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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#1F3995 (CBTS #12883; Barcode #D197093). Fenbuconazole on Pecans. Amendment dated 10/5/93. (No MRID #).

✓ FROM: Nancy Dodd, Chemist *Nancy Dodd*
Tolerance Petition Section II
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

THROUGH: Debra Edwards, Ph.D., Chief *Debra Edwards*
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

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, 3/10/93). This amendment contains a letter dated 10/5/93, a revised Section F for pecans, and an amended Section B/label for pecans.

CONCLUSION

1. All Product Chemistry data deficiencies have been resolved in a concurrent review (PP#1F3989, CBTS #'s 12265 and 12266, N. Dodd, April 1994).
2. CBTS deferred to Registration Division concerning whether the inerts in the formulation Indar® 2F Agricultural Fungicide are cleared under 40 CFR 180.1001. This is under concurrent review by Registration Division. No CBTS action is needed.
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.

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.

5. The metabolism and residue data on the glucose conjugates of RH-4911 were reviewed in a concurrent submission (PP#1F3995, CBTS #13342, N. Dodd, April 1994). CBTS determined that, considering the low residues expected to occur in pecans as a result of the proposed use, the available data are sufficient to indicate that RH-4911 is a minor residue in pecans. (RH-4911 was a minor component of the residue in the metabolism studies on peach fruit and wheat straw and was not detected in the two residue studies on pecans.) The metabolism of fenbuconazole in pecans is adequately understood. The residues of concern in pecans are parent (RH-7592), RH-9129, and RH-9130. For other uses involving higher residues on pecans or any other crop, raw data and storage stability data would be needed to show that RH-4911 is a minor residue.

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).

7. Analytical reference standards for RH-7592, RH-9129, RH-9130, and RH-6467 have been sent to EPA's Chemical Standards Repository.

8. Adequate storage stability data for RH-7592, RH-9129, and RH-9130 on pecan nutmeat have been provided to support the proposed use on pecans.

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.

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

RECOMMENDATIONS

CBTS recommends against the proposed tolerance for fenbuconazole on pecans for reasons given in Conclusions #'s 3, 4, 6, 9, and 10 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 3/10/93 (N. Dodd) are repeated below, followed by the petitioner's responses and CBTS's conclusions. (The deficiencies are numbered as in the 3/10/93 review.)

Deficiencies #1 and #2

The Product Chemistry data are not adequate to support the proposed permanent tolerances. Additional Product Chemistry data under §61-1, 61-2, 61-3, 62-1, 62-3, 63-7, 63-8, 63-12, and 63-13 are needed. [See "Fenbuconazole (RH-7592) Product Chemistry Data Submitted to Support New Registrations", N. Dodd, February 25, 1993.]

The manufacturing process is not adequately delineated. Additional data under §61-2 (Beginning Materials and Manufacturing Process) and §61-3 (Discussion of Formation of Impurities) are needed to support a permanent tolerance. (Refer to the Product Chemistry review, N. Dodd, February 25, 1993.)

Petitioner's Response to Deficiencies #1 and #2

Rohm and Haas has responded to the product chemistry data deficiencies cited in the 2/25/93 review.

CBTS's Conclusions #1 and #2

All Product Chemistry data deficiencies have been resolved in a concurrent review (PP#1F3989, CBTS #'s 12265 and 12266, N. Dodd, April 1994).

Deficiency #3

CBTS defers to Registration Division concerning whether the inerts in the formulation Indar® 2F Agricultural Fungicide are cleared under 40 CFR 180.1001.

CBTS's Conclusion #3

This is under concurrent review by Registration Division. No CBTS action is needed.

Deficiency #4a

The label should be revised to state the maximum number of applications/year.

Petitioner's Response to Deficiency #4a

A revised Section B/label dated 9/30/93 has been submitted. The statement "Do not make more than eight applications per season" has been added.

CBTS's Conclusion #4a

Deficiency #4a has been resolved by submission of the revised label.

