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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID #000707-EGR (CBTS #11306; Barcode #D187549).
Fenbuconazole (RH-7592, Fenethanil, Indar® 2F) on Pecans.
Evaluation of Storage Stability Data (MRID #426345-00 and
-01; MRID #426582-01).

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and

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Rohm and Haas Company has submitted an amendment in response to a review of PP#2G4038 on pecans (S. Willett, 5/14/92). This amendment includes a letter dated 1/22/93 and a summary of storage stability data. A study which was submitted in PP#0F4194 and is referenced (Technical Report No. 34-92-62, MRID #426582-01) is also reviewed here.

Conclusions

1. All residues in nutmeats and RH-9130 in hulls were so low in MRID #426582-01 that CBTS can make no conclusion regarding storage stability.

2. Although residues of RH-7592 and RH-9129 in almond hulls appear to be stable during frozen storage for 1035 days (2.8 years), the length of time and storage conditions from sampling to the initial analysis are not available for RAR Code 87-0327.



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Whether degradation occurred between sampling and the original analysis is not known.

Recommendation

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.

DETAILED CONSIDERATIONS

The deficiency from CBTS's review of PP#2G4038 dated 5/14/92 regarding storage stability data requirements for a permanent tolerance is repeated below, followed by the petitioner's response and CBTS's conclusion.

Deficiency

Additional storage stability data will be needed on pecans prior to the establishment of a permanent tolerance since critical parts of the study on almond nutmeat were conducted by Craven Labs, upon whose data the Agency will not rely until issues surrounding the validity of such data are resolved.

Petitioner's Response

Rohm and Haas indicates that it does not rely on the studies performed by Craven Laboratories to establish storage stability. Instead, Rohm and Haas reanalyzed field residue samples (soil, stone fruit; wheat grain, straw, and processed fractions; and almond nutmeat and hull) which were maintained in frozen storage for extended periods. The petitioner indicates that the storage intervals were long enough to cover the harvest-to-analysis intervals for the crops.

New storage stability studies on soil, peach, apple, pecan, wheat grain, and wheat straw were started in 1991. Data have been analyzed through six months but not yet reported. These studies will continue for three years.

CBTS's Discussion

Storage stability data on almond nutmeats (MRID #418750-36, Technical Report #34-91-17) have previously been reviewed (PP#1F3989, N. Dodd, 3/10/93):

In MRID #418750-36, almond nutmeat was homogenized with dry ice in a food processor, fortified with 1.0 ppm of RH-7592 or RH-9130/RH-9129, and stored in plastic jars at -15 °C for 428

days. Residues were analyzed by method TR #34-89-34. Samples from 0, 6, 13, 27, 60, 91, and 181 days were analyzed by Craven laboratories. The 418 and 428 day samples were analyzed by Rohm and Haas. At each sampling interval, control values and fresh fortification recoveries were determined. No residues were found in control nut samples. Fresh fortification recoveries (from fortifications at 1.0 ppm) were $84 \pm 7\%$ for RH-7592, $87 \pm 10\%$ for RH-9130, and $91 \pm 10\%$ for RH-9129. Frozen storage stability results, reported as % recoveries, are below:

Almonds

<u>day</u>	<u>% Recovery</u>					
	<u>RH-7592</u>		<u>RH-9130</u>		<u>RH-9129</u>	
0	82,	78	108,	93	106,	94
6	84,	74	96,	82	96,	86
13	75,	71	70,	76	72,	80
27	76,	87	73,	82	77,	84
60	72,	74	78,	79	80,	81
91	--,	--	83,	84	87,	84
181	78,	74	71,	75	81,	80
418	93,	87	--,	---	--,	---
428	--,	--	95,	100	96,	100

CBTS determined in connection with a tolerance petition on pecans (PP#1F3995, N. Dodd, 3/10/93) that the storage stability data in MRID #418750-36 were not adequate since the 0-day analyses were performed by Craven Laboratories. (The Agency will not rely upon Craven data to support a regulatory decision until issues surrounding the validity of such data are resolved.) CBTS also noted that the storage stability data on almond nutmeats in MRID #418750-36 is for RH-7592, RH-9130, and RH-9129; however, storage stability data will be needed on all components which will be determined to be residues of concern.

