8-2-91
EFGWB # 91-0747
-0748

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

AUG - 2 1991

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: New Chemical Screen for RH-7592 (Fenethanil)
Other Names: Fenbuconazole, Indar 2F
Chemical No. 129011
CAS Reg. No. 114369-43-6
File Symbol/Reg. No. 707-EGN
DP Barcode: D166377

TO: C. Giles-Parker/D. Wilson
Product Manager 22
Registration Division (H7505C)

THRU: Henry Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

THRU: Paul J. Mastradone, Chief
Review Section 1
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

FROM: Arnet W. Jones, Agronomist
Review Section 1
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

The registrant (Rohm and Haas Co.) has requested a new chemical screen for RH-7592 Agricultural Fungicide (common names Fenethanil, Fenbuconazole, Indar 2F) for use on stone fruits and pecans. At present there are insufficient data for RH-7592 to pass the new chemical screen.

Studies have been submitted in support of all data requirements for terrestrial food crop uses. Some environmental fate data requirements -- hydrolysis (161-1), aerobic soil metabolism (162-1), anaerobic soil metabolism (162-2), and leaching/adsorption/desorption (163-1) -- have been satisfied by studies submitted in support of experimental use permits (see attached DERs). However, additional information for some of the outstanding environmental fate studies is required before RH-7592 will pass the new chemical screen.

The status of the environmental fate data requirements for the registration of RH-7592 for terrestrial food crop use is outlined below:

Data Requirement	Status	MRID No.
Degradation		
Hydrolysis (161-1)	Fulfilled[1]	41031426
Photodegradation water (161-2)	Passed NCS[2]	41875023
Photodegradation soil (161-3)	Passed NCS[2]	41875024
Metabolism		
Aerobic soil metab. (162-1)	Fulfilled[1]	41031247
Anaerobic soil metab. (162-2)	Fulfilled[1]	41031247
Mobility		
Leaching/ads./des. (163-1)	Fulfilled[1]	41031248
Dissipation		
Soil Dissipation (164-1)	Failed NCS[3]	41875026
Soil Dissip.- Long-term (164-5)	Reserved	
Accumulation		
Confined rotational crop (165-1)	Failed NCS[4]	41875027
Field rotational crop (165-2)	Reserved	
Bioaccumulation in fish (165-4)	Partially fulfilled[5]	41073509
Droplet size spectrum (201-1) and Drift field eval. (202-1)	Reserved[6]	

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1 These data requirements are fulfilled and copies of the DERs are attached. See EFGWB No. 90546, Oct. 12, 1989.

2 Studies in support of these data requirements were submitted with the new chemical screen (NCS) package. These studies appear to be reviewable and passed the NCS screen.

3 The terrestrial field dissipation study submitted with the NCS package is an interim study. Because RH-7592 is persistent (see the environmental fate assessment), the final results of field dissipation studies should be submitted.

[4] The confined rotational crop study submitted with the NCS package failed the screen because residues detected in plants were not identified. The study reports that "the identification of the residues found in this study will be reported separately."

[5] A bioaccumulation in fish study was reviewed previously (see EFGWB No. 90546, Oct. 12, 1989). The DER (copy attached) indicates that a residue in fish tissue described as "unknown 3" should be positively identified to fulfill the data requirement. A summary of environmental fate, residue, and metabolism studies submitted with the NCS package (MRID no. 41875021) apparently identifies this metabolite as "benzylic glucuronide", but the method used to identify the residue was not described.

[6] Information submitted with the NCS package indicates that RH-7592 is toxic to fish and aquatic invertebrates. It is likely that droplet size spectrum and field drift evaluation data will be required.

To pass the new chemical screen, additional information is required for the terrestrial field dissipation, confined rotational crop, and fish accumulation data requirements.

Environmental Fate Assessment

At present there is insufficient information to make a comprehensive environmental fate assessment for RH-7592. However, based upon previously reviewed laboratory studies and supplemental information, RH-7592 is stable. The compound does not hydrolyze at pH values found in the environment. It is metabolized slowly in soil under aerobic ($t_{1/2}$ = 285 and 367 days in silty clay loam and sandy loam soils, respectively) and anaerobic conditions ($t_{1/2}$ = 451 and 655 days in silty clay loam and sandy loam soils, respectively). RH-7592 and its degradation products appear to be slightly mobile to immobile in soil. It does not bioaccumulate in fish (maximum bioaccumulation factors were 170X, 50X, and 330X in whole fish, fillet, and viscera tissue, respectively) and 95-98% of accumulated residues were eliminated during a 14-day depuration period.

NOTE TO P.M.: The bean sheet indicates that MRID nos. 41875021-41875031 were included with the package. MRID no. 41875030 was not part of the package received by EFGWB. According to information included in the package, MRID no. 41875030 corresponds to a non-guideline-study titled "Insecticide Screening Report - Insecticidal Activity of RH-7592." This study would not be required by EFGWB.

EFGWB # 91-0747
91-0748

DP BARCODE: D166377

CASE: 006511 DATA PACKAGE RECORD DATE: 07/12/91
SUBMISSION: S399299 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 010 NEW CHEMICAL SCREENING
CHEMICALS: 129011 RH-7592 22.8000%

ID#: 000707-EGR INDAR 2F AGRICULTURAL FUNGICIDE
COMPANY: 000707 ROHM & HAAS COMPANY
PRODUCT MANAGER: 22 CYNTHIA GILES-PARKER 703-557-8540 ROOM: CM2 251
PM TEAM REVIEWER: DOLPHINE WILSON 703-557-3483 ROOM: CM2 255
RECEIVED DATE: 05/17/91 DUE OUT DATE: 06/16/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 166377 EXPEDITE: N DATE SENT: 07/12/91 DATE RET.: / /
CHEMICAL: 129011 RH-7592
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 08/11/91 CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	7/18/91	/ /
BRAN: EFGB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Please do science screen for new chemical. Attached are transmittal letters, MRID Nos 41875021-31, Pet 1F3989-stone fruits and dried prunes, Pet 1F3995-pecans.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
166372	TSCB	07/12/91	08/11/91	Y	Y	Y
166374	TB-2	07/12/91	08/11/91	Y	Y	Y
166375	EEB	07/12/91	08/11/91	Y	Y	Y

MRID #
→ 41875030 not w/ p/cg

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EFGWB# 91-0747
91-0748

DP BARCODE: D166370

CASE: 006510 DATA PACKAGE RECORD DATE: 07/12/91
SUBMISSION: S399293 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 010 NEW CHEMICAL SCREENING
CHEMICALS: 129011 RH-7592 98.3000%

