CONFIDENTIAL

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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: PP#9G3746; 707-EUP-RER; RH-7592 (Fenethanil) on stone fruit. MRID Nos. 410312-01 to 410312-06; 410312-39 to 410312-45; 410735-01 and 410735-08; DEB Nos. 5301 and 5302.

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Dietary Exposure Branch
Health Effects Division (H7509C)

Thru: Richard D. Schmitt, Ph.D. Chief
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To: Susan Lewis, PM-21
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and

TOX Branch
Health Effects Division (H7509C)

Rohm and Haas Company requests establishment of a temporary tolerance for residues of RH-7592, 2-(2-(4-chlorophenyl)ethyl)-2-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile (see attachment #1 for chemical structure) in and on stone fruit at 1.0 ppm. RH-7592 is a new fungicide active ingredient; its proposed common name is fenethalin.

No pesticide tolerances were requested for meat, milk, poultry, and eggs, since animal feed items are not included in the proposed EUP.

No food additive tolerances were requested. The only RAC in the stone fruit crop group requiring a food additive tolerance is plums, which may be processed to dried prunes. To alleviate the need for a food additive tolerance for dried prunes, the petitioner has included the restriction, "For use on only fresh market plums and prunes" on the EUP label.

Conclusions

1. For the purpose of this temporary tolerance request (PP#9G3746), we consider the manufacture and formulation of RH-7592 (technical grade active ingredient) and RH-7592 Fungicide 2F (End Use Product) to have been adequately described. Impurities in the technical material are not expected to pose a residue problem.

Note to PM: The petitioner should be advised that Conclusion 1 applies to this temporary tolerance petition only; additional product chemistry data may be required before issuance of permanent tolerances.

2a. For the purpose of this temporary tolerance request (PP#9G3746), we conclude that the metabolism of RH-7592 in or on stone fruit is adequately understood. The data provided (MRID No. 410735-08) shows two separate metabolic pathways; one pathway involves benzylic oxidation of the parent, followed by cyclization and hydrolysis to a lactone metabolite (RH-9129); the other pathway involves conjugation of free triazole to form an alanine conjugate (RH-3968) which is further metabolized to the acetic acid (RH-4098) conjugate of triazole. The petitioner concluded that only the metabolites of the intact molecule are of toxicological concern.

2b. DEB defers to TOX concerning the toxicological significance of the triazole conjugate RH-3968. RH-3968 accounts for ca. 50% of the identified terminal residue, as shown below:

Components	% TRR (parent equivalent in ppm)
RH-7592 (parent)	15.5 (0.020)
RH-9129	4.3 (0.006)
RH-3968	47.5 (0.062)
RH-4098	6.7 (0.009)
% of TRR identified =	74.0

3a. The petitioner has requested that a temporary tolerance of 1.0 ppm be established for residues of RH-7592 (parent only) in or on stone fruit. This tolerance is being requested in conjunction with 707-EUP-RER.

3b. The petitioner did not request establishment of temporary food/feed additive tolerances, because: 1) there are no animal feed items in the stone fruit crop group; 2) and the treatment of plums will be limited to fresh market fruit only.

4. The use directions for treatment of peaches for Scab are not clear; use directions must clearly state the schedule of application.

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5. The residue data provided indicates that the proposed tolerance of 1.0 ppm for residues of RH-7592 (parent only) in or on stone fruit is adequate to cover the uses proposed in experimental use permit 707-EUP-RER.

6. No storage stability data were provided, however, since the residue data from the field trials (samples stored up to 496 days) were in reasonable agreement with the residue values form the plant metabolism study (samples stored for 2 to 3 weeks), we will assume that RH-7592 is stable under frozen storage (see recommendations below).

7. The analytical method (GC/NPD) described in PP#9G3746 appears to be adequate for the enforcement of the proposed temporary tolerance.

8. If the petitioner has not already done so, 2 grams of (analytical grade) RH-7592 should be sent to:

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

Recommendations

DEB defers to TOX Branch concerning the toxicological significance of the terminal triazole metabolite RH-3968 (conclusion 2b, see also attachment 2 for chemical structure).

TOX considerations permitting, and provided the application schedule for the treatment of peaches for Scab is clarified, we would recommend in favor of a temporary tolerance for residues of RH-7592 (parent only) in or on stone fruit.

