(3-26-90)

Shaughnessy No.: 125601

Date out of EFGWB: ~~FEB 21 1990~~

TO: R. Taylor/C. Giles
Product Manager #25
Registration Division (H7507C)

FROM: Emil Regelman, Supervisory Chemist
Chemistry Review Section #2
Environmental Fate and Ground Water Branch

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

Henry Jacoby 3/26/90

Attached, please find the EFGWB review of ...

Reg./File #: 10182-EAT

Chemical Name: Paclobutrazol

Type Product: Systemic plant growth regulator

Common Name: Clipper

Company Name: ICI Americas, Inc.

Purpose: Review of revised draft label and review of old environmental fate data to support new chemical use

Date Received: 21 November 1989

Date Completed: 5 Feb. 1990

Action Code: 160/161

EFGWB #(s): 88-1024/89-0655

Total Reviewing Time: 5.1 days

Deferrals to: ___Ecological Effects Branch, EFED

___Science Integration and Policy Staff, EFED

___Non-Dietary Exposure Branch, HED

___Dietary Exposure Branch, HED

___Toxicology Branch

1. CHEMICAL:

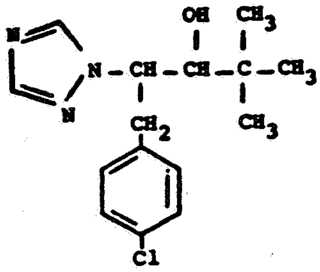
Chemical name: (±)-(R*,R*)-B-[(4-chlorophenyl)methyl]-a-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol

CAS no.: 76738-62-0

Common name: Paclobutrazol, PP333

Trade name: Clipper

Chemical structure:



Molecular formula: $C_{15}H_{20}ClN_3O$

Molecular weight: 293.5

Formulation:

Paclobutrazol	21.8%
Inert ingredients	78.2%

Physical/Chemical properties of active ingredient:

Physical characteristics: White crystalline solid

Melting point: 165°C

Solubility: 35 ppm in water

Octanol/water partition coefficient: Log P 3.2

Vapor pressure: 8×10^{-6} Pa at 30°C

2. STUDY/ACTION TYPE:

To review revised draft label and review environmental fate data submitted to support old chemical registration with new application methods.

3. STUDY IDENTIFICATION:

Woods, T. and Leahey, J. HYDROLYSIS IN WATER AT pH 4, 7, AND 9. Prepared by Imperial Chemical Industries Ltd., Eng.; Submitted and Sponsored by ICI Americas, Inc., Wilmington, DE under Report Series RJ 0316B; MRID No. 00132698.

2

Woods, T. and Leahey, J. PHOTOLYSIS IN AQUEOUS SOLUTION. Prepared by Imperial Chemical Industries Ltd., Eng.; Submitted and Sponsored by ICI Americas, Inc., Wilmington, DE under Report Series RJ 0317B; MRID No. 00132699.

Harvey, B.R., Weissler, M.S., and Zinner, C.R.S. PP333: DEGRADATION IN SOIL. Performed by Plant Protection Division under Laboratory Project ID RJ0256B; Submitted and Sponsored by ICI Americas, Inc., Wilmington, DE; MRID No. 00132700.

Tegala, B.; Clements, C.; and Skidmore, M. PACLOBUTRAZOL: PHOTOLYTIC STABILITY ON A SOIL SURFACE. Prepared and Submitted by ICI Plant Protection Division under Lab. Project ID: RJ 0601B; MRID No. 40685002.

Harvey, B. and Hill, I. PACLOBUTRAZOL: DEGRADATION IN AEROBIC AND FLOODED SOILS. Prepared and Submitted by ICI Plant Protection Division under Lab. Project ID: RJ0370B; MRID No. 40685003.

Mistry, R. and Hill, I. PACLOBUTRAZOL: MOBILITY OF PACLOBUTRAZOL AND ITS DEGRADATION PRODUCTS IN SOIL COLUMNS. Prepared and Submitted by ICI Plant Protection Division under Lab. Project ID: RJ0495B; MRID No. 40685004.

Takacs, M. and White, B. PACLOBUTRAZOL: ADSORPTION AND DESORPTION EQUILIBRIA IN SOILS. Prepared and Submitted by ICI Plant Protection Division under Lab. Project ID: TMJ2377B; MRID No. 40685005.

Hill, I. and Prashad, S. LEACHING IN SOIL. Prepared by Imperial Chemical Industries Ltd., Eng.; Submitted and Sponsored by ICI Americas, Inc., Wilmington, DE; MRID No. 00132701.

Pearson, F. PP333 AND PP333 KETONE RESIDUE DISSIPATION IN U.S. SOILS: :SOIL RESIDUES OF PACLOBUTRAZOL AND ITS KETONE METABOLITE. Prepared by ICI Biological Research Center, Goldsboro, NC under Lab. Project ID: TMU1760/B; Submitted and Sponsored by ICI Americas, Inc., Wilmington, DE; MRID No. 00146597.

Hendley, P. and Francis, P.D. PACLOBUTRAZOL: SHORT-TERM DISSIPATION AND MOVEMENT FOLLOWING A BROADCAST SPRAY. Performed by ICI Biological Research Center, Goldsboro, NC; Submitted and Sponsored by ICI Americas, Inc., Wilmington, DE; MRID No. 00155854.

Mak, C.; Crook, S.; and Atreya, N. PACLOBUTRAZOL: FIELD DISSIPATION FOLLOWING SUBSURFACE APPLICATIONS IN US ORCHARD SOILS UP TO 12 MONTHS. Prepared and Submitted by ICI Plant Protection Division under Lab. Project ID: RJ0574B; MRID No. 40685006.

3

Hendley, P.; Davis, L.; and Oliver, B. PACLOBUTRAZOL: FIELD DISSIPATION AND LEACHING FOLLOWING SUBSURFACE APPLICATION IN ORCHARD SOILS -- CALIFORNIA SITE. Prepared by ICI Biological Research Center, Goldsboro, NC under Lab. Project ID: TMU3346/B; Submitted by ICI Americas, Inc., Wilmington, DE; MRID No. 40685007.

Hendley, P.; Davis, L.; and Oliver, B. PACLOBUTRAZOL: FIELD DISSIPATION AND LEACHING FOLLOWING SUBSURFACE APPLICATION IN ORCHARD SOILS -- FLORIDA -- FOLLOW-UP REPORT OF FIELD DATA. Prepared by ICI Biological Research Center, Goldsboro, NC under Lab. Project ID: TMU3306/B; Submitted by ICI Americas, Inc., Wilmington, DE; MRID No. 40685009.

Hendley, P.; Davis, L.; and Oliver, B. PACLOBUTRAZOL: FIELD DISSIPATION AND LEACHING FOLLOWING SUBSURFACE APPLICATION IN ORCHARD SOILS -- FLORIDA SITE -- SECOND FOLLOW-UP REPORT OF FIELD DATA. Prepared by ICI Biological Research Center, Goldsboro, NC under Lab. Project ID: TMU3345/B; Submitted by ICI Americas, Inc., Wilmington, DE; MRID No. 40685010.

Hendley, P.; Davis, L.; and Oliver, B. PACLOBUTRAZOL: FIELD DISSIPATION AND LEACHING FOLLOWING SUBSURFACE APPLICATION IN ORCHARD SOILS -- WEST VIRGINIA SITE -- FOLLOW-UP REPORT OF FIELD DATA. Prepared by ICI Biological Research Center, Goldsboro, NC under Lab. Project ID: TMU3305/B; Submitted by ICI Americas, Inc., Wilmington, DE; MRID No. ~~40685012.~~ 40685011

Hendley, P.; Davis, L.; and Oliver, B. PACLOBUTRAZOL: FIELD DISSIPATION AND LEACHING FOLLOWING SUBSURFACE APPLICATION IN ORCHARD SOILS -- WEST VIRGINIA SITE -- SECOND FOLLOW-UP REPORT OF FIELD DATA. Prepared by ICI Biological Research Center, Goldsboro, NC under Lab. Project ID: TMU3347/B; Submitted by ICI Americas, Inc., Wilmington, DE; MRID No. 40685012.

Hamer, M.J. and Hill, I.R. PP333: ACCUMULATION IN BLUEGILL SUNFISH IN A FLOW THROUGH SYSTEM. Prepared by ICI Plant Protection Division; Blocknell, Berkshire; UK under Lab. Project ID: RJ0321B; Sponsored and Submitted by ICI Americas, Inc., Wilmington, DE; MRID No. 00133560.

4. REVIEWED BY:

Gail Maske
Chemist, Review section #2
OPP/EFED/EFGWB

Signature:
Date: 5 Feb '90

5. APPROVED BY:

Emil Regelman
Supervisory Chemist
Review section #2
OPP/EFED/EFGWB

Signature:
Date: FEB 21 1990

6. CONCLUSIONS:

a. Hydrolysis:

The hydrolysis study is acceptable to meet Subdivision N data requirement. Even though the experimental design did not follow the Standard Evaluation Procedure (SEP), the study was scientifically sound. EFGWB feels no significant data would be obtained by requiring a new hydrolysis study on paclobutrazol at this time.

Paclobutrazol was stable at pH 4, 7, and 9 when incubated in the dark at 25°C. The recovery of applied radioactivity at 30 days posttreatment was 94.2 to 98.9% which was determined to be [^{14}C]paclobutrazol.

b. Photodegradation in Water:

The photodegradation in water study is acceptable to meet Subdivision N data requirement. Even though the experimental design did not follow the SEP, the study was scientifically sound. EFGWB feels no significant data would be obtained by requiring a new photodegradation in water study at this time.

