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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#1F3989 (CBTS #12905; Barcode #D197241). Fenbuconazole on Stone Fruit. Formulation Bridging Studies (MRID #'s 429790-00 and 429790-01).

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 4/18/94
Health Effects Division (7509C)

TO: Cynthia Giles-Parker, PM #22
Herbicide-Fungicide Branch
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and

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

Rohm and Haas Company has proposed use of a new fenbuconazole formulation [ENABLE™ (RH-7592) 75 WSP Agricultural Fungicide, sold in a water-soluble bag] on stone fruit. The company has submitted bridging data from the 2F formulation to the 75WP formulation. A petition for a permanent tolerance for residues of fenbuconazole on stone fruits resulting from use of the 2F formulation is in reject status (PP#1F3989/4H5689, N. Dodd, 4/12/94).

CBTS (PP#1F3989, R. Loranger, 9/17/92) indicated that a minimum of three side-by-side studies (one on cherries, one on peaches, and one on another stone fruit) would be needed as bridging studies to translate data from the 2F formulation to the 75WP formulation. Applications of each formulation should be made to adjacent groups of trees using the same application rate and timing. Provided similar residues are observed from the two formulations and tolerances have been established based on complete data for the flowable formulation, the WP could then be registered



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on both stone fruits and pecans based on the data from the flowable formulation.

Bridging data were not required for a **temporary tolerance**. CBTS (PP#9G3746, N. Dodd, 3/9/93) recommended for conversion of the existing EUP for fenbuconazole on stone fruits from the 2F to the 75WP formulation in a water soluble pouch.

CONCLUSIONS

1. CBTS defers to Registration Division concerning whether the inerts in the formulation ENABLE™ (RH-7592) 75 WSP are cleared under 40 CFR 180.1001. No CBTS action is required.
 2. The statement "Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock." should be put on the label.
 3. The amount of the surfactant or spray oil (v/v) to be added to the spray solution should be stated on 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. The first sentence under "USE DIRECTIONS FOR STONEFRUIT" on the RH-7592 75WSP label (ie., "Use one 2-ounce pouch of RH-7592 75WSP per acre in a minimum of 50 gallons spray.") should also state the lb active ingredient per acre.
 5. The 75WSP label states the interval between repeat applications for fruit brown rot on apricots, cherries, nectarines, peaches, plums, and prunes.
 6. Residues from use of the 2F and 75WP formulations were similar. Residues were 0.168 - 0.641 ppm for the 2F and 0.226 - 0.588 ppm for the 75WP.
 7. Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted.
 8. CBTS tentatively concludes that the available residue data on the representative commodities peaches, plums, and cherries indicate that residues in stone fruit resulting from the proposed use will not exceed the proposed tolerance of 2 ppm for the stone fruit crop group. However, a final conclusion cannot be made until issues regarding the proposed use and storage stability data are resolved.
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RECOMMENDATIONS

CBTS recommends against the proposed tolerance for fenbuconazole on stone fruit for reasons given in Conclusions #'s 2, 3, 4, 7, and 8 above.

Registration Division will determine whether the inerts in the formulation Enable™ 75 WSP are cleared under 40 CFR 180.1001.

DETAILED CONSIDERATIONSFormulation

Enable™ (RH-7592) 75 WSP Agricultural Fungicide contains 75% α -[2-(4-chlorophenyl)ethyl]- α -phenyl-1H-1,2,4-triazole-1-propanenitrile and 25% inerts. It is packaged in a water-soluble bag.

Conclusion

CBTS defers to Registration Division concerning whether the inerts in the formulation ENABLE™ (RH-7592) 75 WSP are cleared under 40 CFR 180.1001. No CBTS action is required.

Proposed Use

Apply RH-7592 75WSP as a protectant fungicide.

Apply by ground or air.

Use one 2-ounce pouch of RH-7592 75WSP per acre (0.1 lb. ai/A) in a minimum of 50 gallons spray.

For aerial applications, apply in a minimum of 10 gallons of water per acre.

For blossom blight on apricots, cherries, nectarines, peaches, plums and prunes, begin applications at red bud stage (about 5% bloom). If conditions are favorable for disease development, apply again at full bloom and at petal-fall.

For fruit brown rot on apricots, cherries, nectarines, peaches, plums and prunes, begin applications 2 to 3 weeks before harvest using a 7 to 10 day spray interval.

For leaf spot on cherries, follow the blossom blight schedule and continue application at 10 to 14 day intervals. Additional foliar applications may be made after harvest.

For scab on peaches, begin applications at shuck split. Make 2 to 3 subsequent thorough coverage applications at 10 to 14 day intervals.

For rusts on plums and prunes, follow the blossom blight schedule making additional applications on a 10 to 14 day schedule as long as necessary.

For all crops except peaches, do not make more than six applications or apply more than 1 lb RH-7592 75WSP (0.75 lb ai) per acre per season.

For peaches, do not make more than eight applications or apply more than 1.3 lbs RH-7592 75WSP (1.0 lb ai) per acre per season.