Any request for a permanent tolerance for RH-7592 should follow 40 CFR 158 and the Residue Chemistry and Product Chemistry Guidelines. The petitioner should be advised that before we will consider any additional tolerance request for RH-7592 a storage stability study reflecting actual transfer and storage of the raw agricultural commodity prior to laboratory analysis must be conducted. Furthermore, the label restriction, "For use on fresh market plums and prunes" is not considered practical or enforceable for a permanent tolerance.

Detailed Considerations

Manufacturing and Formulation (MRID No. 410312-01)

RH-7592 2F is a fungicide (liquid formulation) containing 24% (2lbs. ai/gal) RH-7592, 2-(2-(4-chlorophenyl)ethyl)-2-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile. RH-7592 is manufactured by Rohm and Haas, Co. Technical grade RH-7592 is certified to be 98% pure. The Confidential Statement of Formulation for RH-7592 Fungicide 2F; the manufacture of the TGAI; and a list of the impurities formed during manufacture of the TGAI are discussed in the Confidential Appendix to this review. We do not anticipate any residue problems from the impurities reported in the TGAI.

For the purpose of these temporary tolerances, we consider the manufacture of RH-7592, and the formulation of RH-7592 Fungicide 2F to be adequately described. However, the petitioner should be advised that a more detailed product chemistry data review will be conducted in connection with any future request for a permanent tolerance for RH-7592; additional product chemistry data may be required at that time.

Proposed Use

Rohm and Haas is requesting this temporary tolerance in connection with a proposed experimental use (707-EUP-RER) of RH-7592 2F fungicide on apricots, cherries, nectarines, peaches, and plums. The petitioner's purpose for requesting this EUP, include:

1.) To evaluate the fungicide's performance under standard field conditions.

2.) To determine the fungicide's optimum use rates, application timings and number of applications.

3.) To generate field residue data in support of a Section 3 registration.

4.) To provide performance characteristics for Rohm and Haas Sales personnel, agricultural dealers, and University and Cooperative Extension Service personnel.

To accomplish these goals, RH-7592 2F Fungicide will be used in accordance with the EUP label as follows:

Apricots, Cherries, and Nectarines

Diseases: Blossom Blight and Fruit Brown Rot.

Rate: 2.0 fl. oz. (0.033 lb ai)/100 gal, or 4 to 6 fl. oz. (0.066 to 0.1 lb. ai)/acre.

Application: For Blossom Blight, begin application 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, apply 3 and 2 weeks before harvest.

Restrictions: Do not apply within 7 days of harvest; do not apply more than 1.5 quarts (0.75 lb ai) RH-7592 fungicide per acre per season; apply only by ground equipment; do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock.

Peaches, Plums, and Prunes

Diseases: Blossom Blight, Fruit Brown Rot, and Scab.

Rate: 2.0 fl. oz. (0.033 lb ai)/100 gal, or 4 to 6 fl. oz. (0.066 to 0.1 lb. ai)/acre for Blossom Blight and Fruit Brown Rot. 3.0 fl. oz. (0.05 lb. ai)/100 gal. or 7.5 fl. oz. (0.125 lb ai)/A for Scab.

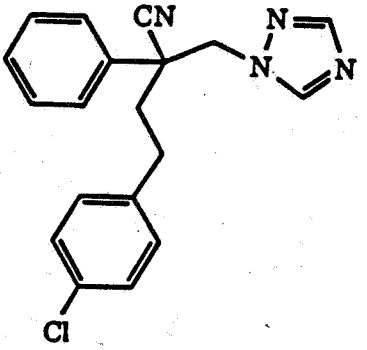
Application: For Peach, plum, and prune Blossom Blight; begin application at red bud stage (about 5% bloom). If conditions are favorable for disease development, apply again at full bloom and at petal-fall. For Fruit Brown Rot, apply 3 and 2 weeks before harvest. For Plum and Prune Rust begin application at Red Bud stage (about 5% bloom) making additional applications on a 10 to 14 day schedule as long as necessary. For treatment of peaches for Scab, the directions are not clearly stated.

Restrictions: Do not apply within 7 days of harvest; do not apply more than 2.0 quarts (1.0 lb ai) RH-7592 fungicide per acre per season; apply only by ground equipment; do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock; for use on fresh market plums and prunes only.