Paclobutrazol was fairly stable in a pH 7 sterile buffered solution which was irradiated continuously for 10 days at 29 to 40°C with a xenon arc lamp.

c. Photodegradation on Soil:

The photodegradation on soil study is acceptable to meet Subdivision N data requirement. Even though the experimental design did not follow the SEP, the study was scientifically sound. EFGWB feels no significant data would be obtained by requiring a new photodegradation on soil study at this time.

Paclobutrazol demonstrated a half-life of >33 "sun-equivalent days" when applied to loam soil and irradiated with a xenon arc lamp at 24-26°C. 1H-1,2,4-triazole was the major degradate of paclobutrazol on loam soil.

d. Aerobic Soil Metabolism:

The aerobic soil metabolism study (MRID 40685003) is acceptable to meet Subdivision N data requirement. The aerobic soil metabolism study (MRID 00132700) is not acceptable to meet Subdivision N data requirement. No further aerobic soil metabolism data is required on paclobutrazol at this time since there is an acceptable study.

Paclobutrazol with triazole- and methine-labelled rings demonstrated a half-life of >1 year under aerobic conditions in loam soil. The degradates identified were (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one; 1,2,4-triazole; unidentified extractable compounds; unextractable [^{14}C]residues; and CO_2.

e. Leaching, Adsorption/Desorption:

The leaching, adsorption/desorption unaged and aged studies (MRID 40685005 and 40685004, respectively) are acceptable to meet Subdivision N data requirement. The leaching, adsorption/desorption study (MRID 00132701) is not acceptable to meet Subdivision N data requirement. No further leaching, adsorption/desorption data on paclobutrazol is required at this time since the requirements for both unaged and aged have been satisfied by MRID 40685005 and MRID 40685004, respectively.

Unaged paclobutrazol was mobile to very mobile in nine soils which ranged from sand to silt loam when using batch equilibrium experiments. When aged paclobutrazol was tested using column leaching experiments, the methine-labelled [^{14}C]paclobutrazol was immobile in sand, sandy loam, loamy sand, and clay loam soils. When aged paclobutrazol with triazole-label was tested using column leaching experiments, the triazole-labelled [^{14}C]paclobutrazol demonstrated low mobility in sand and sandy loam soils and demonstrated mobility in loamy sand and clay loam soils. The ketone analogue of paclobutrazol{(2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one) was the only degradate present. The ketone analogue was present in both label positions tested.

f. Terrestrial Field Dissipation:

The terrestrial field dissipation studies (MRID 40685006, 40685007, 40685009, 40686010, 40685011, 40685012) are not acceptable to meet Subdivision N data requirement. The study (MRID 00146597) may be acceptable to meet Subdivision N data requirement if the further data is furnished. The study (MRID 00155854) is not acceptable to meet Subdivision N data requirement. Further terrestrial field dissipation studies may be required to support the terrestrial field dissipation data requirement depending on data to be furnished, since the sampling depth of the soil was insufficient to determine the extent of leaching of paclobutrazol and its ketone analogue in MRID 40685004 and 40685005. As well, the mobility studies (MRID 40685004 and 40685005) and the field dissipation studies (MRID 40685006, 40685007, 40685009, 40685010, 40685011, and 40685012) indicated that paclobutrazol and its ketone analogue are potential groundwater contaminants.

Paclobutrazol degraded with a half-life of 450-973 days in orchard soils form California, west Virginia, and Florida. A half-life of 20-26 weeks was demonstrated in loamy sand and silt loam soils from North Carolina, Illinois, and Mississippi. Only one degradate, [(2RS)-1-(2,4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol)-1-yl)pentan-3-one], appeared to be present in any of the studies.

Study (MRID 00155854) demonstrated that paclobutrazol does not leach in the first 30 days of posttreatment, when applied to turf-covered plots which are heavily irrigated.

g. Accumulation in Fish:

The accumulation in fish study is not acceptable to meet Subdivision N data requirement. A new accumulation in fish study is required to meet Subdivision N data requirement.

Triazole-labelled [^{14}C]paclobutrazol at 0.5 ppm did accumulate in the exposed fish with maximum mean bioconcentration factors 20x for edible tissues at day 3, 248x for nonedible at day 3, and 44x for whole fish at day 10.

h. The minor label amendment requested does not apply to EFGWB.

7. RECOMMENDATIONS:

The registrant should be informed of the following:

a. The hydrolysis study is acceptable to meet Subdivision N data requirement. There is no further hydrolysis data required at this time.

b. The photodegradation in water study is acceptable to meet Subdivision N data requirement. There is no further photodegradation in water data required at this time.

c. The photodegradation in soil study is acceptable to meet Subdivision N data requirement. There is no further photodegradation on soil data required at this time.

d. The aerobic soil metabolism study (MRID 40685003) is acceptable to meet Subdivision N data requirements. The aerobic soil metabolism study (MRID 00132700) is not acceptable to meet Subdivision N data requirement. There is no further aerobic soil metabolism data required at this time since MRID 40685003 does support the data requirement.

e. The leaching, adsorption/desorption studies for unaged and aged paclobutrazol (MRID 40685005 and MRID 40685004, respectively) are acceptable to meet Subdivision N data requirement. The leaching, adsorption/desorption study (MRID 00132701) is not acceptable to meet Subdivision N data requirement. There is no further leaching, adsorption/desorption required at this time since MRID 40685005 and MRID 40685004 fulfilled the data requirement for unaged and aged paclobutrazol.

f. The terrestrial field dissipation studies (MRID 40685006, 40685007, 40685009, 40685010, 40685011, 40685012) are not acceptable to meet Subdivision N data requirement for the following reasons:
    1. Sampling depth of the soil was insufficient to determine the extent of leaching of the parent and its residues.
    2. Storage stability data was not furnished with the study. However, it was indicated the two year storage stability data was available.

3. There as no pretreatment and/or control plot data furnished with the study.
4. Characterization of the soils and site were not complete.

The study (MRID 00146597) may be acceptable to meet Subdivision N data requirement if the following are furnished:

1. Storage stability data for paclobutrazol and its ketone analogue must be furnished.

2. Complete characterization of the test soil must be furnished.

The study (MRID 00155854) is not acceptable to meet Subdivision N data requirement for the following reasons:

1. The study was terminated at the end of 30 days, before a pattern of decline was established for paclobutrazol.

2. Storage stability data was not furnished with the study. Prior to analysis the samples were stored at -20°C for up to 3 months.

Further studies may be required to support the terrestrial field dissipation data requirement depending on data furnished, since the sampling depth of the soil was insufficient to determine the extent of leaching of paclobutrazol and its ketone analogue in MRID 40685005 and 40685004. As well, the mobility studies (MRID 40685005 and 40685004) and the field dissipation studies (MRID 40685006, 40685007, 40685009, 40685010, 40685011, 40685012) indicated that paclobutrazol and its ketone analogue are potential groundwater contaminants.

g. The accumulation in fish study is not acceptable to meet Subdivision N data requirement for the following reasons:

1. After 14 days of exposure, the adsorption phase was terminated before adequate data was furnished to determine if adsorption of $[^{14}C]$paclobutrazol residues had plateaued in the fish.

2. The $[^{14}C]$paclobutrazol residues were not characterized in the fish tissues.

A new accumulation in fish study is required to support the data requirement.

h. The minor label amendment requested does not apply to EFGWB.

i. The submission of data required for full registration of paclobutrazol on terrestrial food crop (orchards and greenhouse ornamentals) and terrestrial nonfood (turf grown for seed, trees in nonfood areas) use sites is summarized below):

Environmental Fate Data Requirements	Status of Data Requirement	MRID No.
Degradation Studies-lab		
161-1 Hydrolysis	This Review	00132698
161-2 Photodegradation in water	This Review	00132699
161-3 Photodegradation on soil	This Review	40685002
161-4 Photodegradation in air	Deferred pending the results of 163-2	
Metabolism Studies-lab		
162-1 Aerobic soil	This Review	40685003
162-2 Anaerobic soil	Not required (no field and vegetable crop use)	40685003
Mobility Studies		
163-1 Leaching, Adsorption/ Desorption	This Review	40685005
163-2 Volatility-Lab	Not Submitted	
163-3 Volatility-field	Deferred pending the results of 163-2	
Dissipation Studies-field		
164-1 Soil	This Review	
164-5 Soil, long-term	Deferred pending results of 164-1	
Accumulation Studies		
165-1 Rotational crops-confined	Not required (has no field and vegetable crop, aquatic crop, and rotated food crop uses)	
165-2 Rotational crops-field	Not required (has no field and vegetable crop, aquatic crop, and rotated food crop uses)	
165-4 in Fish	This Review	00133560

8. BACKGROUND:

Paclobutrazol is a systemic plant growth regulator that inhibits the formation of gibberellins, resulting in compact plants and enhanced production of flower and fruit buds. Paclobutrazol was developed for use on terrestrial food crop (orchards and greenhouse ornamentals) and terrestrial nonfood (turf grown for seed, trees in nonfood areas) sites. It may be applied as a foliar spray or to the growing media.

9. DISCUSSION:

See individual DER's.

9

There are still several data gaps that do not allow a complete assessment of the environmental fate of paclobutrazol at the present time.

Paclobutrazol is stable in aqueous solutions at neutral and alkaline pHs. The stability of paclobutrazol increases slightly at pH 9. At 30 days posttreatment, [^{14}C]paclobutrazol comprised 94.9 and 95.0% of the radioactivity recovered in duplicate pH 4 solutions, 94.2 and 95.6% in pH 7 solutions, and 96.6 and 98.9% in pH 9 solutions. The unidentified water-soluble [^{14}C]residues comprised 0.01 - 0.06% of the recovered radioactivity (except for 0.22% in one pH 9 solution).