The referenced study which reported reanalysis of field residue samples of almonds which had been stored ("RH-7592 Almond Nutmeat and Hull Storage Stability, Aged Field Residues", S.S. Stavinski, T.F. Burnett, J.J. Martin, September 1992, Rohm and Haas Technical Report No. 34-92-62, MRID #426582-01) was submitted in PP#OF4194. In this study, storage stability of almond nutmeats and hulls were determined. Residues were analyzed by method TR 34-89-34, with modifications which are detailed in Protocol Amendment 1, Appendix 3 of MRID #426582-01. The method determines RH-7592, RH-9130, and RH-9129. The petitioner indicates that the limit of quantitation is 0.01 ppm. The petitioner indicates that the residues were initially reported in TR 34A-89-44 (PP#9G3801, MRID #412297-03), but RAR Code 87-0327 is not included in MRID #412297-03. The length of time and storage conditions from sampling to the initial analysis are not available for RAR Code 87-0327. Residues

in almonds were determined on 5/15/89 and 5/17/89 and again on 3/15/92 (after 1035 days storage). The residues were reported as follows:

<u>matrix</u>	<u>1989 Analyses</u>			<u>1992 Analyses</u>		
	<u>RH-7592</u>	<u>RH-9130</u>	<u>RH-9129</u>	<u>RH-7592</u>	<u>RH-9130</u>	<u>RH-9129</u>
nutmeat	ND*	ND*	ND	ND	ND	ND
	0.028	0.0038	ND	0.030	ND	ND
	ND	0.0049	ND	ND	ND	ND
hulls	0.95	0.010	0.059	0.98	ND	0.054
	6.0	0.051	0.15	5.8	0.043	0.15
	ND	ND	0.0086	ND	ND	ND

*ND- no detectable residue at the limit of detection (0.0030 ppm)

Validation data for the analyses on 5/15/89 and 5/17/89 and for the later analyses on 3/15/92 (calibration curves for RH-7592, RH-9130, and RH-9129; representative chromatograms of standards, spikes, and samples of hulls and nutmeats) were submitted. Chromatograms of controls for almond nut and hull were submitted with the analytical method in Appendix 1 of MRID #426582-01.

The method which was used to analyze stored almond samples has not been validated at the claimed limit of quantitation of 0.01 ppm by a confirmatory lab or EPA. A method on pecans in Rohm and Haas Technical Report #34-91-14 has been validated by an independent lab at 0.05 ppm (Rohm and Haas Technical Report #34-91-15, MRID #418925-01; PP#2G4038, S. Willett, 5/14/92). An EPA method validation has not been conducted.

The performing laboratory for MRID #426582-01 was Rohm and Haas Company.

CBTS's Conclusions

All residues in nutmeats and RH-9130 in hulls were so low in MRID #426582-01 that CBTS can make no conclusion regarding storage stability.

Although residues of RH-7592 and RH-9129 in almond hulls appear to be stable during frozen storage for 1035 days (2.8 years), the length of time and storage conditions from sampling to the initial analysis are not available for RAR Code 87-0327. Whether degradation occurred between sampling and the original analysis is not known.

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.

cc: RF, SF, Circu, N. Dodd (CBTS), W. Wassell (CBTS),
E. Haerberer (CBTS), PM#22, PP#1F3995, PP#2G4038,
PP#0F4194, A. Kocialski (CCB)

RDI: E. Haerberer: 6/28/93: R. Loranger: 6/28/93
H7509C:CBTS:CM#2:Rm 804F:305-5681:N. Dodd:nd:6/29/93