ID#: 000707-EGN RH-7592 TECHNICAL FUNGICIDE
COMPANY: 000707 ROHM & HAAS COMPANY
PRODUCT MANAGER: 22 CYNTHIA GILES-PARKER 703-557-8540 ROOM: CM2 251
PM TEAM REVIEWER: DOLPHINE WILSON 703-557-3483 ROOM: CM2 255
RECEIVED DATE: 04/24/91 DUE OUT DATE: 05/24/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 166370 EXPEDITE: N DATE SENT: 07/12/91 DATE RET.: / /
CHEMICAL: 129011 RH-7592
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 08/11/91 CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	/ /	/ /
BRAN: EFGB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Please ~~due~~ science screen for new chemical. Attached are transmittal letters, MRID Nos 41875021-31, Pet 1F3989-stone fruits and dried prunes, Pet 1F3995-pecans.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
166361	TSCB	07/12/91	08/11/91	Y	Y	Y
166367	TB-2/IO	07/12/91	08/11/91	Y	Y	Y
166369	EEB	07/12/91	08/11/91	Y	Y	Y

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EFGWB/EFED

New Chemical Screen -- Summary Sheet

Chemical Name: _____

Acceptable Common Name: FENETHANIL

Product Name: RH 7592 INLAR 2F AGRICULTURAL FUNGICIDE

Type of Product: FUNG. Product Manager: D. WILSON Team: 22

Proposed Use Pattern: TERRESTRIAL FOOD CROP

Shaugh #: 129011 Registration #: _____ CAS#: 114369-43-3

Scheduled Date for Completion of EAB Chapter: __/__/__

STUDY SUBMITTED W/PACKAGE FROM RD?	Req?	40CFR§	Requirement	Pass/Fail	
Y	N	R	161-1	HYDROLYSIS	(P) F
	Y	R	161-2	PHOTOLYSIS IN WATER	(P) F NOTE: DID NOT USE
	Y	R	161-3	PHOTOLYSIS ON SOIL	(P) F SUBMITTED AS
		CR	161-4	PHOTOLYSIS IN AIR	P F
Y	N	R	162-1	AEROBIC SOIL METABOLISM	(P) F
Y	N	R	162-2	ANAEROBIC SOIL METABOLISM	(P) F
	N	NR	162-3	ANAEROBIC AQUATIC METABOLISM	P F → NOT SUBMITTED
		NR	162-4	AEROBIC AQUATIC METABOLISM	P F + NOT REQ'D
Y	N	R	163-1	LEACHING/ADSORPTION/DESORPTION	(P) F
		CR	163-2	VOLATILITY (LAB)	P F
		CR	163-3	VOLATILITY (FIELD)	P F
	Y	R	164-1	FIELD DISSIPATION (SHORT TERM)	P (F) SEE 42 FR 5226 PP. 51-79
		NR	164-2	AQUATIC (SEDIMENTS) DISSIPATION	P F
		NR	164-3	FORESTRY DISSIPATION	P F
		CR	164-5	FIELD DISSIPATION (LONG TERM)	P F
	Y	R	165-1	ACCUMULATION IN ROTATIONAL CROPS (CONFINED) — NR for perennial stone fruit	P (F) NO I.D. OF RESIDUES
		CR	165-2	ACCUMULATION IN ROTATIONAL CROPS (FIELD)	P F
		CR	165-3	ACCUMULATION IN IRRIGATED CROPS	P F
Y		CR	165-4	ACCUMULATION IN FISH	P (F) METABOLIT QUESTION
		CR	165-5	ACCUMULATION IN NON-TARGET ORGANISMS	P F

Comments: According to reference list submitted by Rohm + Haas, most studies w/ were missing were submitted by OOB.

Hydrolysis - 41031246

Aerob. Soil - " 47 *

Ads/Des. * - " 48

Aged Leach. " 49

Fish Accum. - " 50

* may include anaerob. soil data, too.

→ ANAEROBIC SOIL NOT SUBMITTED AND NOT INDICATED ON REF. LIST FROM R+H. BUT MAY BE INCLUDED IN AEROBIC SOIL STUDY.

FENETHANIL (RH 7592)

7/91

129011

161-1 HYDROLYSIS

	YES	NO
Was TGAI used?	___	___
Was ai within the known solubility, and below 250 ppm?	___	___
Was study conducted in darkness?	___	___
Was temperature fairly constant at about 25°C?	___	___
Was sterility assured (glassware, reagents, chemicals, etc.)?	___	___
Were volatiles trapped?	___	___
Were solutions buffered?	___	___
Did cosolvent (if any) exceed 1%?	___	___
Were pH's correct (5,7,9) ?	___	___
Was sampling adequate (time 0, and reasonable intervals)?	___	___
Was a reasonable attempt made to identify all degradates/hydrolysates which exceeded 10%?	___	___
Was material balance reasonable (>90% - <110%)	___	___
Were appropriate analytical methods provided?	___	___

COMMENTS: Hydrolysis study (O'Dowd, 41031246) was reviewed and found acceptable (EFGWB # 90546) - 10-12-89. Compound is stable to hydrolysis @ pH 5-9.

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(PH 7592)

7/25/91

FENETHANIL — 129011

Wang, MRID 41875023

161-2 PHOTOLYSIS IN WATER

		YES	NO
Was TGAI used?	p. 10	✓	
Was ai within the known solubility, and below 250 ppm?		✓	
Were volatiles trapped?	p. 11	✓	
Were solutions buffered?		✓	
Was pH correct (at pH of minimal hydrolysis) ?	pH 7	✓	
Did cosolvent (if any) exceed 1%? approx 1%	p. 13	✓	
If artificial light source was used, was comparison made to natural light (nature, intensity, spectrum and time of exposure)? - XENON ARC LAMP	p.	✓	
Were wavelengths <290 nm filtered?	p. 11	✓	
Were dark controls used?	p. 13	✓	
Were dark controls maintained at same temperature as exposed solutions?		✓	
Was temperature fairly constant at about 25°C?	p. 13	✓	
Was sterility assured (glassware, reagents, chemicals, etc.)?	p. 11	✓	
Was sampling adequate (time 0, and reasonable intervals)?	p. 13	✓	
Was material balance reasonable (>90% - <110%)	p. 26	✓	
Was a reasonable attempt made to identify all degradates/hydrolysates which exceeded 10%?	N/A	✓	
Were appropriate analytical methods provided?		✓	

COMMENTS:

conc. = $1.5^{+3.0}$ ppm in solution

- $t_{1/2}$ reported as 1283 days.

- Hydrolysis study indicates compd is stable at pH 5-9.