Photodegradation is not an important degradation route for paclobutrazol. However, degradation under aerobic conditions is a relative important process in the breakdown of paclobutrazol. The half-life of parent paclobutrazol in calcareous clay loam was 6 - 12 weeks and in sandy loam soil was > 20 weeks. The major metabolite/degradate found was the ketone analogue. From the study it was not possible to establish the pattern of decline of this product and therefore, it is not known at this point how persistent the ketone analogue is or to what products it further degrades.

Paclobutrazol was shown to be mobile in nine soils ranging in texture from sand to silt loam based on batch equilibrium experiments. An estimated 65% of the adsorbed [^{14}C]paclobutrazol desorbed from the soil during two desorption steps; K_{des} values for the nine soils ranged from 1.87 to 27.97 following the first desorption steps and from 2.66 to 33.95 following the second desorption step. Based on column leaching experiments, aged [^{14}C]paclobutrazol residues were relatively immobile to mobile in sand, sandy loam, loamy sand, and clay loam soils. One degradate the ketone analogue, was identified in soil columns. [^{14}C]Residues in the leachate were characterized as "very polar material" (they did not move from the origin).

The numerous deficiencies in the terrestrial field dissipation studies prevent defining a depth of leaching. Paclobutrazol degraded with a half-life of 450-973 days in orchard soil from California, West Virginia, and Florida. The major degradate, the ketone analogue, comprised a greater percentage of the total residues in the deeper soil sections that were tested than in the surface soil sections that were tested.

The deficiencies in the bioaccumulation of paclobutrazol in fish prevents defining maximum mean bioconcentration and desorption values.

Based on the fairly low vapor pressure of paclobutrazol, volatilization from soils will not be an important dissipation mechanism. The octanol/water partition coefficient suggests that paclobutrazol will have a low to moderate tendency to accumulate in fish.

10: COMPLETION OF ONE-LINER:

See attached one-liner.

11: CBI APPENDIX:

The information is considered to be CBI by the registrant, and should be treated as such.

ENVIRONMENTAL FATE & GROUND WATER BRANCH
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY

Common Name: **PACLOBUTRAZOL** Date: 12/20/89
Chem. Name : (2RS,3RD)-1-(4-CHLOROPHENYL)-4,4-DIMETHYL-2-(1H-1,2,4-TRI-
: AZOL-1-YL)PENTAN-3-OL
Shaugh. # : 125601 CAS Number: 76738-62-0
Type Pest. : PLANT GROWTH REGULATOR (INHIBITS FORMATION OF GIBBERELLINS)
Formulation: 4G/L SUSP. CONC.; 20 G/L FOR TRUNK INJUNCTION; 250 G/L CONC.
Uses : FOR ORNAMENTAL CROPS (BONZI); AMENITY TREE AND BUSH CONTROL
: (CLIPPER); APPLE AND PEAR ORCHARD (CULTAR).
: Z

Empir. Form: $C_{15}H_{20}ClN_3O$
Mol. Weight: 293.79
Solub.(ppm): 35 @ °C
VP (Torr): 1 E-6
Log Kow : 3.2
Henry's :

Hydrolysis (161-1)
pH 5:[*] STABLE
pH 7:[*] STABLE
pH 9:[*] STABLE
pH :[ ]
pH :[ ]
pH :[ ]

Photolysis (161-2, -3, -4)
Air :[ ]
Soil :[*] 140 DAYS WITH XENON ARC
Water:[*] NO DEGRADATION IN 10 DAYS
:[ ] IRRADIATION WITH ARTIFICIAL
:[ ] LIGHT
:[ ]

MOBILITY STUDIES (163-1)

Soil Partition (Kd)

	Sd	Si	Cl	%OM	pH	Kd
1.[#]						
2.[ ]	28	47	25	3.9	4.9	21.3
3.[ ]	55	28	18	5.2	6.0	10.2
4.[ ]	37	22	41	11.4	8.0	9.5
5.[ ]	21	39	40	5.6	6.4	7.6
6.[ ]	88	4	8	1.6	5.5	2.4

Rf Factors
1.[#] RESIDUES CONTAINING THE METH-
2.[ ] INE MOIETY WERE RELATIVELY
3.[ ] IMMOBILE IN Sd, SdLm, LmSd,
4.[ ] AND ClLm SOILS.
5.[ ]
6.[ ]

METABOLISM STUDIES (162-1,2,3,4)

Aerobic Soil (162-1)
1.[*] APPROXIMATELY 1 YEAR IN AEROB-
2.[ ] IC LOAM SOIL AT 20 C.
3.[*] 9.1 WEEKS IN CLAY LOAM SOIL
4.[ ] AND 30.5 WEEKS IN SANDY LOAM
5.[ ] SOIL AT 25 C.
6.[ ]
7.[ ]

Anaerobic Soil (162-2)
1.[ ]
2.[ ]
3.[ ]
4.[ ]
5.[ ]
6.[ ]
7.[ ]

Aerobic Aquatic (162-4)
1.[ ]
2.[ ]
3.[ ]
4.[ ]

Anaerobic Aquatic (162-3)
1.[#] >1 year
2.[ ]
3.[ ]
4.[ ]

---

[*] - Acceptable Study. [#] = Supplemental Study

Common Name: **PACLOBUTRAZOL** Date: 12/20/89

VOLATILITY STUDIES (163-2,3)

[ ] Laboratory:
[ ] Field:

DISSIPATION STUDIES (164-1,2,3,5)

Terrestrial Field (164-1)
1.[#] T1/2 = 450 - 973 DAYS IN ORCHARD SOIL FROM CA, WVA, AND FLOR
2.[ ] IDA.
3.[#] T1/2 = 95-190 DAYS IN LmSd (NC); 123-189 DAYS IN SiLm (MISS)
4.[ ] 123-337 DAYS IN SiClLm (IL); 7-14 DAYS IN SdLm (CA).
5.[ ]
6.[ ]

Aquatic (164-2)
1.[ ]
2.[ ]
3.[ ]
4.[ ]
5.[ ]
6.[ ]

Forestry (164-3)
1.[ ]
2.[ ]

Other (164-5)
1.[ ]
2.[ ]

ACCUMULATION STUDIES (165-1,2,3,4,5)

Confined Rotational Crops (165-1)
1.[ ]
2.[ ]

Field Rotational Crops (165-2)
1.[ ]
2.[ ]

Irrigated Crops (165-3)
1.[ ]
2.[ ]

Fish (165-4)
1.[*] BLUEGILL SUNFISH BCF: 44 X WHOLE FISH; 20 X MUSCLE;
2.[ ] 248 X VISCERA.

Non-Target Organisms (165-5)
1.[ ]
2.[ ]

---

[*] - Acceptable Study. [#] = Supplemental Study

Common Name: **PACLOBUTRAZOL** Date: 12/20/89

GROUND WATER STUDIES (158.75)

1.[ ]
2.[ ]
3.[ ]

DEGRADATION PRODUCTS

1. Ketone analogue - [2RS]-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-
2. triazol-1-yl)-pentan-3-one
3.
4. 1H-1,2,4-triazole
5.
6.
7.
8.
9.
10.

COMMENTS

References: FARM CHEMICALS HANDBOOK; EPA DATA
Writer : J. HANNAN

---

[*] - Acceptable Study. [#] = Supplemental Study

DYNAMAC
CORPORATION

PACLOBUTRAZOL

TASK 1: REVIEW AND EVALUATION OF INDIVIDUAL STUDIES

TASK 2: ENVIRONMENTAL FATE ASSESSMENT

January 26, 1990

Final Report

Contract No. 68D90058

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

PACLOBUTRAZOL

Table of Contents

Page

Introduction

Scientific Studies

INTRODUCTION

Paclobutrazol is a plant growth regulator registered for use on terrestrial food crop (orchards and greenhouse ornamentals) and terrestrial nonfood (turf grown for seed, trees in nonfood areas) sites. It is a systemic that inhibits the formation of gibberellins, resulting in long-term slowing of vegetative growth which extends the trim cycle of treated trees, produces smaller leaves, and enhances production of flower and fruit buds. Application rates for trees are 300-1000 mL of dilute solution (0.50-0.75 pints formulation per gallon of water); rates are dependent on tree size. Application may be as a foliar spray, by soil injection or basal drench, or by trunk injections if soil is heavily compacted. Application is restricted to established healthy tree plantings growing in linear patterns. Paclobutrazol should only be applied during periods of active tree growth, since uptake will not occur if applied during dormant periods. Treatments should not be made to sugar maples to be tapped for sugar, to fruit or nut trees to be harvested within one year, or to trees that are <8 or >25 inches in diameter. Applications must not be applied through any kind of irrigation system or be made to frozen ground.

DATA EVALUATION RECORD

STUDY 1

CHEM 125601 Paclobutrazol §161-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID None
Woods, T.M., and J.P. Leahey. 1983a. PP333: Hydrolysis in water at pH 4, 7 and 9. Report Series RJ0216B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME = 8

REVIEWED BY: W. Martin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

23 Feb 90

SIGNATURE:

CONCLUSIONS:

Degradation - Hydrolysis

1. This study can be used to fulfill data requirements.

2. Paclobutrazol was relatively stable in sterile aqueous solutions (pH 4, 7 and 9) during 30 days of incubation in the dark at 25 C.

3. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the hydrolysis of triazole ring-labeled [^{14}C]paclobutrazol at pH 4, 7, and 9.

4. No additional data on the hydrolysis of paclobutrazol are needed at this time.

METHODOLOGY:

Triazole ring-labeled [^{14}C]paclobutrazol (radiochemical purity 98%, specific activity 2.22 MBq/mMol, ICI) dissolved in methanol was added at 10.2 ppm to sterile glass vials containing aqueous buffer solutions at pH 4, 7 and 9 (commercial buffer powders, not further characterized). The test solutions were incubated in a thermostated water bath at 25 C in the dark. Duplicate vials of solution were collected at 0, 7, 14 and 30 days posttreatment. Samples that were not analyzed immediately were stored at -15 C.