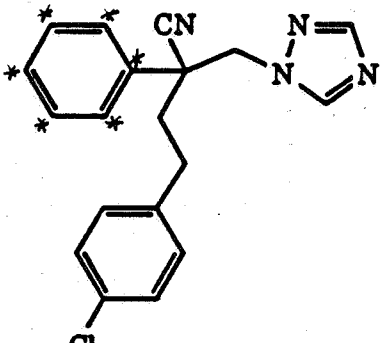
707-EUP-RER calls for conducting 292 field trials over a two year period, as follows:

Region	State	No. Trials	No. Acres	Total lbs. a.i.
Western				
	CA	100	250	188
	ID	10	25	18
	MT	4	10	8
	OR	16	40	30
	UT	8	20	16
	WA	16	40	30
	Subtotal	154	385	290

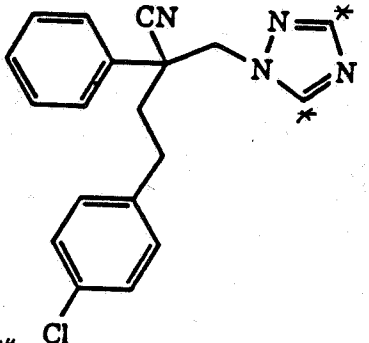
Table continued:



RH-7592

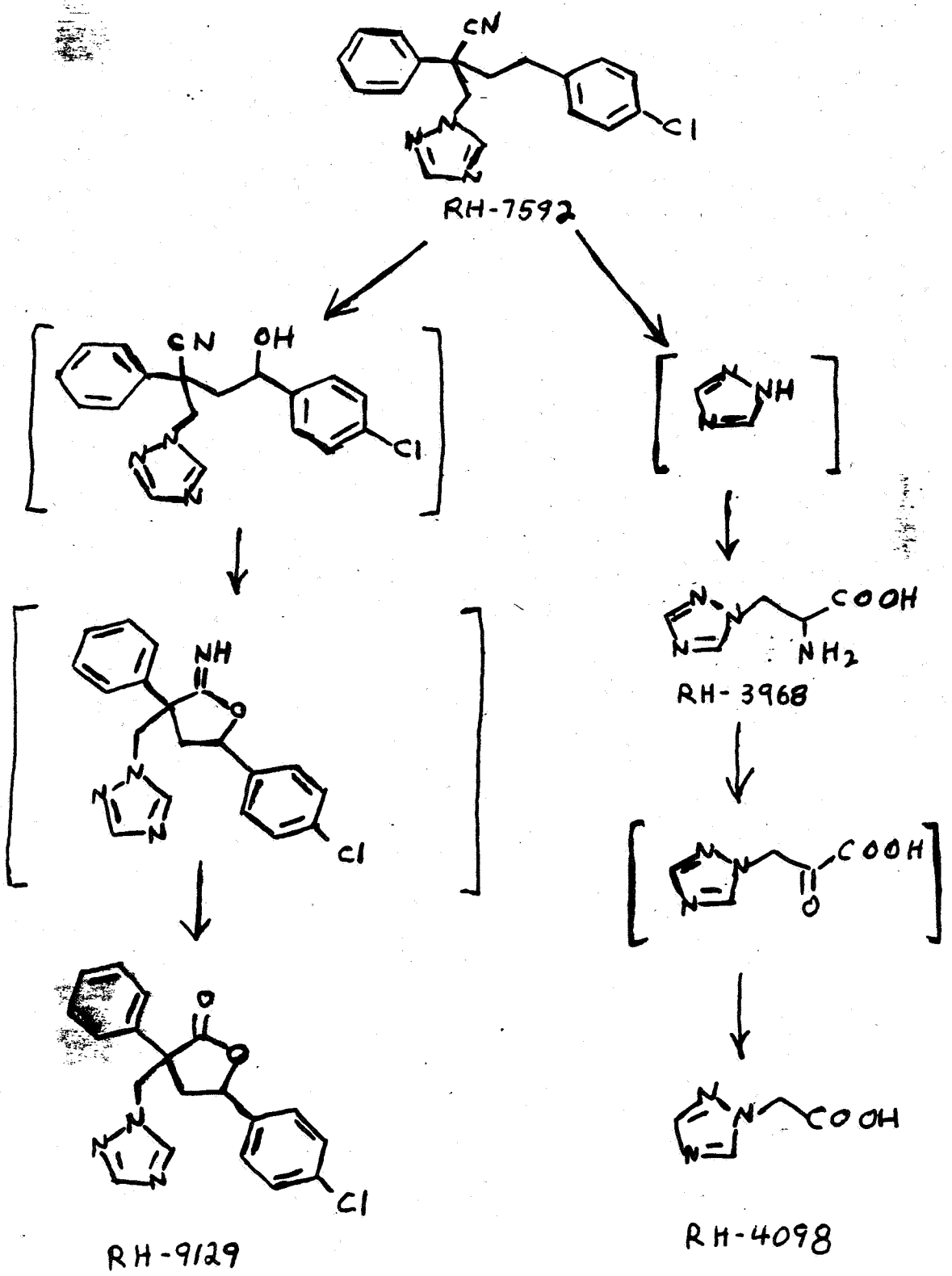


^{14}C-PHE-RH-7592



^{14}C-TRI-RH-7592

Structure of RH-7592 and Position of C-14 Label



Proposed pathway of metabolism on Peaches

FENBUCONAZOLE

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Pages 8 through 9 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

✓ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Region	State	No. Trials	No. Acres	Total lbs. a.i.
Central				
	AL	2	5	4
	AK	4	10	8
	CO	4	10	8
	IL	2	5	4
	IN	2	5	4
	LA	4	10	8
	MI	16	40	30
	MO	2	5	4
	OH	2	5	4
	OK	2	5	4
	TX	8	20	16
	WI	8	20	8
	Subtotal	56	140	110
Eastern				
	GA	16	40	30
	MD	6	15	12
	NJ	12	30	24
	NY	4	10	8
	NC	8	20	16
	PA	8	20	15
	SC	16	40	30
	VA	8	20	16
	WV	8	10	8
	Subtotal	82	204	158
Grand Total		292	730	558

NATURE OF THE RESIDUE (MRID No. 410735-08)

Plants: The petitioner submitted a report entitled: Metabolism of ^{14}C-7592 in Peaches (Rohm and Haas Technical Report No. 34S-88-24, by Douglas R. Hawkins, Ph.D., 9-15-88). This report provides a detailed description of the study, which is briefly discussed below:

TEST MATERIALS AND METHOD

^{14}C RH-7592 labeled in the phenyl-ring (PHE-RH-7592) and triazole-ring (TRI-RH-7592) were utilized for this metabolism study (see attachment #1). ^{14}C-PHE-RH-7592 (lot # 595-0105) was reported to be 98.5% pure with a Specific Activity of 20.83 mCi/g (46,243 dpm/ug). ^{14}C-TRI-RH-7592 (lot 577.0108) was reported to

be 98.8% pure with a Specific Activity of 20.95 mCi/g (46,509 dpm/ug).

^{14}C-PHE-RH-7592 (0.1728 g) was diluted with RH-7592 technical (0.1869 g; 96.7% ai); similarly, ^{14}C-TRI-RH-7592 (0.17178 g) was diluted with RH-7592 technical (0.1887 g). The diluted test materials were dissolved in methylene chloride and divided into six vials each containing ca. 29 mg of ai. These vials were used to formulate a 6.8% EC test substance, as needed.

Three mature Red Haven peach trees, located in field K-1 at Rohm and Haas' Newtown PA research farm, were used in this study. One tree was treated with ^{14}C-PHE-RH-7592, another with ^{14}C-TRI-RH-7592, and the third tree was utilized as an experimental control. Treatments were initiated before blossom and were continued up to 22 days prior to harvest. A total of 5 applications, using a hand held compression air sprayer, were made as shown in Table 1 below:

Table 1: Treatment of peach trees with ^{14}C-PHE-RH-7592 and ^{14}C-TRI-RH-7592.

Date	Rate lbs. ai/A ^{14}C-PHE-RH-7592	^{14}C-TRI-RH-7592
4/27/87	0.21	0.20
5/22/87	0.23	0.20
6/11/87	0.09	0.18
6/29/87	0.12	0.17
7/20/87	0.24	0.24
Total dose =	0.89	0.99
Average rate =	0.18	0.20

Samples of foliage and peaches (when available) were taken before and after the first, third, and fifth application and at regular intervals thereafter until harvest. Mature peaches were harvested on 8/11/87 (22 day PHI), immediately transported to Rohm and Haas' Spring House Laboratories, and frozen (same day) until analyzed. Peach samples were prepared for analysis by grinding the pitted fruit with dry ice. The analysis of ^{14}C-PHE-RH-7592 treated peaches was begun on 8-17-89; while the analysis of ^{14}C-TRI-RH-7592 treated peaches was begun 8-28-89.