RH 7592

FENETHANIL (129011)

Wang, MRID # 41875024

161-3 PHOTOLYSIS ON SOIL

		YES	NO	
Was the TGAI of each active ingredient tested?		✓		
Was soil adequately characterized?	p. 24	✓		
Was soil used the same as in the aerobic soil metabolism study?	pp. 12, 24		✓	SOIL WAS NOT THE SAME AS AEROBIC SOIL METAB.
Was application rate consistent with analytical methods, so that degradates (if any) could be identified?		✓		
If artificial light source, was comparison made to natural light (nature, intensity, spectrum and time of exposure)?	p. 33	✓		
If natural light, were meteorological conditions reported?		N/A		
Were dark controls used?	p. 15	✓		
Were dark controls maintained at about the same temperature as the exposed soils?	p. 14	✓		
Was sampling adequate (time 0, and reasonable intervals)?		✓		
Were volatiles trapped?		✓		
Were halflives reported?		✓		
Was the temperature maintained fairly constantly between 20 and 30°C?		✓		
Was material balance reasonable (>90% - <110%)		✓		
Was a reasonable attempt made to identify all photoproducts which exceeded 10%?	p. 19	✓		
Were appropriate analytical methods provided?		✓		

NOTE:

COMMENTS: $t_{1/2}$ reported as 79 days; persistent

→ 3.8% of applied was highest amt. of applied as unknown; did not match any of reference stds.

10 ppm = appl. rate.

PES = post extraction solids

FENETHANIL - (129011)
Conditionally req'd

161-4 PHOTOLYSIS IN AIR

	YES	NO
Was the TGAI of each active ingredient tested?	___	___
Was application rate consistent with analytical methods, so that degradates (if any) could be identified?	___	___
If natural sunlight, was intensity measured, and compared to typical use site?	___	___
If artificial light source, was comparison made to natural light (nature, intensity, spectrum and time of exposure)?	___	___
Were dark controls used?	___	___
Were the dark controls maintained at about the same temperature as the experimental soil?	___	___
Was sampling adequate (time 0, and reasonable intervals)?	___	___
Was a reasonable attempt made to identify all photoproducts which exceeded 10%?	___	___
Were halflives reported?	___	___
Was material balance reasonable (>90% - <110%)	___	___
Were appropriate analytical methods provided?	___	___

COMMENTS:

→ Schieber (41031247)

already reviewed; acceptable; data entered satisfied

FENEMIPHOS (129011)

162-1 AEROBIC SOIL METABOLISM

	YES	NO
If radiolabeled, was purity specified?	___	___
Was TGAI of each active ingredient tested?	___	___
Were soil characteristics reported?	___	___
Was soil moisture maintained at approximately 75% of 0.33 bar?	___	___
Was soil a sandy loam, silt loam, or representative of intended use area?	___	___
Was temperature maintained fairly constantly, between 18 and 30°C throughout experiment?	___	___
Was sampling adequate (time 0, and reasonable intervals)?	___	___
Was a reasonable attempt made to identify degradates which exceeded 0.01 ppm?	___	___
Was halflife of parent reported?	___	___
Were halflives of major degradates reported?	___	___
Was material balance reasonable (>90% - <110%)	___	___
Were appropriate analytical methods provided?	___	___

COMMENTS:

FENOXYCARB (129011)

Schicker (41031247) - data waived, not
in EFGWB # 90546, 10-12-89

162-2 ANAEROBIC SOIL METABOLISM

	YES	NO
If radiolabeled, was purity specified?	___	___
Was the TGAI of each active ingredient tested?	___	___
Were soil characteristics reported?	___	___
Was soil moisture maintained at approximately 75% of 0.33 bar?	___	___
Was soil a sandy loam, silt loam, or representative of intended use area?	___	___
Was soil the same as in the aerobic metabolism study?	___	___
Were anaerobic conditions assured?	___	___
Was temperature maintained fairly constantly at between 18 and 30°C throughout experiment?	___	___
Was treated soil aged for one half-life or 30 days (whichever is lower) prior to initiation of anaerobic conditions?	___	___
Was sampling adequate (time 0, and reasonable intervals)?	___	___
Was a reasonable attempt made to identify degradates which exceeded 0.01 ppm?	___	___
Was the unextractable fraction excessively high?	___	___
Was halflife of parent reported?	___	___
Were halflives of major degradates reported?	___	___
Was material balance reasonable (>90% - <110%)	___	___
Were appropriate analytical methods provided?	___	___

COMMENTS:

162-3 ANAEROBIC AQUATIC METABOLISM

	YES	NO
If radiolabeled, was purity specified?	___	___
Was the TGAI of each active ingredient tested?	___	___
Were soil/sediment characteristics reported?	___	___
Was a 30-day flood used to assure anaerobic conditions?	___	___
Were aqueous conditions maintained?	___	___
Was temperature maintained fairly constantly at between 18 and 30°C throughout experiment?	___	___
Was sampling adequate (time 0, and reasonable intervals)?	___	___
Was a reasonable attempt made to identify degradates which exceeded 0.01 ppm?	___	___
Was the unextractable fraction excessively high?	___	___
Was halflife of parent reported?	___	___
Were halflives of major degradates reported?	___	___
Was material balance reasonable (>90% - <110%)	___	___
Were appropriate analytical methods provided?	___	___

COMMENTS:

FENETHANIL (129011)

Data reqm't satisfied – Schiober 41031248 & 49

EFGWB # 90546

163-1 LEACHING/ADSORPTION/DESORPTION

	YES	NO
Was the testing method one of the three acceptable ones?	___	___
If radiolabeled, was purity specified?	___	___
Was the TGAI of each active ingredient tested?	___	___
Were 4 soils used?	___	___
Were all soil pH's between 4 and 8?	___	___
Did one soil have a %OM < 1%?	___	___
Was one of the soils the same sandy loam used in the aerobic metabolism study?	___	___
Was the soil moisture maintained at 75% of 1/3 bar during the aging process?	___	___
Were soils completely characterized?	___	___
Was the amount of test substance which was added to the soil equivalent to the highest recommended label rate for a single application?	___	___
Was material balance reasonable (>90% - <110%)	___	___
If use pattern is domestic outdoor, greenhouse, aquatic or aquatic impact, was a Batch Equilibrium done?	___	___
For SOIL TLC...		
Was a reference standard used?	___	___
Was the soil R_f reported for parent and degradates?	___	___

(continued...)

FENETHANIL

Data requirement satisfied.