The samples were extracted three times with methylene chloride. The extracts were combined and concentrated by rotary evaporation, and total radioactivity in the extracts and extracted buffer solutions was determined by LSC. Additional aliquots of the extracts were analyzed by one-dimensional TLC on silica gel plates to identify specific compounds. The following solvent systems were used: pH 4 buffer solution samples, chloroform:ethyl acetate (3:2); pH 7, chloroform:diethylamine (9.5:1.5); and pH 9, diethyl ether:hexane:-methanol (7:2:1). The extracts were cochromatographed with unlabeled paclobutrazol as a reference standard. The location of the unlabeled paclobutrazol was located using either UV fluorescence quenching or iodoplatinate staining; the radioactive compounds were located and quantified using a TLC linear analyzer and autoradiography.

DATA SUMMARY:

Triazole ring-labeled [^{14}C]paclobutrazol (radiochemical purity 98%), at 10.2 ppm, was relatively stable in sterile aqueous buffered solutions (pH 4, 7, or 9) that were incubated in the dark at 25 C for 30 days (Table 1; Figures 1-3). At 30 days posttreatment, [^{14}C]paclobutrazol comprised 94.9 and 95.0% of the radioactivity recovered in duplicate pH 4 solutions, 94.2 and 95.6% in pH 7 solutions, and 96.6 and 98.9% in pH 9 solutions. Unidentified water-soluble [^{14}C]-residues comprised 0.01-0.06% of the recovered radioactivity (except for 0.22% in one pH 9 solution). The material balances at day 30 ranged from 97 to 108% of the applied.

COMMENTS:

1. The composition and molarity of the commercial buffers (pH 4, 7 and 9) were not reported.

2. The pH of the solutions was apparently not confirmed at each sampling interval.

3. Recovery efficiencies and method detection limits were not reported.

4. EFGWB prefers that [^{14}C]residues in samples be separated by chromatographic methods (such as TLC, HPLC, or GC) with at least three sol-

vent systems of different polarity, and that specific compounds isolated by chromatography be identified using a confirmatory method such as MS in addition to comparison to the R_f of reference standards.

In this study, the sample extracts were analyzed using one-dimensional TLC with a single solvent system. Radioactive areas on the TLC plates were identified only by comparison to the location of known reference standards chromatographed on the same plates. It was assumed by the study authors that the radioactive areas contained a single compound; the radioactive areas were not analyzed further to confirm the identification. However, although the analytical method may have been inadequate in this case, the results of this hydrolysis study (that paclobutrazol is relatively stable to hydrolysis) were confirmed by the behavior of paclobutrazol in the dark control from the photodegradation in water study (Woods and Leahey, no study ID; Study 2).

5. Although paclobutrazol was the only [^{14}C]compound in the methylene chloride extracts that migrated from the origin, slight differences in the concentration of paclobutrazol in the pH 4 and 7 solutions compared to the pH 9 solution at 30 days posttreatment suggest that a very slow pH-dependent reaction may have been occurring.

6. Data were presented only for the day 30 sampling interval; however, samples from days 7 and 14 were also analyzed. The study authors stated that chromatographic analysis of the solutions after days 7, 14, and 30 indicated that "virtually no degradation" had occurred.

7. Although it was not specified in the methodology, the data suggest that the sample solutions were analyzed for total radioactivity prior to extraction.

STUDY AUTHOR(S)'S RESULTS AND/OR CONCLUSIONS

(INCLUDING PERTINENT TABLES AND FIGURES)

10182 - EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 23 through 27 are not included in this copy.

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.

X______ 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.

DATA EVALUATION RECORD

STUDY 2

CHEM 125601 Paclobutrazol §161-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID None

Woods, T.M., and J.P. Leahey. 1983b. PP333: Photolysis in aqueous solution. Report Series RJ0317B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME = 10

REVIEWED BY:	E. Hirsh, W. Martin	TITLE:	Staff Scientist
EDITED BY:	K. Patten	TITLE:	Task Leader
APPROVED BY:	W. Spangler	TITLE:	Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

5 Jul '90

SIGNATURE:

CONCLUSIONS:

Degradation - Photodegradation in Water

1. This study can be used to fulfill data requirements.
2. Paclobutrazol was relatively stable in a sterile aqueous pH 7 buffer solution that was continuously irradiated for 10 days with a xenon arc lamp at 29 to 40 C.
3. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the photodegradation of triazole ring-labeled [^{14}C]paclobutrazol in an aqueous pH 7 buffer solution.
4. No additional data on the photodegradation of paclobutrazol in water are needed at this time.

METHODOLOGY:

Triazole-labeled [^{14}C]paclobutrazol (radiochemical purity 98%, specific activity 2.2 MBq/uMol, ICI) dissolved in acetonitrile was added to three sterile quartz round-bottomed flasks containing sterile (autoclaved) pH 7 buffer solution (commercial buffer powder, not further characterized). A subsample of each solution was collected immediately after treatment for later analysis. At time 0, the concentration of [^{14}C]paclobutrazol in the solutions was 10.4 ug/mL; the concentration of acetonitrile was <1%. One of the flasks was covered with aluminum foil to serve as a dark control, and all three stoppered flasks were placed on a rotating table within a "photolysis apparatus" (Figure 2.3). The solutions were continuously irradiated using a xenon arc lamp (Ushio UXL 1600) filtered through borosilicate glass. The photolysis apparatus was maintained at 29 to 40 C by a forced air draught and an extractor fan. The intensity of the light at test distance (not specified) was 1.94-2.50 W/m^2 (measured at 420 nm) during the 10-day study (Appendix 2, Figure 5). Solution subsamples were removed from the irradiated and dark control solutions at 10 days. Samples were stored at -15 C in screw-capped glass vials prior to analysis.

Aliquots of each sample were analyzed for total radioactivity using LSC. The samples were extracted three times with methylene chloride. The extracts were combined and concentrated by rotary evaporation, and total radioactivity in the extracts and extracted buffer solutions was determined by LSC. Additional aliquots of the extracts were analyzed by one-dimensional TLC on silica gel plates developed in either: chloroform:ethyl acetate (3:2); chloroform:diethylamine (9.5:1.5); or diethyl ether:hexane:methanol (7:2:1). The extracts were cochromatographed with unlabeled paclobutrazol as a reference standard. The location of the unlabeled paclobutrazol was located using iodoplatinate staining; the radioactive compounds were located and quantified using a TLC linear analyzer.

DATA SUMMARY:

Triazole-labeled [^{14}C]paclobutrazol (radiochemical purity 98%), at 10.4 ug/mL, was relatively stable in a sterile aqueous pH 7 buffer solution that was continuously irradiated for 10 days with a xenon arc lamp at 29 to 40 C. The measured intensity of the xenon lamp at test distance (not specified) was 1.94-2.50 w/m^2 at 420 nm compared to measured sunlight intensity of 1.14-1.63 w/m^2 at 420 nm (Appendix 2, Figure 5). At 10 days posttreatment, [^{14}C]paclobutrazol comprised 96.6 and 100% of the radioactivity recovered in duplicate irradiated solutions and 97.6% in the dark control (Table 1, Figures 2-4). In the irradiated samples, unidentified water-soluble [^{14}C]residues comprised 1.2 and 1.8% of the recovered radioactivity; no unidentified [^{14}C]residues were present in the dark control. The material balances at day 10 were 93 and 94% for the irradiated samples and 98% for the dark control.

COMMENTS:

1. The light from the filtered xenon arc lamp was reported to be slightly more intense than the midday sun in southern England (latitude 51 23'N), which had measured intensities of 1.14 and 1.63 W/m^2 (420 nm) at midday in the months of February and July, respectively. The study authors therefore claimed that 10 days of continuous irradiation with the xenon arc lamp would give an excess of irradiation as compared to the light which the samples would receive from exposure to 30 days of sunlight. The data are such that conducting the study for an additional 5 days of continuous irradiation would not change the overall conclusions.

2. The absorption maxima for paclobutrazol were said to be at 200 and 222 nm. Unlike sunlight, xenon arc lamps normally emit radiation below 290 nm which may supply energy for photolysis of paclobutrazol. However, the study authors displayed in Figure 5 that the borosilicate glass used as a filter adequately altered the spectra so that no light below 250 nm was emitted.

3. Subsamples were also collected at 3, 5, and 7 days from the irradiated flasks; however, these samples were not analyzed.

4. The composition and molarity of the commercial buffers (pH 4, 7 and 9) were not reported.

5. Although paclobutrazol was the only [^{14}C]compound in the methylene chloride extracts that migrated from the origin, slight differences in the total radioactivity in solution and in the concentration of unidentified residues remaining in the water phase after extraction suggest that a very slow photodegradation may have been occurring.

6. Recovery efficiencies and method detection limits were not reported.

7. EFGWB prefers that [^{14}C]residues in samples be separated by chromatographic methods (such as TLC, HPLC, or GC) with at least three solvent systems of different polarity, and that specific compounds isolated by chromatography be identified using a confirmatory method such as MS in addition to comparison to the R_f of reference standards.

   In this study, the sample extracts were analyzed using one-dimensional TLC with three solvent systems. Radioactive areas on the TLC plates were identified only by comparison to the location of known reference standards chromatographed on the same plates.

36

10182 - EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 31 through 38 are not included in this copy.

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.

X_____ 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.