Deficiency #4b

The label should be revised to indicate the names and quantities (v/v) of wetting agents/surfactants or emulsifiable spray oils to be added to the spray solution. (The petitioner must be reminded that representative residue data reflecting use of the wetting agents/surfactants and emulsifiable spray oils should be available. In cases where such data are not available, reference to the wetting agents/surfactants or emulsifiable spray oils should be deleted from the label.)

Petitioner's Response to Deficiency #4b

"The EPA initially requested that Rohm and Haas specify which adjuvants were acceptable. The language proposed to EPA to address this concern was accepted by them in phone conversations. This language has been added to the label as General Information."

"The EPA also inquired how the residue trials were conducted. The trials were nearly all conducted with a spray adjuvant. Since this practice creates a maximum likelihood for crop residues, EPA accepted the data submitted as adequate support for the proposed tolerances."

CBTS's Discussion #4b

This issue was discussed by phone in connection with the petition on stone fruits (PP#1F3989, N. Dodd, 5/26/93). CBTS determined that a term such as "nonionic surfactant" is specific enough. EPA also had no objection to the statement "Use of a surfactant improves performance but is not a required additive".

Under "General Information", the previous label stated "A wetting agent or emulsifiable spray oil should be added to spray solutions to achieve optimum disease control". The revised label (under "General Information") states "A wetting agent such as LATRON B-1956 OR LATRON CS-7 spray adjuvant should be added to spray solutions to achieve optimum disease control." Under "USE DIRECTIONS FOR PECANS", the following statement was added: "For optimum disease control, an agricultural surfactant or emulsifiable spray oil should be co-applied with RH-7592 2F fungicide". (To

summarize: Instead of the terms "wetting agent or emulsifiable spray oil" which were on the previous label, the revised label names "LATRON B-1956 OR LATRON CS-7 spray adjuvant" under "GENERAL INFORMATION" and refers to "an agricultural surfactant or emulsifiable spray oil" under "USE DIRECTIONS FOR PECANS".)

The terms "agricultural surfactant or emulsifiable spray oil" under "USE DIRECTIONS FOR PECANS" in the revised label are as nonspecific as the previous term "wetting agent or emulsifiable spray oil". However, two examples (Latron B-1956 or Latron CS-7) are given under "GENERAL INFORMATION".

Concerning the availability of representative residue data reflecting use of the wetting agents/surfactants and emulsifiable spray oils, CBTS indicated by phone (PP#1F3989, N. Dodd, 5/26/93) that a statement that most of the residue studies were conducted with a nonionic surfactant would probably be accepted.

CBTS's Conclusion #4b

Deficiency #4b is not resolved because 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.

Deficiency #4c

The label should be revised for full coverage sprays so that the dosage is expressed as pounds active ingredient per 100 gallons spray solution to run-off. For concentrated sprays, the amount of active ingredient per acre should be stated and should be the same or less active ingredient per acre as the amount which would be applied using a full coverage spray. The label should contain the following additional instructions:

In order to apply the correct amount of pesticide to your orchard, you must know the number of gallons of water needed to spray one acre of your trees to the point of drip. If you do not already know this gallonage, you should conduct a test to determine it. For a dilute spray, this volume (containing "x" lbs./100 gals) should be used to treat the orchard. For a concentrate spray, the amount of pesticide required to treat the orchard is the same or less as that contained in the above gallonage of dilute spray. For a concentrate spray, the recommended gallonage is "y" gallons/A.

Petitioner's Response to Deficiency #4c

The following directions have been added for ground applications:

Ground- "Thorough coverage sprays generally result in optimum disease control. To achieve good coverage use proper spray pressure, gallonage per acre, nozzles, nozzle spacing and tractor speed. Consult spray nozzle and accessory catalogues for specific information on proper equipment calibration. For tree fruits and nuts, the same amount of RH-7592 2F fungicide should be applied per acre in either dilute or concentrate sprays."