163-1 LEACHING/ADSORPTION/DESORPTION (cont'd)

	YES	NO
For SOIL COLUMN...		
Was elution volume equivalent to 20" (50.8 cm) times the cross-sectional area of the column?	___	___
Was the column length adequate?	___	___
Was distribution within the column determined?	___	___
For AGED LEACHING...		
Was test substance aged for 30 days or one half-life (whichever was shorter)?	___	___
Was a reasonable attempt made to identify degradates?	___	___
For BATCH EQUILIBRIUM...		
Was the test substance equilibrated at 4 concentrations?	___	___
Was adequate time allowed for complete equilibration?	___	___
Was a 0.01N Ca^{++} solution used?	___	___
Were the K_{ads} and K_{des} determined?	___	___
Were appropriate analytical methods provided?	___	___

COMMENTS:

GA - " " "
S. CA - cover crop (wheat)
N. CA - bare ground - 5 appl. @ 0.2 lb a.i/A

Appendix VII ⇒ methods

164-1 FIELD DISSIPATION (SHORT TERM)

	YES	NO	
Was the study conducted domestically (USA)?	✓		
Was a typical EP used? ~~[redacted]~~ (RH 7592-2F)	✓		
Was application at the highest recommended rate?	✓		
Were 2 sites used? - FOUR SITES USED	✓		
Were the sites typical of the proposed use pattern?		✓	Bare ground + cover crop ...
Were they large enough to be representative? 20' x 60'	✓		
Was meteorological data provided? (but not according to GLPs per protocol stmt)	✓		
Was soil completely characterized? p. 113	✓		
Were samples selected randomly? p - 114		✓	↗ composite ...
Were individual samples analyzed (vs composited)?		✓	composited into ...
Was sampling taken to a sufficient depth to define leaching (if any)?	✓		
Was material balance reasonable (>90% - <110%)			
Was the depth to the water table reported? p. 113	✓		
Were sampling intervals adequate to define $T_{1/2}$?	✓		
Was halflife of parent under field conditions reported?	✓		
Was the pesticide history of the site reported?	✓		
Was study conducted under typical use conditions?	✓		BUT NOT ON CROP WH/ WOULD BE MORE ...
Were appropriate analytical methods provided?	✓		

COMMENTS: ⇒ Minnesota $t_{1/2}$ = 77 days (much shorter than other locations) appl. in spring

PECANS - rate is 0.125 lb a.i/A (max. of 1 lb a.i/A) - multiple appl.

165-4 ACCUMULATION IN FISH

	YES	NO
Was a typical EP used?	___	___
Was the correct fish specie used (Bluegill Sunfish or Channel Catfish)?	___	___
Was study a flow-through type?	___	___
Was the pesticide concentration in the water reasonably constant?	___	___
Did the pesticide concentration exceed 1/10 the 96 hr LC_{50}?	___	___
Was a control group used?	___	___
Were fish exposed about 28 days?	___	___
Was a plateau reached for accumulation?	___	___
Was depuration about 14 days?	___	___
Was water sampled at appropriate intervals?	___	___
Was fish tissue appropriately analyzed (edible vs. viscera) at the various stages of accumulation and depuration?	___	___
Were extractable residues which exceeded 50 ppb adequately identified?	___	___
Were test conditions adequately described?	___	___
Were concentrations in H_2O/Fish adequately compared?	___	___
Was the level of degradates in the water unreasonably high?	___	___
Were appropriate analytical methods provided?	___	___

COMMENTS: EFGWB # 90546 indicates that "unknowns" also were identified. The environmental fate summary submitted by registrant indicates that parent + all degradates have been identified in fish tissue.

FENETHANIL (129011)

O'Dowd (41875027)

165-1 ACCUMULATION IN ROTATIONAL CROPS (CONFINED)

	YES	NO
Was application rate at/above maximum label rate for a single application?	✓	
Was a Sandy Loam used, or another type justified? p. 39		✓
Was the soil adequately characterized? p. 39	✓	
Were all three crop groupings used (small grain, leafy vegetable, root crop?	✓	
Were analyses performed on plant parts?	✓	
Were the residues adequately characterized?		✓
Was radiolabelled analytical grade pesticide used?	✓	
Was extraction scheme described, including all methodology?	✓	
Was material balance reasonable (>90% - <110%)		
Was soil analyzed at appropriate intervals, especially on day 0 (pre/post application)?	✓	
Were representative crops planted at appropriate intervals (30, 120, 210 and/or 360 days)?	✓	
Were appropriate analytical methods provided?	✓	

- WAS IT CONFINED?
- SERIOUSNESS OF PLANTBACK ISSUE/FAILURES?
- SANDY LOAM SOIL NOT USED (but used ex proposed appl.
- RESIDUES NOT IDENTIFIED

COMMENTS:

→ ID of residues will be reported separately."

DATA EVALUATION RECORD

STUDY IDENTIFICATION:

O'Dowd, M. L. 1988. RH-7592: Hydrolysis Study. Technical Report No. 34S-88-05. Rohm and Haas Company. MRID No. 410312-46.

TYPE OF STUDY: 161-1 Hydrolysis

REVIEWED BY:

Clinton Fletcher, Chemist
Review Section 1, EFGWB, EFED

Signature: Clinton Fletcher
Date: 10-3-88

APPROVED BY:

Paul J. Mastradone, Section Chief
Review Section 1, EFGWB, EFED

Signature: Paul J. Mastradone
Date: OCT 12 1988

CONCLUSIONS:

EFGWB concludes that the study is acceptable and satisfies the data requirement for the hydrolysis study. RH-7592 was stable to hydrolysis at pH 5, 7, and 9 during the 30 day incubation period.

Based on the results of the study, EFGWB concludes that RH-7592 will be stable to hydrolysis at pH levels found in the environment.

MATERIALS AND METHODS:

Sterile solutions of 0.1 ppm of ^{14}C-triazole-RH-7592 (specific activity 20.95 miCi/g or 46,509 dpm/ug, chemical purity 99.1%) in 0.1 M buffer solutions at pH 5 (acetate), 7 (phosphate) and 9 (borate). Individual sample tubes were maintained at 25 $\pm$ 1° C for 30 days in the dark. Samples were taken at days 0, 1, 2, 4, 8, 15, 22, and 30 after initiation of the study. Aqueous solutions were extracted with ethyl acetate and analyzed by thin-layer chromatography (TLC) with comparison with known standards. The separated radioactivity was located with autoradiography and quantitated by liquid scintillation counting (LSC) of the scraped plates. (Note: HPLC did not give reproducible chromatography separation due to interfering buffer salts.)

All buffers and glassware were autoclave sterilized.

REPORTED RESULTS:

The author reported that ^{14}C-RH 7592 was almost quantitatively extracted with ethyl acetate (extraction efficiency was 99.3%). Recovery ranged from 94.2% to 103.3% (average 99.4%). Table 2

During the course of the study, parent ^{14}C-RH-7592 accounted for 97.6% to 100% of the extracted radioactivity. Table 5.

Based on the results of the study, the author concluded that RH-7592 is stable to hydrolysis in aqueous solutions at pH 5, 7, and 9.

DISCUSSION:

EFGWB concludes that the study is acceptable and satisfies the data requirement for the hydrolysis study.

Based on the results of the study, EFGWB concludes that RH-7592 will be stable to hydrolysis at pH levels found in the environment.

Fenbuconazole

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DATA EVALUATION RECORD

STUDY IDENTIFICATION:

Schieber, C. 1988. Soil Metabolism of RH-7592. Technical Report No. 345-88-13. Rohm and Haas Co. MRID 410312-47.

