtained, the method must be revised according to ACB's suggestions. (See concurrent memo by N. Dodd.)

Deficiency #9

The adequacy of the proposed tolerance of 0.1 ppm on pecans cannot be determined until a satisfactory analytical method validation is conducted by EPA.

Petitioner's Response to Deficiency #9

This is an EPA issue which is not under the control of Rohm and Haas.

CBTS's Conclusion #9

Since a satisfactory method validation for fenbuconazole (RH-7592), RH-9129, and RH-9130 on pecans has been conducted by EPA's Analytical Chemistry Branch, CBTS can conclude that residues resulting from the proposed use will not exceed 0.1 ppm on pecans.

Deficiency #10

The statement " Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock. " should be put back on the label.

Petitioner's Response to Deficiency #10

A revised Section B/label has been submitted which contains the requested statement, " Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock. "

CBTS's Conclusion #10

Deficiency #10 is resolved by submission of the revised Section B/label.

Other

A revised Confidential Statement of Formula (CSF) dated 5/3/94 has been submitted for fenbuconazole technical to correct a typographical error for the impurity listed on page two, line item four.

cc: RF, Circu., N. Dodd (CBTS), E. Haeberer (CBTS),
W. Wassell (CBTS), PP#1F3995, PM #22, Albin Kocialski (CCB)

RDI:E. Haeberer:10/24/94:M. Flood:10/24/94
7509C:CM#2:Rm 804F:305-5681:N. Dodd:nd:10/24/94