Determination of Total Radioactive Uptake and Residue Decline

Samples of fruit and leaves were combusted using a Packard Tri-Carb Oxidizer. Radioactive $^{14}CO_2$ was trapped in Oxisorb-Oxiprep solution and counted utilizing a Packard Tri-Carb Liquid Scintillation Counter. The initial uptake/distribution and

subsequent decline of the total radioactive residue (TRR) resulting from 5 treatments are summarized in Table 2 below:

Table 2: Uptake/distribution and decline in radioactivity

	TRR (ppm as RH-7592 equivalent)			
	^{14}C-PHE-RH-7592		^{14}C-TRI-RH-7592	
PHI	Leaves	Fruit	Leaves	Fruit
0	9.9	0.44	3.8	0.37
7	5.3	0.06	3.5	0.11
14	5.3	0.08	3.1	0.11
22	3.0	0.084	0.8	0.12

These data show a substantial decline in the TRR in or on fruit after the first 7 days, followed by a period of constant residue values. The decline in the TRR in or on leaves was less abrupt. Based on linear regression analysis of these data, the half life for RH-7592 ranged from 10.7 to 15.3 days on fruit, and from 10.3 to 14.1 days on leaves.

Extraction of Radioactivity

Three separate extraction techniques were tested.

Soxhlet Extraction: ca. 55 to 60 g of peach homogenate was extracted overnight with refluxing methanol. The sample remaining in the thimble was allowed to cool and assayed for unextracted radioactivity by combustion analysis. The methanol extraction solvent was concentrated to dryness, diluted with Hydroflur, then counted for radioactivity.

Polytron Extraction: ca 50 g of peach homogenate and 300 mL of methanol were further homogenized with a Polytron at high speed for 2 minutes. The suspension was centrifuged and the supernatant liquid was removed. The solid material was assayed by combustion analysis for unextracted residues; the supernatant was concentrated to dryness, diluted with Hydroflur, then counted for radioactivity.

Blender Extraction: ca. 150 g of peach homogenate was placed in Waring Blender, methanol was added and the mixture was blended at high speed for 1 minute, then filtered. The filter cake was assayed by combustion analysis for unextracted radioactivity. The filtrate was concentrated to dryness, diluted with Hydroflur then counted for radioactivity.

The efficiencies of these extraction techniques with respect to the removal of ^{14}C-TRI-RH-7592 from treated peaches are shown in Table 3 below:

Table 3: Extraction of TRR from ^{14}C-TRI-RH-7592 treated peaches using 3 separate techniques:

Ext. Method	Extraction Efficiency
Soxhlet	98%
Polytron	95%
Blender	95%
Average	96% (ca 0.08 ppm equivalent)

Since the Soxhlet technique was the most efficient, it was also used to extract ^{14}C-PHE-RH-7592 treated peaches. The extraction efficiency was 93.6%.

Partitioning of Radioactivity

The methanol extract was concentrated to dryness, and the residue was partitioned between water and chloroform or water and methylene chloride. The aqueous and organic phases were separated and the aqueous phase was washed with organic solvent. The organic wash was combined with the organic phase. In select samples, the organic phase was subjected to acid and base washes. Aqueous extracts of some ^{14}C-TRI-RH-7592 treated samples were pH adjusted (1 to 10) and partitioned against ethyl ether or 1-butanol. Ethyl acetate was used to extract minor components not extracted by ethyl ether. The results of these various extraction schemes are summarized in Table 4 and 5 below:

Table 4: Partitioning of extracted TRR (0.084ppm) from ^{14}C-PHE-RH-7592 treated peaches.

Solvent	% TRR	Equivalent in ppm (as RH-7592)
Chloroform	70.5	0.057
Ethyl Acetate, pH 4	5.4	0.004
Ethyl Acetate, pH 10	10.3	0.008
Butanol, pH 10	4.3	0.003
Butanol, pH 1	1.5	0.001
Aqueous	1.6	0.001
total =	93.6%	0.075 ppm

Table 5: Partitioning of extracted TRR (0.12ppm) from ^{14}C-TRI-RH-7592 treated peaches.