DATA EVALUATION RECORD

STUDY 3

CHEM 125601 | Paclobutrazol | §161-3

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40685002
Tegala, B., C.B. Clements, and M.W. Skidmore. 1987. Paclobutrazol: Photolytic stability on a soil surface. Laboratory Project ID RJ0601B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME = 10

REVIEWED BY: S. Syslo TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

5 Feb 90

SIGNATURE:

CONCLUSIONS:

Degradation - Photodegradation on Soil

1. This study can be used to fulfill data requirements.

2. Paclobutrazol degraded with a half-life of >33 "sun-equivalent days" on loam soil irradiated with a xenon arc lamp at 24-26 C; paclobutrazol was stable in the dark control. The major photodegradate was 1H-1,2,4-triazole.

3. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the photodegradation of triazole-labeled [^{14}C]paclobutrazol on loam soil.

4. No additional data on the photodegradation of paclobutrazol on soil are needed at this time.

METHODOLOGY:

An aqueous slurry of sieved (0.5 mm) loam soil (46% sand, 28% silt, 23% clay, 4.3% organic matter, pH 6.6, CEC 18 meq/100 g) was spread on stainless steel plates in a 1 mm-thick layer. Soil was removed from the plates so that two discrete areas measuring 2- x 2-cm remained soil-covered on each plate, and the soil plates were dried overnight. Triazole-labeled [14C]paclobutrazol (radiochemical purity >99.1%, specific activity 562 Bq/ug, ICI), dissolved in methanol, was applied to the soil at 100 ug/area (equivalent to 2.48 kg/ha), and the soil was again air-dried. The soil plates (including one plate containing untreated soil) were placed inside a water-cooled photoreactor (Suntest Accelerated Exposure Table Unit), and the photoreactor was covered with a quartz glass lid (Figure 3). Humidified, CO_2-free air was drawn through the photoreactor, then sequentially through a polyurethane foam bung, one tube of 1 M hydrochloric acid, one tube of 2-methoxyethanol, and two tubes of ethanolamine. A thermocouple was imbedded in the untreated soil in the photoreactor, and the soil temperature was maintained at 24-26 C. The plates were irradiated in "cycles of light and dark" using a filtered xenon arc lamp (Figure 7) with measured intensities at the soil surface of: 1.65-1.80 x 10^{-4} W/cm^2 at 297 nm; 8.8-9.2 x 10^{-4} W/cm^2 at 365 nm; 1.68-1.82 x 10^{-1} W/cm^2 at 280-420 nm; and 9.0-9.5 x 10^{-3} W/cm^2 at 430-700 nm (Table 9). Additional plates were prepared, treated, and stored in a constant temperature room at 25 ± 1 C to serve as dark controls. Irradiated soil plates were removed at "predetermined sampling intervals" (approximately 20, 40, 60, 80, and 105 hours of irradiation); the dark control soil was incubated "for the duration of the photolysis period". Plates were wrapped in aluminum foil and stored at -15 ± 5 C until analysis (duration of storage not specified).

The soil was scraped from the plates and refluxed with acetonitrile:water (1:1, v:v) for 2 hours. The samples were centrifuged, the supernatants were decanted, and aliquots were analyzed for total radioactivity using LSC. The extracts were analyzed for specific compounds using normal-phase, one-dimensional TLC on silica gel plates developed in ethyl acetate:propanol:water (4:2:7, v:v:v), chloroform:methanol:acetic acid (18:1:1, v:v:v), or ethyl acetate:toluene:methanol:formic acid (13:4:2:1, v:v:v:v). The samples were cochromatographed with reference standards. The reference standards were visualized using potassium iodoplatinate spray. Radioactive compounds were located and quantified using a TLC linear scanner and autoradiography, and were identified by comparison to the reference standards. Radioactivity remaining in the extracted soils was determined using LSC following combustion.

The trapping solutions were analyzed for total radioactivity using LSC. The polyurethane bungs were ultrasonicated for 25 minutes in acetonitrile:water (1:1, v:v); aliquots of the extract were analyzed for total radioactivity by LSC.

DATA SUMMARY:

Triazole-labeled [^{14}C]paclobutrazol (radiochemical purity >99.1%), at 2.48 kg/ha, photodegraded with a half-life of >>33 "sun-equivalent days" in loam soil irradiated with a xenon arc lamp at 24-26 C for 105.24 hours (according to the study authors, 3.17 hours of irradiation was equivalent to approximately 1 Florida spring day). After 105.24 hours of irradiation, [^{14}C]paclobutrazol comprised an average 87.4% of the applied radioactivity,

1H-1,2,4-triazole comprised 4.2%,

unidentified extractable compounds comprised 2.6% (four compounds, each ≤1.8%), other extractable radioactivity (origin material and "background") comprised 3%, and unextractable residues comprised 2.8% (Tables 2 and 3). No radioactivity was volatilized from the soil during the study period. In the dark control, [^{14}C]paclobutrazol did not degrade during the 105-hour study period. In the irradiated samples and the dark control, the material balances ranged from 97.7 to 101.9% of the applied during the study (Table 2).

Mean intensities of light measured at the soil surface during the irradiation period were: 1.65-1.80 x 10^{-4} W/cm^2 at 297 nm; 8.8-9.2 x 10^{-4} W/cm^2 at 365 nm; 1.68-1.82 x 10^{-1} W/cm^2 at 280-420 nm; and 9.0-9.5 x 10^{-3} W/cm^2 at 430-700 nm (Table 9). The mean intensity of radiation received per sample was 1.72-1.77 x 10^{-1} W/cm^2 (Table 1).

COMMENTS:

1. Data were expressed in terms of "sun-equivalent days" by the study authors. It was calculated that 3.17 hours of irradiation with the xenon arc lamp was equivalent energy produced during 1 day of "Florida spring sunlight". Therefore, the study duration, reported as 33 days, 5 hours of sunlight, was in fact 105.24 hours of artificial light irradiation (Table 1). The study authors provided detailed sample calculations (Appendix 7, pages 33-46 of original document), and the mathematics appear to be correct.

   Although the total irradiation received by the soil may be equivalent to 33 days of sunlight, the calculations do not account for additional degradation that might occur in the soil outdoors during the night. In the case of paclobutrazol, the amount of microbial degradation should be minimal because the half-life in aerobic soil was determined to be >1 year (Harvey and Hill, 40685003; Study 4); how-

41

ever, with other pesticides, dark period degradation could be significant.

2. It was stated that the dark control samples were incubated for the "duration of the photolysis period". It was assumed that this referred to the 105.24 hours of actual irradiation rather than the 33 days, 5 hours of "sun-equivalent days".

3. In the text, the authors describe the soil used as a sandy loam; however, soil characterization data for the particular soil used were not reported. Average values for soil characteristics of previously-taken samples (n=11) from the same field are presented in Appendix 4 of the original document; the soil would be classified as a borderline loam-sandy clay loam.

4. Recovery efficiencies and method detection limits were not reported.

5. EFGWB prefers that [^{14}C]residues in samples be separated by chromatographic methods (such as TLC, HPLC, or GC) with at least three solvent systems of different polarity, and that specific compounds isolated by chromatography be identified using a confirmatory method such as MS in addition to comparison to the R_f of reference standards.

   In this study, the sample extracts were analyzed using one-dimensional TLC with three solvent systems. Radioactive areas on the TLC plates were identified only by comparison to the location of known reference standards chromatographed on the same plates.

10182 - EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 43 through 50 are not included in this copy.

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.

X 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.

DATA EVALUATION RECORD

STUDY 4

CHEM 125601 Paclobutrazol §162-1, 162-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40685003
Harvey, B.R., and I.R. Hill. 1985. Paclobutrazol: Degradation in aerobic and flooded soils. Report Series RJ0370B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME = 20

REVIEWED BY: S. Syslo TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

25 Jul '90

SIGNATURE:

CONCLUSIONS:

Metabolism - Aerobic Soil

1. This portion of the study can be used to fulfill data requirements.

2. Triazole- and methine-labeled [^{14}C]paclobutrazol degraded with half-lives of >1 year in aerobic loam soil incubated at 20 C. The major degradate was (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one; other degradates were 1,2,4-triazole, unidentified extractable compounds, unextractable [^{14}C]residues, and CO_2.

3. This portion of this study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the aerobic metabolism of triazole- and methine-labeled [^{14}C]paclobutrazol in loam soil.

4. No additional data on the metabolism of paclobutrazol in aerobic soil are needed at this time.

Metabolism - Anaerobic Aquatic

1. This portion of the study can be used to fulfill data requirements.

2. Triazole- and methine-labeled [^{14}C]paclobutrazol degraded with half-lives of >1 year in flooded loam and silt loam soils incubated at 20 C. The major degradate was (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one; other degradates were 1,2,4-triazole, unidentified extractable compounds, unextractable [^{14}C]residues, and CO_2.

3. This portion of this study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the anaerobic aquatic metabolism of triazole- and methine-labeled [^{14}C]paclobutrazol in flooded loam soil, and triazole-labeled [^{14}C]paclobutrazol in flooded silt loam soil.

4. No additional data on the anaerobic aquatic metabolism of paclobutrazol are needed at this time.

METHODOLOGY:

Metabolism - Aerobic Soil

Metabolism - Anaerobic Aquatic

Partially air-dried, sieved "18 Acres" loam soil (25% coarse sand [2-0.2 mm], 32% fine sand [0.2-0.02 mm], 19% silt [0.02-0.002 mm], 24% clay, 4.6% organic matter, pH 6.6, CEC 19 meq/100 g, obtained from England; Table 2) was weighed into glass pots (3- or 6-cm height, 3.8-cm diameter). The soil was then surface-treated either at approximately 183 ug/pot with triazole-labeled [14C]paclobutrazol (radiochemical purity 91.8%; specific activity 2.22 mBq/mMol; ICI) or at approximately 161 ug/pot with methine-labeled [14C]paclobutrazol (radiochemical purity 93.5%; specific activity 1.87 mBq/mMol; ICI).