TYPE OF STUDY: 162-1 Aerobic Soil Metabolism
162-2 Anaerobic Soil Metabolism

REVIEWED BY:

Clinton Fletcher, Chemist
Review Section 1, EFGWB, EFED
Signature: Clinton Fletcher
Date: 9-20-89

APPROVED BY:

Paul J. Mastradone, Section Chief
Review Section 1, EFGWB, EFED
Signature: Paul J. Mastradone
Date: OCT 12

CONCLUSIONS:

EFGWB concludes that the study satisfies the data requirements for both the aerobic and anaerobic soil metabolism studies.

Based on the results of the two studies, EFGWB concludes that RH-7592 will degrade in soil under aerobic conditions with a half-life of 285 and 367 days in Lawrenceville silty clay loam and Pasquotank sandy loam soils, respectively. Under anaerobic soil conditions RH-7592 will degrade with a half-life of 451 and 655 days in the Lawrenceville and the Pasquotank soils.

Mineralization to CO_2 and soil binding appear to be the major routes of dissipation of RH-7592 in soil maintained under aerobic conditions in the laboratory. Soil binding appears to be the major route of dissipation in soil maintained under anaerobic soil conditions in the laboratory.

MATERIALS AND METHODS:

1. Aerobic

Two soils, Lawrence silty clay loam and Pasquotank sandy loam (See Table II for characteristics) sieved through 2 mm mesh screen were fortified with either ^{14}C-triazole-RH-7592 or ^{14}C-phenyl-UL-RH-7592 to approximately 1 ppm by mixing soil with ^{14}C-RH 7592-spiked cellulose. A treated soil sample was taken of each soil and frozen for later analysis. A control sample was prepared by adding unspiked cellulose to soil sample. To facilitate isolation and identification of metabolites, a soil sample was treated with ^{14}C-RH-7592 to 30 ppm level. To measure microbial effects, a soil sample was autoclave sterilized and fortified to 1 ppm with ^{14}C-RH-7592.

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Fortified soil samples were placed in biometer flasks with a side arm containing NaOH to trap volatilized $^{14}CO_2$. Samples were maintained in the dark at a constant temperature of 25 ± 1° C. Soil moisture was monitored by either a moisture balance apparatus or by oven drying a soil sample.

A subsample of soil was taken at days 7, 14, 21, 28, 44, 61, 90, 120, 181, 240 and 363 days after treatment and frozen 1 to 3 days before analysis. The NaOH trap was replaced on days 5, 7, 14, 21, 28, 44, 61, 90, 120, 140, 153, 181, 216, 240, 282 and 363 (but not replaced).

2. Anaerobic

A soil sample was fortified and maintained under aerobic conditions as described above and aged for 30 days prior to initiating anaerobic conditions. After the 30 day aerobic aging (day 0 of anaerobic conditions) a soil sample was taken, the flask containing the soil was repeatedly evacuated with nitrogen gas then covered with oxygen-purged water (boiled) and then gassed with nitrogen. Soil and water samples were taken at days 17, 30 and 60 days after initiating anaerobic conditions. At sampling, the soil and water were swirled to mix than sampled. The slurry was filtered and soil air-dried.

3. Analytical

Total radioactivity in the NaOH trap was quantitated by liquid scintillation (LSC) counting of an aliquot of the trapping solution. The trapping solution was analyzed for residual radioactivity by LSC after barium chloride precipitation of the $^{14}CO_2$.

Total radioactivity in the soil samples was quantitated by LSC counting of $^{14}CO_2$ from combustion of soil samples. Total radioactivity in the various extraction phases was also quantitated by LSC of aliquots of the extracted fraction.

Soil samples were extracted with 70:30 acetonitrile/1.0 M acetic acid three times, aliquots combined, extracted with ethyl acetate and reduced in volume. Extracted radioactivity was re-dissolved in methanol then analyzed by normal phase thin-layer chromatography (TLC). Separated radioactive material was visualized on the TLC plate with autoradiography. The plates were then scraped of the radioactive areas and total radioactivity was measured by LSC.

^{14}C-Triazole residues were extracted from the aqueous phase of the extractions using affinity resin chromatography. After elution from the resin column the residues were derivatized with pentafluorobenzyl bromide and cleaned-up with column chromatography. The 1-pentafluorobenzyl-1,2,4-triazole was separated using TLC with co-chromatography of derivatized reference standard.

After organic solvent extraction, soil samples were refluxed with 70:30 acetonitrile/1.0 M acetic acid then extracted with 0.5 N NaOH to remove the bound humic and fulvic acid fractions. The aqueous fractions were partitioned with ethyl acetate and n-butanol then extracted radioactivity was analyzed by TLC. The aqueous fraction was extracted with resin chromatography to extract any triazole residues.

The preparative soil sample was extracted and analyzed as described above. Metabolites Nos. 1 (RH-9129), 2 (RH-9130), and 3 (RH-6467), were identified using co-chromatography (TLC and HPLC) of known chemical reference standards and structures were verified by GC/MS.

REPORTED RESULTS:

The author reports that recovery ranged from 88.3% to 116% of the applied radioactivity. The reported low recovery for day 28 was attributed to erroneous combustion data. Tables VII-X

The author noted that soil moisture was not maintained at 75% of 1/3 bar in the Pasquotank soil because of the difficulty in handling the soil at that moisture level. Although the soil moisture level was maintained at a relatively constant level during the study. During the study the soil moisture levels were 15.0%0 (day 0) to 11.5% (day 363) for the Lawrenceville soil and 19.7% (day 0) to 16.1% (day 363) for the Pasquotank soil. Table IV

1. Aerobic Metabolism Study

After 363 days incubation, $^{14}CO_2$ accounted for 35-37% and 21% of the applied ^{14}C-phenyl-RH-7592 in the Lawrenceville and Pasquotank soils, respectively. $^{14}CO_2$ accounted for 1.2%-1.5% of the applied ^{12}C-triazole-RH-7592 in both soils. Table V

Extractable ^{14}C in the Lawrenceville soil treated with either ^{14}C-triazole- or ^{14}C-phenyl-RH 7592 declined with increasing incubation time. 96.5%-97.4% at day 0 to 72.4%-75.2% at day 363. Correspondingly, bound residues increased with incubation from 2.3%-3.5% at day 0 to 24.8%-27.6% at day 365. Similar results were reported for the Pasquotank soil. Tables XI-XVIII.