Solvent	% TRR	Equivalent in ppm (as RH-7592)
Chloroform	21.5	0.028
Ether, pH 4	0.3	<0.001
Ether, pH 1	---	---
Ether, pH 10	---	---
Butanol, pH 10	4.4	0.005
Butanol, pH 1	3.9	0.005
Aqueous	68.6	0.084
total =	98.7%	0.122 ppm

The data presented in Tables 4 and 5 shown that both polar and non-polar metabolites are present. Furthermore, these data indicate that the non-polar metabolite(s) are molecules which include the intact parent structure; and that the polar metabolite(s) contain the triazole moiety.

Identification of Extracted Radioactivity

Chloroform Extracted Radioactivity: TLC characterization of the chloroform extracted radioactivity (0.028 ppm) from ^{14}C-TRI-RH-7592 treated peaches showed 77% (0.020 ppm equivalent) of the radioactivity to be RH-7592, and 21.4% (0.006) of the radioactivity to be the lactone metabolite (RH-9129) of RH-7592. TLC characterization of the chloroform extracted radioactivity (0.057 ppm) from ^{14}C-PHE-RH-7592 treated peaches showed 40.9% (0.033 ppm) of the radioactivity to be RH-7592, and 14.2% (0.011 ppm) to be the lactone metabolite RH-7592. GC quantification of TLC scraped eluents showed similar results. The identification of these components were verified by GS/MS.

Aqueous Extracted Radioactivity: Ion exchange (cation) separation followed by TLC characterization of the aqueous extracted radioactivity (0.084 ppm) from the ^{14}C-TRI-RH-7592 treated peaches showed 74% (0.062 ppm) of the radioactivity to be triazole alanine (RH-3968), and 11% (0.009 ppm) to be triazole acetic acid (RH-4098).

Chemical identification of the extracted radioactivity is summarized in Table 6 below:

Table 6: Characterization of extracted Radioactivity from ^{14}C-RH-7592 treated peaches:

	Peaches treated with	
Componentsa	^{14}C-TRI-RH-7592 % TRR (equivalent)[b]	^{14}C-PHE-RH-7592 % TRR (equivalent)[b]
RH-7592 (parent)	15.5 (0.020)	45.0 (0.036)
RH-9129	4.3 (0.006)	14.2 (0.011)
RH-3968	47.5 (0.062)	---
RH-4098	6.7 (0.009)	---
Identified subtotal =	74.0 (0.097)	59.2 (0.047)
unknowns: extracted with EtOAc, butanol, or ether		
1	1.3 (0.002)	1.7 (0.001)
2	1.5 (0.002)	1.8 (0.001)
3	1.0 (0.001)	1.1 (0.001)
4	0.6 (0.001)	0.3 (<0.001)
Aqueous unknown	7.9 (0.01)	-------
Unk. Subtotal =	12.30 (0.016)	4.9 (0.003)
Grand total =	86.30 (0.11)	64.1 (0.05)

a. see attachment #2 for chemical structures.

b. based on molecular weight of RH-7592, actual concentration of RH-3968 is 0.029 ppm, and for RH-4098 is 0.003 ppm.

Based on these data, Rohm and Haas Co. has proposed the metabolite pathway shown in attachment 2 of this review. We concur that these data support this metabolic pathway.

Magnitude of the residue

Analytical method (MRID No. 410312-39)

Residue data were generated using a capillary column gas chromatograph equipped with an thermionic detector operated in the nitrogen mode. The method is entitled: "A Residue Analytical Method for Parent RH-7592 in Stone fruit", and is fully described in Rohm and Haas Technical Report No. 34S-88-20. The method is briefly described below:

Sample preparation: Stone fruit received by the laboratory in a frozen state (packed in dry ice) were pitted, and chopped with

dry ice. The dry ice was allowed to sublime overnight in a freezer (4 F) then frozen at -10 F until analyses.

Extraction/partition step: 25 g of sample plus 5 to 10 g. of Celite-545 and 100 mL of methanol are blended and filtered. The filtrate is diluted with 250 mL of 10% NaCl solution and partitioned against 150 mL of methylene chloride. The organic phase is removed, concentrated to dryness, and reconstituted in 25 mL of toluene/acetone (100/15).