"Ibaraki" silt loam soil (4% coarse sand, 31% fine sand, 34% silt, 31% clay, 10.2% organic matter, pH 5.7, CEC 31 meq/100 g, obtained from Japan; Table 2) was weighed into glass pots (6-cm height, 3.8-cm diameter) and surface-treated at approximately 77 or 183 ug/pot with triazole-labeled [14C]paclobutrazol.

The pots were divided into three experiments:

> an aerobic soil metabolism experiment (using loam soil treated with either the triazole- or methine-labeled [^{14}C]paclobutrazol) in which the soils were maintained at 40% moisture holding capacity and attached to a flow-through volatile trapping system (Figure 2);
>
> an anaerobic aquatic metabolism experiment (using loam soil treated with either the triazole- or methine-labeled [^{14}C]-paclobutrazol; and silt loam soil treated with triazole-labeled [^{14}C]paclobutrazol) in which the soils were treated, then immediately flooded to a depth of 2 cm and attached to a flow-through volatile trapping system (Figure 2); and
>
> an anaerobic aquatic metabolism experiment (using silt loam soil treated with triazole-labeled [^{14}C]paclobutrazol) in which the soils were flooded and incubated for 1 week at 20 ± 1 C before application of the pesticide solution to the surface of the water, then incubated without being attached to a flow-through volatile trapping system.

The pots designated for the flow-through system were placed inside glass cylinders (three pots per cylinder), and humidified, CO_2-free air was passed (0.16 L/minute) through the cylinders, then through two tubes of ethanolamine trapping solution (Figure 2). The pots designated for the static system were "closely covered" with aluminum foil during incubation. All soil samples were incubated at 20 ± 1 C (technique not specified), and water was added to the samples as needed. Soil samples were removed from all three treatments at 0, 1, 3, 8, and 12 months posttreatment. The trapping solutions were changed at "regular intervals".

In the flooded soils, surface water was removed by pipette. The soil fraction was Soxhlet-extracted with acetone for 18 hours, then refluxed with methanol:water (1:1) for an additional 18 hours. The 12-month soil samples only were refluxed a third time with deionized water for 18 hours. Radioactivity in aliquots of the soil extracts was determined by LSC; additional aliquots were analyzed by normal-phase one-dimensional TLC on heat-activated silica gel plates developed in chloroform:methanol (98:2) or ethyl acetate:isopropanol:water (4:2:7). The soil extracts were cochromatographed with unlabeled reference standards of paclobutrazol and its keto analogue. The standards were visualized using UV light or by spraying with potassium iodoplatinate reagent. Radioactive areas on the plates were visualized by autoradiography and quantified by TLC linear scanning. The extracted soil was freeze-dried and ground, and aliquots were analyzed for bound radioactivity by LSC following combustion. The trapping solutions were analyzed for total radioactivity by LSC. Radioactivity in aliquots of the surface water was determined by LSC; additional aliquots were analyzed by TLC as described above.

In an attempt to identify [^{14}C]residues that did not migrate from the origin on the TLC plates, the 12-month aerobic samples were further analyzed using paper electrophoresis. [^{14}C]Compounds separated by electrophoresis were identified by comparison to reference standards.

DATA SUMMARY:

Metabolism - Aerobic Soil

Triazole- and methine-labeled [14C]paclobutrazol (radiochemical purities ≥92.0%), at approximately 1.5 kg ai/ha, degraded with a half-life of >1 year in loam soil incubated at 20 C and 40% of its moisture holding capacity for 1 year. At 1 year posttreatment, 54.0% of the applied triazole-labeled [^{14}C]paclobutrazol and 50.4% of the applied methine-labeled [^{14}C]paclobutrazol (60.0 and 57.9% of the recovered, respectively) remained undegraded (Tables 5 and 7).

The major degradate of both test substances was

> (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one [the ketone analogue of paclobutrazol; Compound II],

at a maximum concentration of 15.0 and 16.8% of the applied (17.2 and 18.7% of the recovered) at 1 year posttreatment (Table 7). In the soil treated with triazole-labeled [^{14}C]paclobutrazol,

> 1,2,4-triazole

was detected at a maximum concentration of 2.6% of the recovered at 1 year posttreatment, unidentified extractable compounds (origin and "background" on the TLC plate) were 11.6% of the recovered, a total of 1.1% of the recovered had been evolved as CO_2, and 6.0% was unextractable. In the soil treated with methine-labeled [^{14}C]paclobutrazol, unidentified extractable compounds were 8.0% of the recovered at 1 year posttreatment, a total of 12.1% of the recovered had been evolved as CO_2, and 5.0% was unextractable. The material balances during the study for the triazole label ranged from 77% (at 4 months posttreatment) to 105% (at 8 months) of the applied; material balances for the methine label ranged from 87% (at 12 months posttreatment) to 98% (at 0 months) of the applied (Table 5).

Metabolism - Anaerobic Aquatic

Triazole- and methine-labeled [14C]paclobutrazol (radiochemical purity ≥92%), at approximately 1.5 kg ai/ha, degraded with a half-life of >1 year in flooded loam and silt loam soils incubated at 20 C for 1 year. At 1 year posttreatment in the loam soil, 72.4% of the applied triazole-labeled [^{14}C]paclobutrazol and 60.5% of the applied methine-labeled [^{14}C]paclobutrazol (78.7 and 70.4% of the recovered, respectively) remained undegraded; in the silt loam soil, approximately 76% of the applied triazine-labeled [^{14}C]paclobutrazol (approximately 82% of the recovered) remained undegraded (Tables 5 and 8).

The major degradate of both test substances was

> (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one [the ketone analogue of paclobutrazol; Compound II],

at a maximum concentration 9.6-9.7% of the recovered in the loam soil and 1.1% in the silt loam soil at 1 year posttreatment (Table 8).

> 1,2,4-Triazole

was detected at a maximum concentration of ≤1.8% of the recovered at 1 year posttreatment in the loam and silt loam soils treated with triazole-labeled [^{14}C]paclobutrazol. CO_2 evolution was greater from the soil treated with the methine label than that treated with triazole label (5.3% versus 0.1-0.3% of the recovered at 1 year). In all samples, unidentified extractable compounds (origin and "background" on the TLC plate) were ≤10.4% of the recovered, and 2.6-4.0% was unextractable. The material balances during the study ranged from 85 to 103% of the applied (Table 5).

Results from a static system (flooded silt loam soil in beakers) were similar to those reported for the flow-through system (Tables 5 and 8).

COMMENTS:

1. Attempts to identify material remaining at the origin had limited success. The radioactivity separated into three bands: one was identified as 1,2,4-triazole; one was very tentatively identified as containing a mixture of paclobutrazol and its ketone analogue; and one did not chromatograph with any reference standard used.

2. Label position for the radiolabeled materials is presented in Figure 1.

3. The amounts of paclobutrazol applied per sample were calculated at approximately 0.68, 1.42, and 1.63 kg ai/ha for the triazole static, methine flow-through, and triazole flow-through samples, respectively (Table 4).

4. The study authors did not calculate half-lives for the study. The statistical estimations of the half-lives of paclobutrazol were not calculated by the reviewer because results would be of limited value. Such estimates involve extrapolation beyond the experimental time limits of the study. Data are often incapable of accurately predicting trends outside of their range because small differences are mag-

55

nified and reactions which appear to be linear may, in fact, be curvilinear.

5. Mechanical analysis of the soils was done using the New Jersey system which identifies coarse and fine sand fractions, silt, and clay. The fine sand fraction (0.2-0.02 mm) straddles the sand and silt fractions recognized by the USDA textural classification system; therefore, soils classified under the New Jersey system cannot be readily reclassified using the USDA system.

   Also, studies conducted using Japanese soils are generally not accepted by the EPA because many Japanese soils are not typical of those in the US, i.e. many Japanese soils are high in volcanic ash, which is typical only of Hawaii. In this case, the Japanese soil data will be accepted because of the similarity to the English soil data; if the Japanese soil data alone had been submitted, it is probable that the study would not have been fully acceptable without additional soil characterization.

6. During the aerobic incubation, the treated soils were maintained at 40% of their moisture holding capacity, rather than the recommended 75% of 0.33 bar.

7. Recovery efficiencies and method detection limits were not reported.

8. EFGWB prefers that [^{14}C]residues in samples be separated by chromatographic methods (such as TLC, HPLC, or GC) with at least three solvent systems of different polarity, and that specific compounds isolated by chromatography be identified using a confirmatory method such as MS in addition to comparison to the R_f of reference standards.

   In this study, the sample extracts were analyzed using one-dimensional TLC with two solvent systems. Radioactive areas on the TLC plates were identified only by comparison to the location of known reference standards chromatographed on the same plates.

9. The initial extraction of the soil, a Soxhlet-extraction for 18 hours in acetone, is extremely severe. The study authors did not provide information demonstrating that the extraction procedure did not produce artifacts or cause further degradation of compounds present in the soil.

10182 - EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 57 through 67 are not included in this copy.

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.

X_____ 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.

DATA EVALUATION RECORD

STUDY 5

CHEM 125601 Paclobutrazol §162-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID None

Harvey, B., M. Weissler, C. Zinner, and I. Hill. 1982. PP333: Degradation in Soil. Report Series RJ0256B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME = 10

REVIEWED BY: E. Hirsh TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

G. Maske
5-26-'90

SIGNATURE:

<u>CONCLUSIONS</u>:

<u>Metabolism - Aerobic Soil</u>

1. This study cannot be used to fulfill data requirements.

2. These data are considered to be of uncertain value and should not be used to predict the environmental behavior of paclobutrazol and its degradates.