Parent compound accounted for average of 47.8% and 59.0% of the extractable residues from application of ^{14}C-triazole-RH 7592 in the Lawrenceville and Pasquotank soils, respectively, after 363 days incubation. Parent compound accounted for 32.9% and 50.3% of the applied ^{14}C-phenyl-RH-7592 in the Lawrenceville and Pasquotank soils, respectively. Metabolites RH-9129, RH-9130 and RH-6467 increased with time during the incubation period, accounting for 2.5%-9.6% of the applied radioactivity in both soils treated with both radiolabels. Triazole accounted for 11.2%-13.6% and for 6.5%-6.6% of applied ^{14}C-triazole-RH-7592 in the Lawrenceville and Pasquotank soils, respectively. Tables XIX-XXVI (See Figure 2 for structures of metabolites and proposed metabolic degradation pathway.)

Based on the results of the study the author calculated the half-lives of RH-7592 to be 258 and 367 days in the Lawrenceville and Pasquotank soils, respectively.

No degradation was observed in the sterile soils.

2. Anaerobic Metabolism Study

The author reported a material balance ranging from 81.0% to 119% and 75.7%-95.9% of the applied radioactivity in both the Lawrenceville and Pasquotank soils treated with ^{14}C-triazole- and ^{14}C-phenyl-RH-7592, respectively. For the most part, the higher values occurred at the beginning of the study and the lower values after 30 and 60 days incubation. Tables XXXI-XXXII.

Of the applied radioactivity, 90.9%-93.8% was extracted at day 0 and that extractable declined to 76.8%-78.3% by day 363 of anaerobic soil conditions. Also, 6.2%-9.7% of the applied radioactivity was bound to the soil at day 0 and increased to 23.6% by day 60 under anaerobic soil conditions. Tables XXXIII-XXXVI.

Parent-RH-7592 accounted for the majority of the radioactive residues under anaerobic soil conditions. Parent RH- 7592 accounted for an average of 80.9% of the applied radioactivity at day 0 of anaerobic conditions (day 30 of aerobic conditions) and averaged 73.2% of the applied radioactivity after 60 days incubation under anaerobic soil conditions. During the study metabolites RH-9129 and combined RH-9130/RH-6467 accounted for 0.6% (at day 0) to 7.33% (at day 60) of applied radioactivity, respectively. Table XL

Based on the results of the study, the author calculated the half-life of RH-7592 to be 451 and 655 days in the Lawrenceville and the Pasquotank soils, respectively, maintained under anaerobic conditions.

DISCUSSION:

EFGWB concludes that the study satisfies the data requirements for the aerobic and anaerobic soil metabolism studies.

Based on the results of the two studies, EFGWB concludes that RH-7592 will degrade in soil under aerobic and anaerobic conditions with a half-life of 285 and 367 days in Lawrenceville silty clay loam and Pasquotank sandy loam soils, respectively, under aerobic soil conditions and a half-life of 451 and 655 days in the Lawrenceville and the Pasquotank soils, respectively, under anaerobic condition.

In the aerobic study, metabolites RH-9129, RH-9130 and RH-6467 increased with time during the 363 day incubation period and accounted for 2.5%-9.6% of the applied radioactivity in both soils treated with both radiolabels.

In the anaerobic study, metabolites RH-9129 and combined RH-9130/RH-6467 accounted for 0.6% (at day 0) to 7.33% (at day 60) of applied radioactivity, respectively.

Mineralization to CO_2 and soil binding appear to be the major routes of dissipation of RH-7592 in soil maintained under aerobic conditions maintained in the laboratory. Soil binding appears to be the major route of dissipation in soil maintained under anaerobic conditions in the laboratory.

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DATA EVALUATION RECORD

STUDY IDENTIFICATION:

Schieber, C. 1988. Adsorption and Desorption of RH-7592. Technical Report No. 34S-88-06. Rohm and Haas Company. MRID No. 41312-49.

TYPE OF STUDY: 163-1 Mobility/Leaching

REVIEWED BY:

Clinton Fletcher, Chemist
Review Section 1, EFGWB, EFED
Signature: Clinton Fletcher
Date: 9-20-89

APPROVED BY:

Paul J. Mastradone, Section Chief
Review Section 1, EFGWB, EFED
Signature: Paul J Mastradone
Date: OCT 12 1989

CONCLUSIONS:

EFGWB concludes that this study satisfies the data requirement for 163-1 adsorption/desorption study.

Based on the results of the study, EFGWB concludes that RH-7592 will be only slightly mobile to immobile in soils. Adsorption appears to be associated with percent organic matter present. RH-7592 was slightly mobile in soils containing a low percent of organic material ($\leq$ 1%) and relatively immobile in soils with higher levels or organic material

MATERIALS AND METHODS:

1. Adsorption

^{14}C-triazole-RH-7592 (specific activity 20.29 miCi/g (46,509 dpm/ug, chemical purity 98%) in 0.01 N calcium chloride stock solutions ranging from 0.039 to 0.334 ppm concentration was added to air-dried (and sieved through 2 mm mesh screen) clay, sand, sandy loam and silty clay loam in duplicate tubes, wrapped in foil and shaken for 24 hours to reach equilibrium in enclosed chamber maintained at 25 $\pm$ 1° C. See Table II for soil characteristics.

Samples were centrifuged and aliquots of the supernatant were taken. Radioactivity in the supernatant solution was quantitated by liquid scintillation counting (LSC).

2. Desorption

Following adsorption study, soil was re-suspended in 0.01 N calcium chloride and shaken for 72 hours then centrifuged. An aliquot of the supernatant was taken and the radioactivity was quantitated by LSC.

Total radioactivity in the soil was determined by combustion and quantitated by LSc of the released $^{14}CO_2$.

Test solutions without soil were shaken for 24 hours to measure any loss of radioactivity due to adhesion of RH-7592 to the vessel walls during the study.

Adsorption and desorption coefficients were calculated based on the Freundlich Equation.

The organic material from the adsorption supernatant was passed through Sep-paks (adsorption chromatography), eluted from the column with methanol, evaporated to dryness and redissolved in methanol. Extracted radioactivity was analyzed by normal phase thin-layer chromatography (TLC). Radioactive areas were located by autoradiography then quantitated by scrapping the plate of the radioactive areas and quantitating by LSC. High performance liquid chromatography was also used to identify ^{14}C-RH-7592 in the supernatant of the adsorption test.

REPORTED RESULTS:

The author reported the material balance averaged 95.8% (range 86.2-107.5%) of the applied ^{14}C-RH-7592. Table V

The author reports that TLC and HPLC analysis that RH-7592 was stable under the test conditions. Based on the results of the study, the following K_d values were calculated:

Soil	% OM	K_d Values		K_{oc}
		Adsorption	Desorption	
Clay	0.4	5.07	7.09	2185
Loam	2.4	75.21	147.66	5402
Sand	0.5	7.56	2.33	2607
Sandy loam	2.2	115.40	132.20	9042
Silty Clay Loam	1.2	20.08	33.0	2884

Based on these results, the author concluded that RH-7592 varied from slightly mobile in clay, sand and silty clay loam soils to being immobile in sandy loam and loam soils.