Column cleanup: the reconstituted sample (25 mL toluene/acetone: 100/15) is loaded on a 14.5 mm ID chromatographic column packed with 10 cc of activated BioSil A (Bio-Rad) topped with a 1 inch layer of anhydrous sodium sulfate. The column is rinsed with an 35 mL of toluene/acetone (100/15) then eluted with 150 mL of toluene/acetone (100/25). The eluent is concentrated to dryness, reconstituted in 25 mL of toluene and loaded on a 14.5 mm ID chromatographic column packed with 7 cc of activated florisil topped with 1 inch of anhydrous sodium sulfate. The column is rinsed with 10 mL of toluene, then eluted with 150 mL of toluene/acetone (100/10). The eluent is concentrated to dryness and reconstituted in an appropriate volume of toluene/acetate (100/3) and analyzed by gas-chromatography.

Gas chromatography: an aliquot (ca 2 uL) of the sample workup is injected into a capillary column gas-chromatograph operated under the following set of conditions:

Detector: Thermionic operated in the nitrogen mode.

Column: 0.53 mm ID Fused silica (SPB-608), 15 meters, 0.5 um df

Temperatures: Column 245 C
Injector 255 C
Detector 300 C

Flows: Air: 175 mL/MIN
Hydrogen: 4.5 mL/min
Helium: 18.7 mL/min

Under these conditions, RH-7592 eluted at 4.2 minute.

Quantification: The concentration of RH-7592 in treated samples was calculated by construction of a least squares linear regression curve, constructed using external standards. The method's limit of detection is 0.01 ppm. Data showing the recovery of RH-7592 from stone fruit fortified with RH-7592 are summarized in Table 7 below:

Table 7: Recovery of RH-7592 from fortified stone fruit.

Commodity	Fortification Level (ppm)	% Recovery Range	Average
Peaches	0.04 - 1.6	62 - 116	93.95 (N=20)
Cherries	0.10 - 0.49	75 - 110	93.9 (N=10)
Plums	0.01 - 0.49	75 - 97	90.0 (N=8)

Over all recovery = 93 % with a Std. Dev. of 12%

Residue Data

Peaches (MRID No. 410312-41): 5 field trials in CA(2), PA(1), AK(1), and NC(1) were conducted during 1987. These 5 States accounted for ca. 42% of the peach production during the 1987 growing season (Agricultural Statistics, 1988). Residue data generated in these field studies reflect multiple applications (7 to 10) of RH-7592 Fungicide 2F at 0.1 and 0.2 lbs. ai/A using hand operated spray equipment. Peaches harvested 0, 7, 14, and 21 days after the final application of RH-7592 Fungicide, were packed in dry ice and shipped to Rohm and Haas Research Laboratory at Spring House, PA. When received by the laboratory, all samples were pitted, homogenized and stored (186 to 447 days) at -10 C. Samples were analyzed using the GC/NPD method described in MRID No. 410312-39. Data generated from these field trials are summarized in Table 8 below:

Table 8: RH-7592 residues in or on peaches from field trials.

Site	Rate lbs/A	Total lbs/A	PHI (days)	Residue[a] in ppm
CA	0.1	0.7	0	0.278
			14	0.196
			21	0.136
CA	0.2	1.4	0	1.190
			14	0.257
			21	0.237
CA	0.1	0.7	7	0.184
			14	0.088
CA	0.2	1.4	7	0.290
			14	0.372
PA	0.1	0.8	0	1.490
			7	0.408
			14	0.308
			21	0.238
PA	0.2	1.6	0	0.922
			7	0.778
			14	0.842
			21	0.396
AK	0.2	1.8	7	0.219
			14	0.062
NC	0.1	1.0	7	0.437
			14	0.457
NC	0.2	2.0	7	1.330
			14	1.400

a. average value, where n=2 for most of the reported values.

Residue data, reflecting a 7 day PHI and an application rate 0.7 to 1.4 times the rate proposed by 707-EUP-RER, ranged from 0.184 to 0.437 ppm.

Residue data, reflecting a 7 day PHI and an application rate 1.6 to 2 times the rate proposed by 707-EUP-RER, ranged from 0.219 to 1.33 ppm. The high value corresponded to a 2x rate.