3. This study is unacceptable for the following reason:

   the analytical method was inadequate to accurately quantify paclobutrazol and its degradates in soil;

the analytical method may have been inadequate to extract paclobutrazol and its degradates from the soil without the formation of artifacts; and

degradates present at >0.01 ppm were not adequately identified.

4. Since the extraction and analytical methods used in this study may have been inadequate, and it is unlikely that the soil samples can be reextracted and reanalyzed, the problems with this study cannot be resolved with the submission of additional data. A new study must be conducted.

METHODOLOGY:

Samples (29.5 g) of sieved (2 mm) "Gore" calcareous clay loam soil (5% coarse sand, 38% fine sand, 44% silt, 13% clay, 14% organic matter, pH 7.7, CEC 45 meq/100 g) or "18 Acres" coarse sandy loam soil (30% coarse sand, 30% fine sand, 24% silt, 15% clay, 4% organic matter, pH 6.8, CEC 20 meq/100 g) were adjusted to 40% of moisture holding capacity, weighed into glass pots (4-cm diameter), and treated with triazole-labeled [^{14}C]paclobutrazol (radiochemical purity 85%, specific activity 3.5 uCi/Mmol, ICI) at a nominal concentration of 0.5 kg ai/ha (approximately 0.2 ppm). There were four pots per soil type; all pots containing the same soil type were placed within a single glass cylinder. Humidified CO_2-free air was pumped continuously (0.1 L/min) through the glass cylinders, then sequentially through two tubes of ethanolamine trapping solution (Figure 2). The samples were maintained at 25 C, and moisture levels in the soil were adjusted every 4 weeks. A single pot of each soil type and the ethanolamine trapping solutions were collected for analysis at 2 hours and 6, 12, and 20 weeks posttreatment.

The soil samples were Soxhlet-extracted with methanol for 18 hours, then refluxed with n-hexane:acetone (1:1) for an additional 18 hours. Separate aliquots of the extracts were analyzed for total radioactivity by LSC. The separate extracts were concentrated by rotary evaporation under vacuum. Duplicate silica gel plates were spotted with two aliquots of each extract: one sample was applied to the plate without additional treatment, the second was mixed with a paclobutrazol standard prior to application. The plates were developed in one direction with either n-hexane:acetone (33:66) or chloroform:diethylamine (95:15) as the solvent. The radioactive compounds were located using autoradiography, and the paclobutrazol standard visualized under UV light (254 nm). Radioactive areas on the plates were scraped and analyzed for total radioactivity by LSC following combustion of the silica. Unextractable [^{14}C]residues remaining in the extracted soils were quantified by LSC following combustion. The ethanolamine trapping solutions were analyzed by LSC; all radioactivity in the solutions was assumed to be $^{14}CO_2$.

69

When the study authors discovered that the TLC system did not adequately separate paclobutrazol from other [^{14}C]residues, an aliquot of the 12-week clay loam soil extract was further analyzed using two-dimensional TLC on silica gel plates developed in n-hexane:acetone (33:66) or chloroform:diethylamine (95:15). Paclobutrazol was found to cochromatograph with compound "a" in the n-hexane solvent and compound "c" in the chloroform solvent; compound "c" was resolved separate from paclobutrazol in the n-hexane solvent. The concentration of paclobutrazol in all samples was then calculated by subtracting the concentration of "c" measured by TLC using the n-hexane solvent from the concentration of paclobutrazol plus "c" measured using the chloroform solvent.

DATA SUMMARY:

Triazole-labeled [^{14}C]paclobutrazol (radiochemical purity 85%), at 0.45 kg ai/ha (approximately 0.2 ppm), degraded with observed half-lives of 6-12 weeks in calcareous clay loam and >20 weeks in coarse sandy loam soils that were incubated for 20 weeks at 25 C and 40% moisture-holding capacity (Table 4).

In the coarse sandy loam soil at 20 weeks posttreatment, [^{14}C]paclobutrazol comprised 52.0% of the recovered radioactivity, a degradate tentatively identified as the keto-analog comprised 9.4%, unidentified organosoluble radioactivity comprised 20.8%, unextractable radioactivity comprised 17.0%, and [^{14}C]volatiles comprised 0.8% (Table 4). During the study, the material balance ranged from 98.2 to 101.0% of the applied (Table 2).

In the calcareous clay loam soil at 20 weeks posttreatment, [^{14}C]paclobutrazol comprised 17% of the recovered radioactivity, a degradate tentatively identified as the keto-analog comprised 11.7% (maximum 14.5% at 12 weeks), unidentified organosoluble radioactivity comprised 23.3%, unextractable radioactivity comprised 36.9, and [^{14}C]-volatiles comprised 11.0% (Table 4). During the study, the material balance ranged from 95.8 to 100.7% of the applied (Table 2).

COMMENTS:

1. The analytical method used to analyze all sample extracts, one-dimensional TLC, did not appear to be adequate to accurately quantify paclobutrazol and its degradates in the soil. An extract of the 12-week clay loam soil was also analyzed by two-dimensional TLC and, in this case, paclobutrazol was found to have cochromatographed with at least one additional compound in both one-dimensional solvent systems. The concentration of paclobutrazol in all other samples was determined by subtraction on the assumption that the single two-dimensional analysis was representative of all study intervals.

2. The initial extraction of the soil, a Soxhlet-extraction for 18 hours in methanol, is extremely severe. The study authors did not provide information demonstrating that the extraction procedure did not produce artifacts or cause further degradation of compounds present in the soil.

3. [^{14}C]Compounds present in the soil at >0.01 ppm were not adequately identified. Up to 23.3% of the recovered radioactivity was classified only as "remainder". Identification of degradate II as the keto-analog of paclobutrazol was by cochromatography with a reference standard only, and was described by the study authors as tentative.

   Also, this aerobic soil metabolism study was not conducted at a concentration near at the maximum registered application rate. In this study, paclobutrazol was applied to the soil at 0.5 kg ai/ha (approximately 0.45 lb ai/A); although current labels were not available for all uses, field dissipation studies were conducted at 2 lb ai/A. If the study had been conducted at the higher rate, additional degradation products may have been isolated.

4. The radiochemical purity of the [^{14}C]paclobutrazol was only 85%. The study authors made no attempt to purity the material prior to use and the identity of the contaminants was not determined.

5. The soils were analyzed at only four intervals, which is inadequate for accurate statistical analyses. Residue decline curves run by EPA provided calculated half-lives of 9.1 weeks in the clay loam soil and 30.5 weeks in the sandy loam soil (Table 5).

6. It could not be determined if the samples were incubated in darkness or light.

7. The soil moisture was at 40% holding capacity instead of the recommended 75%.

8. Mechanical analysis of the soils was done using the New Jersey system which identifies coarse and fine sand fractions, silt, and clay. The fine sand fraction (0.2-0.02 mm) straddles the sand and silt fractions recognized by the USDA textural classification system; therefore, soils classified under the New Jersey system cannot be readily reclassified using the USDA system.

9. Although aliquots of the paclobutrazol stock solution were analyzed, an equipment malfunction caused a possible underestimate of the concentration of paclobutrazol applied to the soil. The study authors stated that a "minimum" of 0.448 kg ai/ha was applied to the soil.

10. The portion of the study using coarse sandy loam soil was terminated before the half-life of paclobutrazol had been reached.

11. Recovery efficiencies and method detection limits were not reported.

10182-EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 72 through 78 are not included in this copy.

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.
- X 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.

DATA EVALUATION RECORD

STUDY 6

CHEM 125601 Paclobutrazol §163-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40685005
Takacs, M.G., and B.G. White. 1986. Paclobutrazol: Adsorption and desorption equilibria in soils. Laboratory Project ID TMJ2377B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME = 6

REVIEWED BY:	J. Harlin	TITLE:	Staff Scientist
EDITED BY:	K. Patten	TITLE:	Task Leader
APPROVED BY:	W. Spangler	TITLE:	Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

5 Feb '90

SIGNATURE:

CONCLUSIONS:

Mobility - Leaching and Adsorption/Desorption

1. This study can be used towards the fulfillment of data requirements.

2. Based on batch equilibrium experiments, paclobutrazol was mobile to very mobile in nine soils ranging in texture from sand to silt loam. In general, adsorption increased with an increase in soil organic matter content and a decrease in soil pH.

3. This study is acceptable and partially fulfills EPA Data Requirements for Registering Pesticides by providing information on the mobility (batch equilibrium) of <u>unaged</u> triazole-labeled [^{14}C]paclobutrazol in nine soils ranging in texture from sand to silt loam.

4. No additional information on the mobility of unaged paclobutrazol is required at this time. The requirement for data on the mobility of aged paclobutrazol has also been fulfilled (Study 7; 40685004).

METHODOLOGY:

Nine soils ranging in texture from sand to silt loam (Tables 1 and 2) were sieved twice (2-mm mesh followed by 1-mm mesh), weighed into glass centrifuge tubes, and mixed with pesticide-free 0.01 M calcium chloride solutions (4 g moist soil:9 mL solution). The soil:solution slurries were stoppered and agitated in an end-over-end shaker for 16 hours at 21 C in the dark. Then, the soil:solution slurries were treated with triazole-labeled [^{14}C]paclobutrazol (radiochemical purity ≥95.3%, specific activity 1961 mBq/mMol, ICI) dissolved in a 0.01 M calcium chloride solution; the final paclobutrazol concentrations were 0.026, 0.052, 0.079, 0.105, and 0.22 ug/g of moist soil, and the final solution volume was 10 mL. The tubes were again stoppered and the slurries equilibrated on an end-over-end shaker for 16 hours. Following equilibration, the solutions were centrifuged and 1-mL aliquots of the supernatants were analyzed for total radioactivity by LSC.