Dilute Sprays:

"To apply the correct amount of RH-7592 2F fungicide to your orchard, you must know the number of gallons of water needed to spray one acre of trees to the point of drip. If you do not already know this gallonage, you should conduct a test to determine it. For a dilute spray, this volume (containing 2 fluid ounces or 0.03 pounds active RH-7592 2F fungicide per 100 gallons) should be used to treat the orchard."

Concentrate Sprays:

"The amount of RH-7592 2F fungicide required to treat the orchard is the same as that contained in the above gallonage for dilute sprays. For a concentrate spray, a minimum of 50 gallons per acre is recommended."

CBTS's Conclusion #4c

Deficiency #4c is resolved by submission of the revised Section B/label with the requested instructions.

Deficiencies #5a and #5b

The registrant must provide the chemical name for RH-7592 according to CAS nomenclature (or another well-defined nomenclature) on the Section B/label and Section F if this has not been done. To verify that the name for the active ingredient on the Section B/label and Section F is a Chemical Abstracts Service (CAS) name (or another well-defined name from another source), the petitioner should submit to EPA a copy of the appropriate memoranda from CAS (or another source) which identifies the CAS name (or other well-defined name).

The names for the metabolites of concern should correspond to the appropriate name for RH-7592.

Petitioner's Response to Deficiencies #5a and #5b

The petitioner has submitted revised Sections B and F.

CBTS's Discussion re. Deficiencies #5a and #5b

CAS nomenclature for fenbuconazole and its metabolites RH-9129, RH-9130, and RH-6467 have been submitted (PP#1F3989/PP#1F3995, N. Dodd, 9/29/93).

The revised Section B/label contains the CAS name for fenbuconazole.

The revised Section F contains the CAS nomenclature for fenbuconazole, RH-9129, RH-9130, and RH-6467.

CBTS's Conclusions #5a and #5b

Deficiencies #5a and #5b are resolved by submission of the revised Sections B and F containing CAS nomenclature for fenbuconazole and its metabolites.

However, 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.

Deficiency #6b

In light of the different metabolites on different crops, a metabolism study on pecans would normally be required. However, provided that the wheat metabolism study in the concurrent petition is found to be adequate, such a study will not be needed considering the low total residues of parent, RH-9129, RH-9130, and RH-6467 found in the pecan field trials. The decision as to which residues should be included in the tolerance expression will be deferred to the HED Metabolism Committee. The peach, peanut, and wheat studies will be used to reach that decision.

Note: The HED Metabolism Committee determined on 3/1/94 that the residues of concern on pecans, stone fruit, wheat, bananas, apples, and almonds are parent (RH-7592) and the metabolites RH-9129 and RH-9130, provided that the petitioner shows that RH-4911 is only a minor residue in these crops (PP#1F3989, N. Dodd and W. Wassell, 3/16/94). The petitioner has formally submitted data concerning the conjugated metabolite RH-4911 in the metabolism studies and residue field trials. This data is under concurrent review.

Petitioner's Response to Deficiency #6b

The petitioner provided metabolism and residue data on the glucose conjugates of RH-4911.

CBTS's Conclusion #6b

Deficiency #6b is resolved. The metabolism and residue data on the glucose conjugates of RH-4911 were reviewed in a concurrent

submission (PP#1F3995, CBTS #13342, N. Dodd, April 1994). CBTS determined that, considering the low residues expected to occur in pecans as a result of the proposed use, the available data are sufficient to indicate that RH-4911 is a minor residue in pecans. (RH-4911 was a minor component of the residue in the metabolism studies on peach fruit and wheat straw and was not detected in the two residue studies on pecans.) The metabolism of fenbuconazole in pecans is adequately understood. The residues of concern in pecans are parent (RH-7592), RH-9129, and RH-9130. For other uses involving higher residues on pecans or any other crop, raw data and storage stability data would be needed to show that RH-4911 is a minor residue.