DISCUSSION:

EFGWB concludes that this study satisfies the data requirement for 163-1 adsorption/desorption study.

Based on the results of the study, EFGWB concludes that RH-7592 will be only slightly mobile to immobile in soils. Adsorption appears to be associated with percent organic matter present. RH-7592 will be slightly mobile in soils containing a low percent of organic material ($\leq$ 1%) and relatively immobile in soils with

higher levels or organic material

While no reports on various equilibrium times were reported, the results of the study indicate the 24 hour equilibration time used in this study was sufficient.

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DATA EVALUATION RECORD

STUDY IDENTIFICATION:

Schieber, C. 1988. Aged Leaching Study of RH-7592. Technical Report No. 34S-88-09. Rohm and Haas Company. MRID No. 410312-48

TYPE OF STUDY: 163-1 Mobility/Leaching-Aged Residues

REVIEWED BY:

Clinton Fletcher, Chemist
Review Section 1, EFGWB, EFED
Signature: Clinton Fletcher
Date: 10-3-89

APPROVED BY:

Paul J. Mastradone, Section Chief
Review Section 1, EFGWB, EFED
Signature: Paul J Mastradone
Date: OCT 12 [illegible]

CONCLUSIONS:

EFGWB concludes that the study is acceptable and satisfies the data requirement for 163-1 mobility/leaching-aged residue study.

Based on the results of the study, EFGWB concludes that RH-7592 residues have only a slight potential to leach in the soil environment.

MATERIALS AND METHODS:

^{14}C-triazole-RH-7592 (specific activity [illegible].95 mCi/g, radiopurity 98.6%) and ^{14}C-phenyl-RH-7592 (specific activity 20.83 mCi/g, 98.0% radiopurity) sorbed onto cellulose were added to Pasquotank sandy loam soil (sieved through 2 mm mesh screen) to level of 1.0 ppm. Soil was aged under aerobic soil conditions in biometer flasks for 30 days in an environmental chamber maintained at 25 ± 1° C. Flasks were equipped with side arm containing 0.5 N NaOH solution to trap any volatilized $^{14}CO_2$. See Table II for soil characteristics

Prior to incubation, one soil sample was taken and frozen for later analysis, one sample was taken for combustion. A control blank soil sample was also maintained.

Four soil columns (5.5 cm dia.) were prepared using 6 cm segments of glass rings taped together. Sufficient soil was added for a final column height of 30 cm soil, pre-wetted and allowed to drain. After ageing, duplicate soil samples were taken and added to complete final 30 cm column height. A soil subsample was taken and frozen for later analysis.

Columns were eluted with 997 ml of water placed onto column in 200-300 ml aliquots over a 5-7 day period. Columns were maintained at

ambient temperature of 22° C. Elution time varied from 7 to 14 days.

After elution period, columns were divided into 5 6-cm segments and the soil air-dried then frozen at -6° C until analysis. Leachate and aqueous extraction fractions were refrigerated at 36° F prior to analysis.

The radioactivity in leachate fractions was quantitated by liquid scintillation counting (LSC), and in the soil by combustion and quantitation of $^{14}CO_2$. Volatilized radioactivity was quantitated by LSC and verified as $^{14}CO_2$ by barium chloride precipitation. Soil was extracted with 70:30 acetonitrile/1.0 M acetic acid twice, decanted and soil filtered. Soil was later re-extracted with the solution under heat (60° C) to remove additional radioactivity. The extraction fraction was partitioned with ethyl acetate, evaporated, re-dissolved in methanol then analyzed by normal phase thin-layer chromatography (TLC). Identity of extracted residues was by co-chromatography with known standard reference compounds. Separated radioactive areas were located with autoradiography. Located radioactivity was quantitated by scrapping the TLC plates and analyzing the scrapings by LSC.

REPORTED RESULTS:

The author reports that material balance for the four columns averaged 98% (range was 89.6% to 102.2%). Extractability of radioactivity from the soil before and after leaching was greater than 90%. Tables IVa and IVb

During the aging period, less than 1% of the applied radioactivity had volatilized as $^{14}CO_2$. Also, 99.0%-99.5% and 89.1%-101.7% of the ^{14}C-triazole- and ^{14}C-phenyl-RH-7592, respectively, applied to the soil column was found in the 0-6 cm soil column segment. (Note: 0-2 cm was applied fortified soil and 3-6 cm was upper portion of soil column.) No significant radioactivity (> 1%) was found below segment 1 of the soil column. The leachate contained 0.1-0.2% of the applied radioactivity. Tables IVa and IVb

Of the radioactivity in segment 1 of the column, 93.4%-94.8% and 78.0%-89.8% was extracted from the soil. Of this amount, 78.0% to 89.8% was parent RH-7592. Three degradation products ["1"-RH-99129 (diastereomer A); "2"-RH-99130 (diastereomer B); "3"-RH-96467] accounted for 1.5%-12.8% of the radioactivity applied. Table VI See Table VII for structures

Based on the results of the soil column study, the author calculated the sorption coefficient (K^{oc}) (correlating leaching potential with the sorption coefficient in soil column experiments) for RH-7592 to be 3445, indicating a slight potential for leaching. Compare values in Table VIII

DISCUSSION:

EFGWB concludes that the study is acceptable and satisfies the data requirement for 163-1 mobility/leaching-aged residue study.

Based on the results of the study, EFGWB concludes that aged RH-7592 residues have only a slight potential to leach in the soil environment.

EFGWB notes:

1. RH-7592 was adsorbed to cellulose then added to the soil for the aerobic aging period. This could affect the leaching potential. However, in this case, the adsorption study showed that RH-7592 adsorbed strongly to the same sandy loam soil (K_d of 115.4) as used here. Thus, EFGWB does not believe the use of celulose affected the results of this study. EFGWB does not recommend this practice for this study.

2. That the author did not report the time period that samples were stored prior to analysis and results of the storage stability study. However, the lack of these results do not affect the conclusions drawn from the study. The registrant should provide such data in future studies submitted to support registration.

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DATA EVALUATION RECORD

STUDY IDENTIFICATION:

O'Dowd, M. L. 1988. Laboratory Studies of Pesticide Accumulation in Fish; RH-7592 Metabolism in Bluegill Sunfish. ABC Laboratories for Rohm and Haas. MRID No. 410735-09.

TYPE OF STUDY: 165-4 Fish Accumulation

REVIEWED BY:

Clinton Fletcher, Chemist
Review Section 1, EFGWB, EFED

Signature: Clinton Fletcher
Date: 10-3-89

APPROVED BY:

Paul J. Mastradone, Section Chief
Review Section 1, EFGWB, EFED

Signature: Paul J Mastradone
Date: OCT 12 1989

CONCLUSIONS:

EFGWB concludes that this study partially satisfies the data requirement for a fish accumulation study.