Cherries (MRID No. 410312-42): 7 field trials in CA(2), PA(1), MI(2), WI(1) and OR (1) were conducted during 1987/88. These 5 States accounted for ca. 61% of the sweet cherries, and 72% of the tart cherries production during the 1987 growing season (Agricultural Statistics, 1988). Residue data generated in these field studies reflect multiple applications (4 to 6) of RH-7592 Fungicide 2F at 0.1 and 0.2 lbs. ai/A using hand operated spray equipment. Cherries harvested 7 and 14 days after the final application of RH-7592 Fungicide, were packed in dry ice and shipped to Rohm and Haas Research Laboratory at Spring House, PA. When received by the laboratory, all samples were pitted, homogenized and stored (416 to 496 days) at -10 C. Sample were analyzed using the GC/NPD method described in MRID No. 410312-39. Data generated from these field trials are summarized 9 below:

Table 9: RH-7592 residues in or on cherries from field trials.

SITE	Rate lbs/A	Total lbs/A	PHI (days)	Residue[a] in ppm
CA	0.1	0.5	7	0.252
			15	0.284
CA	0.1	0.1	7	0.216
			15	0.409
MI	0.1	0.6	7	0.471
			14	0.209
MI	0.1	0.6	7	0.427
			14	0.274
PA	0.1	0.4	14	0.144
	0.2	0.8	14	0.272
OR	0.1	0.5	7	0.01
			14	ND (<0.01)

a. average value, where n=3

Residue data, reflecting a 7 day PHI and an application rates 0.66 to 1.07 times the rate proposed by 707-EUP-RER, ranged from 0.01 to 0.427 ppm.

Plums (MRID No. 410312-43): 4 field trials in CA(3), and WA(1) were conducted during 1987. Residue data generated in these field studies reflect multiple applications (7-9) of RH-7592 Fungicide 2F at 0.1 lbs. ai/A using hand operated spray equipment. Plums harvested 6, 7, 9, and 14 days after the final application of RH-7592 Fungicide, were packed in dry ice and shipped to Rohm and Haas Research Laboratory at Spring House, PA. When received by the laboratory, all samples were pitted, homogenized and stored (441 to 486 days) at -10 C. Sample were analyzed using the method described in MRID No. 410312-39. Data generated from these field trials are summarized 10 below:

Table 10: RH-7592 residues in or on plums from field trials.

SITE	Rate lbs/A	Total lbs/A	PHI (days)	Residue[a] in ppm
CA	0.1	0.9	6	0.072
			14	0.015
CA	0.1	0.7	9	0.026
			14	0.008
CA	0.1	0.8	7	0.046
			14	0.071
WA	0.1	0.8	7	ND (<0.01)
			14	0.274

a. average value, where n=3 in most cases.

Residue data, reflecting a 6 or 7 day PHI and an application rate 0.7 to 0.9 times the rate proposed by 707-EUP-RER, ranged from <0.01 to 0.076.

Storage stability study

Samples of stone fruit, used to generate field residue data, were stored at -10 C for up to 496 days. No storage stability data were provided to assure that these data reflect "at-harvest" residues. Since residue data from the field trials (samples stored up to 496 days) were in reasonable agreement with residue data from the plant metabolism study (samples stored for 2 to 3 weeks), we will assume (for the purposes of this temporary tolerance request only) that RH-7592 is stable under frozen storage, and that the submitted data reflect "at-harvest" residues.

Processing Studies

No processing studies were provided. The only RAC in the stone fruit crop group requiring a food additive tolerance is plums. Plums may be processed to dried prunes. To alleviate the need for a food additive tolerance for dried prunes, the petitioner has included the restriction " For use on only fresh market plums and prunes" on the EUP label.

For the purpose of this temporary tolerance request, we conclude that plums treated in accordance with 707-EUP-RER will remain under the control of the grower, and that the proposed label restriction is reasonable.

Meat, milk, poultry and eggs

No animal feed items are included in 707-EUP-RER.

Attachments: 1. Chemical Structures for RH-7592, and position of C-14 Label.

2. Chemical structures for metabolites RH-9129, RH-3968, and RH-4098; also proposed metabolic pathway in stone fruit.

cc with confidential appendix: R.F., S.F., PP#9G3746, Reviewer, PMSD/ISB

cc without confidential appendix: Circ., SACB (Tomerlin)

RDI:LC:11/13/89:EZ:11/15/89
H7509C:FBS:fbs:557:1883:CM#2:RM810:11/15/89

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Page 22 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

✓ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.