Apply up to the day of harvest.

An agricultural spray adjuvant should be used to achieve optimum disease control. (Under "GENERAL INFORMATION", the label 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.")

Do not apply through any type of irrigation system.

Conclusions

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

The amount of the surfactant or spray oil (v/v) to be added to the spray solution should be stated on 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.

The first sentence under "USE DIRECTIONS FOR STONEFRUIT" on the RH-7592 75WSP label (ie., "Use one 2-ounce pouch of RH-7592 75WSP per acre in a minimum of 50 gallons spray.") should also state the lb active ingredient per acre.

The 75WSP label states the interval between repeat applications for fruit brown rot on apricots, cherries, nectarines, peaches, plums, and prunes.

Residue Data- Bridging Studies

Five bridging studies (two on apricots, two on cherries, and one on peaches) were conducted in CA (1), WA (2), PA (1), and GA (1) in 1993 (MRID #429790-01). Applications were made by ground with an airblast sprayer. Latron B-1956 is listed as an additive in each of the five studies. Applications were made in 100 gals water per acre (study #'s 93-0070, 93-0075, 93-0087); 60.5 gals water per acre (study #93-0084), or 50.9 gal water per acre (study #93-0089). Samples were either delivered overnight or shipped

frozen (dry ice) and then stored frozen (-10°C). All samples were processed at Rohm and Haas. Residues were determined using the analytical method TR 34-90-47, "Residue Analytical Method for Parent RH-7592 and its Lactone Metabolites RH-9129 and RH-9130 in Stone Fruit" (MRID #41875038), with modifications. (One modification was analysis of RH-6467. The other was use of an RTX-200 column for the SPB-608 column in the gas chromatography step.) Residues of RH-7592, RH-9130, RH-9129, and RH-6467 were determined. Recoveries at fortification levels of 0.01 to 0.2 ppm were 75-118% (average 98%) for RH-7592; 78-107% (average 95%) for RH-9130; 74.6-110% (average 96%) for RH-9129; and 74.6-128% (average 103%) for RH-6467. Residue data are tabulated below:

Study # Crop State	# of appli- cations	inter- vals between appli- cations (days)	lb ai/ appli- cation	total lb ai/A	formu- lation	PHI/SAI (days)*
93-0070 apricot CA	6	15-19	0.125	0.75	2F 75WP	0/ 104
93-0075 cherry WA	6	10-17	0.125	0.75	2F 75WP	0/ 62
93-0084 cherry PA	6	10-15	0.125	0.75	2F 75WP	0/ 51
93-0087 apricot WA	6	10-22	0.125	0.75	2F 75WP	0/ 44
93-0089 peach GA	10	8-21	0.125	1.25	2F 75WP	0/ 24

* PHI = preharvest interval; SAI = sampling to analysis interval

Residues for each component and total uncorrected residues are reported below. All control values were 0.00 ppm.

Study # Crop	Formu- lation	RH-7592	RH-9130	RH-9129	RH-6467	total residue **
93-0070 apricot	2F	0.157	0	0.0114	0	0.168
	75WP	0.214	0	0.012	0	0.226
93-0075 cherry	2F	0.525	0.0068	0.039	0	0.571
	75WP	0.553	0.0057	0.0292	0	0.588
93-0084 cherry	2F	0.468	0	0.164	0.0088	0.641
	75WP	0.434	0	0.103	0.0087	0.546
93-0087 apricot	2F	0.268	0	0.011	0	0.279
	75WP	0.254	0	0.0135	0	0.268
93-0089 peach	2F	0.376	0	0.0105	0	0.387
	75WP	0.477	0	0.0152	0	0.492

** uncorrected residues

Conclusion

Residues from use of the 2F and 75WP formulations were similar. Residues were 0.168 - 0.641 ppm for the 2F and 0.226 - 0.588 ppm for the 75WP.

Other

Other deficiencies from the review of the 2F formulation on stone fruit (PP#1F3989, N. Dodd, 4/12/94) which also apply to the 75WSP formulation are as follows:

Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted. [CBTS has determined (PP#1F3989, N. Dodd, 2/24/94) that residues of fenbuconazole and its metabolites RH-9129 and RH-9130 are stable during frozen storage at approximately -10°C for up to approximately 18 months in or on peaches. The storage stability data are adequate to support the bridging study since samples were stored a short time (ie., 24-104 days). However, this storage stability data deficiency which concerns the previously submitted residue data remains outstanding.]

CBTS tentatively concludes that the available residue data on the representative commodities peaches, plums, and cherries indicate that residues in stone fruit resulting from the proposed use will not exceed the proposed tolerance of 2 ppm for the stone fruit crop group. However, a final conclusion cannot be made until issues regarding the proposed use and storage stability data are resolved.

cc: RF, N. Dodd (CBTS), E. Haeberer (CBTS), W. Wassell (CBTS),
PP#1F3989, PM#22

RDI:E. Haeberer:4/14/94:R. Loranger:4/14/94
7509C:CM#2:Rm804F:305-5681:N. Dodd:nd:4/18/94