



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

OCT 26 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#1F03989 (CBTS #14199; Barcode #206533). Fenbuconazole on Stone Fruit. Storage Stability Data. Amendment dated 8/1/94 (MRID #433335-00 AND 433335-01).

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

THROUGH: Richard Loranger, Ph.D., Acting Chief *R. Loranger*
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 submitted additional storage stability data for fenbuconazole on stone fruit in response to reviews of PP#1F3989 (N. Dodd, 4/12/94 and 4/18/94). This amendment contains a letter dated 8/1/94 and storage stability data through 30 months. Additional data to cover a storage interval of 54 months will be submitted later.

CONCLUSIONS

1. Adequate storage stability data have been submitted for fenbuconazole (RH-7592), RH-9129, and RH-9130 on stone fruit for a period of 30 months. Based on average corrected percent recoveries of stored samples, residues in peaches decreased 12.52% for RH-7592, 26.19% for RH-9130, and 20.99% for RH-9129 over the 30-month period.



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2. Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted.

3. Pending submission of the requested storage stability data for stone fruit for a period of 49 months, CBTS tentatively concludes that residues of fenbuconazole (RH-7592), RH-9129, and RH-9130 on the stone fruit crop group (except plums and prunes) will not exceed the proposed tolerance of 2.0 ppm. A final conclusion regarding the adequacy of the proposed tolerance cannot be made until storage stability data reflecting a 49-month storage period are provided.

RECOMMENDATIONS

Although Deficiencies #2 and #3 above remain outstanding, CBTS could use the storage stability data for the 30-month storage interval on an interim basis to support the proposed tolerance for fenbuconazole on stone fruit until the 49-month storage stability data can be provided. Other CBTS deficiencies are discussed in a concurrent review (PP#1F3989, N. Dodd, October 1994; CBTS #13769, D203669).

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

DETAILED CONSIDERATIONS

Deficiencies related to storage stability from reviews of PP#1F3989 (#8 and #9 from the review by N. Dodd dated 4/12/94; #7 and #8 from the review by N. Dodd dated 4/18/94) are repeated below, followed by the petitioner's responses and CBTS's conclusions. The other deficiencies from the 4/12/94 and 4/18/94 reviews are under concurrent review (PP#1F3989, N. Dodd, October 1994, CBTS #13769, Barcode #D203669). (The deficiencies are numbered as in the 4/12/94 and 4/18/94 reviews.)

Deficiency #8 (4/12/94 review) and #7 (4/18/94 review)

Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted.

Petitioner's Response to Deficiency #8 (4/12/94 review) and #7 (4/18/94 review)

Storage stability data for stone fruit (MRID #433335-01) are submitted for a period of 30 months. The study is continuing for a period of 54 months.

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Discussion re. Deficiency #8 (4/12/94 review) and #7 (4/18/94 review)

CBTS has previously concluded (PP#1F03989, CBTS #'s 12565 and 12566, 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. However, since some of the residue data were analyzed or reanalyzed at much longer PHI's, additional storage stability data for stone fruit reflecting storage intervals up to 49 months were requested.

The tabulated storage stability data on peaches reflecting a storage interval of 907 days (30 months) are attached. Refer to Attachments 1, 2, and 3 for the storage stability data on RH-7592, RH-9130, and RH-9129, respectively.

CBTS's Conclusion re. Deficiency #8 (4/12/94 review) and #7 (4/18/94 review)

Adequate storage stability data have been submitted for fenbuconazole (RH-7592), RH-9129, and RH-9130 on stone fruit for a period of 30 months. Based on average corrected percent recoveries of stored samples, residues in peaches decreased 12.52% for RH-7592, 26.19% for RH-9130, and 20.99% for RH-9129 over the 30-month period.

Additional storage stability data for stone fruit reflecting storage intervals up to 49 months should be submitted.

Deficiency #9 (4/12/94 review) and #8 (4/18/94 review)

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.

Petitioner's Response to Deficiency #9 (4/12/94 review) and #8 (4/18/94 review)

The petitioner has responded to issues regarding the proposed use and storage stability.

CBTS's Conclusion #9 (4/12/94 review) and #8 (4/18/94 review)

Pending submission of the requested storage stability data for stone fruit for a period of 49 months, CBTS tentatively concludes that residues of fenbuconazole (RH-7592), RH-9129, and RH-9130 on the stone fruit crop group (except plums and prunes) will not

exceed the proposed tolerance of 2.0 ppm. A final conclusion regarding the adequacy of the proposed tolerance cannot be made until storage stability data reflecting a 49-month storage period are provided.