Deficiency #7

An EPA method validation is needed for the analytical method for pecans which is described in Rohm and Haas Technical Report #34-91-14 (MRID #418925-03) for parent, RH-9129, RH-9130, RH-6467, and/or any residues which will be determined to be residues of concern.

Petitioner's Response to Deficiency #7

No Rohm and Haas action is required.

CBTS's Conclusion #7

Deficiency #7 remains outstanding. An EPA analytical method validation is needed. A method validation for RH-7592, RH-9129, and RH-9130 on pecans has been requested [PP#1F3995, memo dated 3/23/94 from N. Dodd (CBTS) to Don Marlow (ACB/BEAD)].

Deficiency #8

The petitioner should send analytical reference standards and individual Material Safety Data Sheets (as required by OSHA in 29 CFR 1910.1200) for RH-9129, RH-9130, and RH-6467 to the following address:

Pesticide and Industrial Chemical Repository (MD-8)
U.S. Environmental Protection Agency
Research Triangle Park, N.C. 27711

Petitioner's Response to Deficiency #8

The petitioner has submitted a letter dated 1/12/94 from Seymour Gold of the U.S. EPA's Chemical Standards Repository to Dr. Richard Costlow of Rohm and Haas. This letter acknowledges receipt of analytical reference standards for fenbuconazole technical (707-EGN), fenbuconazole 2F (707-EGR), and the fenbuconazole metabolites RH-9129, RH-9130, and RH-6467.

CBTS's Conclusion #8

Deficiency #8 is resolved. Analytical reference standards for RH-7592, RH-9129, RH-9130, and RH-6467 have been sent to EPA's Chemical Standards Repository.

Deficiencies #10a and #10b

The available storage stability data are not adequate to support the proposed use on pecans. Additional storage stability data are required on pecans or another nut.

Storage stability data will be needed on all components determined to be residues of concern in pecans.

Petitioner's Response to Deficiency #10a and #10b

All requested data have been submitted.

CBTS's Discussion re. Deficiencies #10a and #10b

CBTS determined that adequate storage stability data for RH-7592, RH-9129, RH-9130, and RH-6467 on pecan nutmeat have been provided to support the proposed use on pecans (PP#1F3995, CBTS #'s 12565 and 12566, N. Dodd, 2/24/94).

As explained under #6b above, CBTS has determined that the residues of concern for the proposed use on pecans are fenbuconazole, RH-9129, and RH-9130.

CBTS's Conclusions #10a and #10b

Deficiencies #10a and #10b have been resolved by submission of the requested data. Adequate storage stability data for RH-7592, RH-9129, and RH-9130 on pecan nutmeat have been provided to support the proposed use on pecans.

Deficiency #11

Storage conditions of samples from study #90-0251 before and during shipping and of study #90-0250 before shipping should be reported.

Petitioner's Response to Deficiency #11

All requested data have been submitted.

CBTS's Conclusion #11

Deficiency #11 was resolved by submission of the requested information (PP#1F3995, CBTS #'s 12716 and 12717, N. Dodd, 2/24/94).

Deficiency #12

The adequacy of the proposed tolerance of 0.1 ppm on pecans cannot be determined until the metabolism, analytical method, and storage stability issues are resolved.

Petitioner's Response to Deficiency #12

All requested data have been submitted. Concerning the method trial, no Rohm and Haas action is required.

CBTS's Conclusion #12

Deficiency #12 remains outstanding. 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. Metabolism and storage stability issues have been resolved as discussed above.

Other

Several changes have been made to the label as described below:

The previous label allowed application by ground equipment. The revised label allows both ground and aerial applications. Aerial applications are to be made in a minimum of 5 gallons water per acre on annual crops and 10 gallons water per acre on perennial tree fruits and nuts.

The previous label said "Do not apply within 28 days of harvest." The revised label says "Do not apply after shuck split or within 28 days of harvest."

The previous label said " Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock." This was left off the revised label.

Conclusion re. Label Changes

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.

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

RDI:E. Haeberer:4/5/94:R. Loranger:4/5/94
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