The results of this study indicated that bluegill sunfish had maximum bioaccumulation factors of 170X, 50X and 330X in whole fish, fillet and viscera tissues, respectively, after 28 days exposure and that 95-98% of these residues were eliminated during the 14 day depuration period. Based on the results of the study, EFGWB concludes that RH-7592 will not bioaccumulate in fish and any residues that are taken up will be depurated when fish are no longer exposed to RH-7592 residues.

In order to satisfy the data requirement for this study, the registrant should provide additional characterization of the unknown polar metabolite identified in the study as "metabolite 3".

MATERIALS AND METHODS:

In-life phase

Bluegill Sunfish [7.7 (± 1.5)g weight; 62 (± 3.8) mm length] maintained in a flow-through system were exposed for 28 days to nominal water concentration of 0.01 ppm ^{14}C-triazole-RH-7592 (specific activity 20.95 mCi/g, 98% radiopurity)/technical RH-7592 (96.8% purity) followed by a 14 day depuration period. The exposure tank, with flow of aerated well water (See Table 1 for characteristics), was maintained at 21° C during the test duration. A control tank was also maintained under identical conditions.

Fish and water were sampled at time 0 and after 0.17, 1, 3, 7, 14,

21, 28 days of exposure. During the depuration period, fish were sampled after 1, 3, 7, 10, and 14 days depuration. Fish were dissected into fillet (edible) and viscera (inedible) tissues, homogenized, and frozen until analysis.

Note: In addition, additional fillet and viscera tissues were generated by a supplemental uptake study wherein the tissues were used in methods development and metabolite identification. In this second in-life phase study bluegill sunfish were exposed to a nominal concentration of 0.045 ppm residues of RH-7592.

Analytical phase

Total radioactivity in samples was quantitated by combustion of samples and liquid scintillation counting (LSC) of $^{14}CO_2$ trapped during combustion. During extraction and analysis procedures radioactivity in aliquots of partition supernatants and thin-layer chromatograms scrapings was quantitated by LSC.

The 21 and 28 day viscera samples were extracted with methanol, partitioned with hexane then with deionized millipore filtered water followed with ethyl acetate. The ethyl acetate was evaporated, residues re-dissolved in methanol for analysis by TLC. The aqueous phase was partitioned with n-butanol, then the n-butanol evaporated and residues were re-dissolved in methanol for TLC analysis.

The 7 and 28 day fillet samples were extracted with methanol in blender (28 day sample) or hand blended (7 day sample), then centrifuged. The methanol supernatant was decanted and concentrated, then deionized millipore filtered water was added. The aqueous solution was partitioned with ethyl acetate for analysis by TLC. The aqueous phase was partitioned with n-butanol, then the n-butanol evaporated and residues re-dissolved in methanol for TLC analysis.

Extracted radioactive residues were separated by TLC using reverse phase chromatography. Separated radioactive areas on the TLC plate were located with proportional scanner. Separated radioactive spots were identified by co-chromatography with known standards. Quantitation of radioactivity was accomplished by scrapping the TLC plates and quantitating the radioactivity by LSC. High performance liquid chromatography (HPLC) was used as additional aid to identify the residues. Confirmation of the identity of residues was attempted by gas chromatography/mass spectroscopy but was not successful.

REPORTED RESULTS:

The sampling schedule is presented in Figure 2. The nominal water concentration was 0.01 ppm (ranging from 0.0073 to 0.012 ppm) during the uptake phase.

During the uptake phase, ^{14}C-RH-7592 residues ranged from 0.089 ppm

(day 0) to 0.50 ppm (maximum, day 7) to 0.44 ppm at day 28 for fillet tissue; 0.24 ppm (day 0) to 1.6 ppm (maximum, day 21) to 1.4 ppm at day 28 for whole fish; and from 0.41 ppm (day 0) to 4.1 ppm (maximum, day 21) to 3.3 ppm at day 28 for viscera tissue samples. Table 5

The maximum bioaccumulation factors were 170X for whole fish at 7 days exposure, 50X for fillet tissue at 7 days exposure and 330X for viscera at 28 days exposure. Based on the results and using the BIOFAC non-linear kinetic fish accumulation computer model, the author calculated the bioconcentration factor (BCF) for RH-7592 to be 160. Table 5

During the 14 day depuration period, accumulated ^{14}C-RH-7592 residues dropped 95, 98, and 98% of the observed concentration at day 28 of uptake exposure in the fillet, whole fish and viscera, respectively. Table 3

The identity of accumulated residues were determined on the samples with the highest concentration of residues (found in the 7 and 28 days fillet samples and the 21 and 28 day viscera samples).

Material balance averaged 90% (range 76.1%-96.6%) for radioactive residues taken up during the exposure period. The majority of the residues were extracted from the fish samples. The radioactivity extracted by ethyl acetate was identified by TLC and HPLC co-chromatography with known standards as three compounds: parent RH-7592, lactone A (RH-9129) and the ketone (RH-6467). See Figure 1 for structures. The n-butanol extract contained an additional amount of these compounds and, in addition, three unknown areas, described as "polar unknowns 1, 2, and 3".

About 10-15% of the radioactivity was unextractable and remained in the fish tissue samples. Also, 2.6 - 9.5% of the extracted radioactivity remained in the aqueous phases of the extraction procedures and could not be identified. Table 2

Parent RH-7592 constituted 20-23% of the residue; the ketone 9-13%; and the lactone 7-10% and the polar unknown 3 8-13% of the radioactivity extracted from the fillet samples. Polar unknowns 1 and 2 accounted for 4-10% each of the radioactivity extracted from the fillet sample. Table 2

In the viscera, parent RH-7592 and the ketone accounted for 7-11% of the radioactivity extracted from the viscera sample. Polar compounds unknowns 2 and 3 accounted for 9-10% and 23-29%, respectively, of the radioactivity extracted from the viscera.

In the summary statement, the author concluded that the polar unknown 3 has been tentatively identified as a conjugate (probably the glucuronide) of the benzyl alcohol proposed to be an intermediate in the formation of the lactone and ketone metabolite. The proposed metabolic pathway for RH-7592 in fish is given in Figure 3.

DISCUSSION:

EFGWB concludes that this study partially satisfies the data requirement for a fish accumulation study. It is adequate to support the application for the EUP. However, for registration the registrant should identify more conclusively the residues associated with the polar unknown metabolite 3.

The results of this study indicated that bluegill sunfish had maximum bioaccumulation factors of 170X, 50X and 330X in whole fish, fillet and viscera tissues, respectively, after 28 days exposure and that 95-98% of these residues were eliminated during the 14 day depuration period. Based on the results of the study, EFGWB concludes that RH-7592 will not bioaccumulate in fish and any residues that are taken up will be depurated when fish are no longer exposed to RH-7592 residues.

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