Attachment 1: Storage stability data for RH-7592 in peaches
Attachment 2: Storage stability data for RH-9130 in peaches
Attachment 3: Storage stability data for RH-9129 in peaches

cc with Attachments 1, 2, and 3: RF, Circu., N. Dodd (CBTS),
E. Haeberer (CBTS), W. Wassell (CBTS), PP#1F3989, PM #22,
Albin Kocialski (CCB)

RDI:E. Haeberer:10/25/94:M. Flood:10/25/94
7509C:CM#2:Rm 804F:305-5681:N. Dodd:nd:10/26/94

TABLE-1A STORAGE STABILITY IN STONEFRUIT (PEACH)

COMMODITY STONEFRUIT (PEACH)
 ANALYTE RH-7502
 RESIDUE LEVEL 0.5 PPM

STORAGE PERIOD(days)	FRESH FORT. RECOVERY (%)		APPARENT RECOVERY IN STORED SAMPLE (%)			AV. CORR. % RECOVERY IN STORED SAMPLE
	# 1	# 2	# 1	# 2	# 3	
0	109	103	102	103	126	104.09
91	67.6	92.0	84.6	71.8	90.2	103.01
182	105	121	80.4	92.4	80.2	74.63
212*	117	116	92.2	97.4	94.6	81.32
364	86.6	90.2	81.2	86.0	75.8	91.63
554	111	106	92.4	98.6	89.8	86.27
721	81.4	84.0	92.6	91.4	85.6	100.60
907	87.0	90.2	80.2	80.2	83.0	91.57

NOTES:

(1) Formula Average Corrected Recovery (%) =

100 x (Average of apparent recoveries in stored samples / Average of Fresh Fortification Recoveries)

(2) When recovery is > 100%, decimals are ignored in reporting data

* Extra sample. Control showed 0.045 ppm RH-7502. No correction was made.

TABLE-1B STORAGE STABILITY IN STONEFRUIT (PEACH)

COMMODITY STONEFRUIT (PEACH)
ANALYTE RH-0130
RESIDUE LEVEL 0.5 PPM

STORAGE PERIOD (day)	FRESH FORT. RECOVERY (%) # 1	FRESH FORT. RECOVERY (%) # 2	APPARENT RECOVERY IN STORED SAMPLE # 1	APPARENT RECOVERY IN STORED SAMPLE # 2	APPARENT RECOVERY IN STORED SAMPLE # 3	AV. CORR. RECOVERY IN STORED SAMPLE
0	96.8	100	107	96.8	119	109.35
91	84.2	89.4	81.6	69.2	88.8	103.99
182	103	120	82.6	94.8	82.6	77.73
212*	108	111	85.4	97.0	88.6	82.50
364	82.8	85.2	74.6	79.4	69.2	88.57
554	108	108	83.2	92.2	81.6	79.32
721	71.4	75.0	73.4	70.0	71.0	97.63
907	84.4	89.4	71.2	71.8	73.8	83.16

NOTES:

- (1) Formula Average Corrected Recovery (%) =
 $100 \times (\text{Average of apparent recoveries in stored samples} / \text{Average of Fresh Fortification Recoveries})$
- (2) When recovery is >100%, decimals are ignored in reporting data
- * Extra sample

TABLE-IC STORAGE STABILITY IN STONEFRUIT (PEACH)

COMMODITY STONEFRUIT (PEACH)
ANALYTE RH-9129
RESIDUE LEVEL 0.5 PPM

STORAGE PERIOD (day)	FRESH FORT. RECOVERY (%)		APPARENT RECOVERY IN STORED SAMPLE			AV. CORR. RECOVERY IN STORED SAMPLE	
	# 1	# 2	# 1	# 2	# 3		
0	106	106	111	104	125		106.92
91	71.6	93.8	88.2	70.8	91.0		100.77
182	104	121	82.6	94.6	80.8		76.44
212*	112	114	88.6	96.8	92.0		81.83
364	83.0	84.8	75.4	78.8	68.2		88.36
554	111	109	92.0	99.4	89.0		84.97
721	81.2	84.0	85.0	95.0	80.0		104.92
907	85.4	91.8	75.4	74.4	78.6		85.93

NOTES:

(1) Formula Average Corrected Recovery (%) =

100 x (Average of apparent recoveries in stored samples / Average of Fresh Fortification Recoveries)

(2) When recoveries are >100%, decimals are ignored in reporting data

* Extra sample