In order to characterize the desorption of paclobutrazol, the 0.079 and 0.22 ug/g adsorption slurries (from which a total of 3 mL of solution had been removed) were restored to their original weight with pesticide-free 0.01 M calcium chloride solution. The soil:solution slurries were shaken for 16 hours and centrifuged, and aliquots of the supernatants were analyzed for total radioactivity by LSC. The desorption procedure was repeated (an additional 6 mL of supernatant were replaced with pesticide-free solution), and the resulting supernatants were again analyzed for total radioactivity by LSC.

Adsorption and desorption were calculated using the equation:

K_d = ug of chemical per g of dry soil ÷ ug of chemical per mL of solution.

Also, tangent "fits" were drawn through the isotherm origins and "the coordinates for at least the two lowest concentrations of chemical added".

DATA SUMMARY:

Based on batch equilibrium experiments, triazole-labeled [^{14}C]paclobutrazol (radiochemical purity ≥95.3%) was mobile to very mobile in nine soils ranging in texture from sand to silt loam that were equilibrated at 21 C in 4:10 soil:calcium chloride solution slurries that contained 0.026, 0.052, 0.079, 0.105, or 0.22 ug of paclobutrazol/g of moist soil. K_{ads} values (ug of pesticide per g of dry soil ÷ ug of pesticide per mL of solution) ranged from 1.3 to 23.0 (Table 3). In

80

general, adsorption increased with an increase in soil organic matter content and a decrease in soil pH. An estimated 65% of the adsorbed [^{14}C]paclobutrazol desorbed from the soil during two desorption steps; K_{des} values for the nine soils ranged from 1.87 to 27.97 following the first desorption step and from 2.66 to 33.95 following the second desorption step (Table 5).

COMMENTS:

1. The soils were not analyzed after equilibration to confirm adsorption and to provide a material balance.

2. Simple distribution coefficients (K_d = ug of chemical per g of dry soil ÷ ug of chemical per mL of solution) were calculated instead of Freundlich K values.

3. The soils were classified by a system different from the USDA Soil Textural Classification System. The soils could not be reclassified because the particle size distribution was not similar to the USDA system.

4. A preliminary experiment was not conducted to determine if the time required for equilibrium to be achieved. However, a 16-hour equilibration period should be adequate.

5. The equilibrating solution was not completely removed after each desorption step. The authors called it a "sequential dilution".

6. The study authors used soil that passed a 1-mm sieve. Soils should include everything <2 mm; coarser material usually exhibits decreased adsorption, which would increase the observed mobility. However, since the pesticide was found to be mobile to very mobile in all soils studied, the exclusion of the coarse fraction of the soil apparently did not significantly change the results.

7. Recovery efficiencies and method detection limits were not reported.

10182 - EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 82 through 90 are not included in this copy.

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.

X 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.

DATA EVALUATION RECORD

STUDY 7

CHEM 125601 Paclobutrazol §163-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40685004
Mistry, R., and I.R. Hill. 1986. Paclobutrazol: Mobility of paclobutrazol and its degradation products in soil columns. Laboratory Project ID RJ0495B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME = 8

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

5 Jul '90

SIGNATURE:

CONCLUSIONS:

Mobility - Leaching and Adsorption/Desorption

1. This study can be used towards the fulfillment of data requirements.

2. Based on column leaching experiments, aged methine-labeled [^{14}C]paclobutrazol residues were relatively immobile in sand, sandy loam, loamy sand, and clay loam soils. Aged triazole-labeled [^{14}C]paclobutrazol residues had low mobility in sand and sandy loam soils and were mobile in loamy sand and clay loam soils. One degradate, (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one, the ketone analogue of paclobutrazol, was identified in the soil columns of both label positions.

3. This study is acceptable and partially fulfills EPA Data Requirements for Registering Pesticides by providing information on the mobility (column leaching) of <u>aged</u> methine- and triazole-labeled [^{14}C]paclobutrazol residues in sandy loam, loamy sand, clay loam, and sand soils.

4. No additional data on the mobility of aged paclobutrazol is required at this time. The requirement for data on the mobility of unaged paclobutrazol has also been fulfilled (Study 6, 40685005).

METHODOLOGY:

Four soils (sandy loam, loamy sand, clay loam, and sand; soil characteristics presented in Table 2) were partially air-dried and sieved (2 mm) prior to use. Samples of each soil were placed in glass pots and treated with triazole- or methine-labeled [^{14}C]paclobutrazol (radiochemical purities 97 and 96%, respectively; specific activities 2.22 and 1.87 GBq/mMol, respectively; ICI) at a nominal application rate of approximately 1 kg ai/ha. The soil pots were placed inside glass cylinders (Figure 2) and incubated aerobically in the dark at 40% of moisture-holding capacity and 20 ± 1 C for 9 weeks. Humidified CO_2-free air was passed (0.16 L/minute) through the cylinders and then through two tubes of ethanolamine to trap $^{14}CO_2$. Distilled water was added to the soils at 4-week intervals to maintain moisture levels. The soils were sampled at 0 and 9 weeks posttreatment for residue characterization; the trapping solutions were sampled at various intervals (unspecified) up to 9 weeks posttreatment to quantify volatilization.

Following the 9-week aging period, the aged soils were transferred to the top of columns (30 cm height x 5.1 cm id) of corresponding untreated soil (<5-mm mesh). There were five columns prepared per soil type (two per label position, and one untreated control). A 2-cm-deep layer of sand was placed over the aged soil layers. The columns were leached with 30 ml (equivalent to 1.5 cm of "rain") of 0.01 M calcium chloride solution each weekday over a 9-week period, for a total of 1350 mL (corresponding to 66.1 cm of "rain"). Leachates were collected daily, bulked into weekly samples, and stored at 4 C. The bulked leachates were analyzed for total radioactivity, and then stored at <-18 C for an unspecified period. Following leaching, the sand layer was removed from the top of the columns, and each soil column was separated into six 5-cm-thick segments.

Total radioactivity in subsamples of each soil segment, in the surface sand from each soil column, and in whole pots of the soil collected at 0- and 9-weeks during the aging period was quantified by LSC following combustion; the control columns were used to determine background radioactivity. To characterize [^{14}C]residues, the soil column segments were Soxhlet-extracted with acetone for 18 hours, then refluxed with methanol:water (1:1) for 18 hours. The soil segments were further extracted by refluxing in deionized water for

92

18 hours. All extracts were analyzed for total radioactivity by LSC. The acetone extracts only were concentrated by rotary evaporation and analyzed by one-dimensional TLC on heat-activated silica gel plates developed in chloroform:methanol (98:2). The methanol:water and water extracts were not analyzed for specific compounds because these extracts contained less than 5% of the applied radioactivity. Unlabeled reference compounds were cochromatographed with the samples. Following development, reference compounds were visualized by fluorescence quenching or by spraying with potassium iodoplatinate reagent. Radioactive areas were detected by autoradiography and quantified using a TLC linear analyzer. Unextractable radioactivity remaining in the soil was quantified by LSC following combustion.

Gas trap solutions and the weekly bulked leachates were analyzed for total radioactivity by LSC. Leachates from the columns treated with triazole-labeled [^{14}C]paclobutrazol residues were concentrated by rotary evaporation and analyzed by TLC as described above; leachates from the columns treated with triazole-labeled [^{14}C]paclobutrazol residues were not further analyzed because they contained <1% of the applied radioactivity.

DATA SUMMARY:

Using column leaching techniques, aged (9 weeks) residues of methine-labeled [^{14}C]paclobutrazol (radiochemical purity 96%) were determined to relatively immobile (<1% of the applied in the leachate) in 30-cm columns of sand, sandy loam, loamy sand, and clay loam soils leached with 66.1 cm (1350 mL) of 0.01 M calcium chloride solution over a 9-week period (Table 14). In contrast, aged residues of triazole-labeled [^{14}C]paclobutrazol were determined to be of low mobility (2-3% of the applied in the leachate) in sand and sandy loam soils and mobile (6-13% of the applied in the leachate) in loamy sand and clay loam soils (Table 13). In all cases, the majority (58.6-90.7% of the applied) of the aged [^{14}C]residues did not leach out of the upper 10-cm of the treated soil columns (Tables 9-12).

[^{14}C]Residues in the leachate were characterized as "very polar material" (they did not move from the origin using TLC). In all soil columns after leaching, [^{14}C]paclobutrazol was the major extractable degradate, ranging from 17.5% of the applied (triazole-labeled) in the clay loam to 84.4% (methine-labeled) in the sand (Table 8). One degradate,

> (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one [the ketone analogue of paclobutrazol],

was isolated from the soil columns at up to 12.6% of the applied; the remaining radioactive residues in the columns were either unidentified extractable compounds ($\leq$6.3% of the applied) or unextractable compounds ($\leq$18.7%) (Table 8).

After 9 weeks of aging and immediately prior to leaching, parent paclobutrazol comprised 71.6-91.0% of the applied in the sandy loam, loamy sand, and sand soils; the ketone analogue comprised up to 9% of the applied in the three soils (Table 8). Degradation of the parent compound was greater in the clay loam soil; paclobutrazol accounted for 49.9-55.0% of the applied and its ketone analogue was 15.9-17.6% of the applied at 9 weeks posttreatment.

Material balances after the 9-week incubation period ranged from 92.8 to 99.3% (Table 7). Material balances after the leaching period were 85-112% for the triazole-labeled [^{14}C]paclobutrazol and 61-95% for the methine-labeled [^{14}C]paclobutrazol (Table 5).

COMMENTS:

1. Total recovery of radioactivity from the soil columns (soil and leachate) treated with triazole-labeled [^{14}C]paclobutrazol was approximately 85% in the clay loam, and >100% in the remaining three soils (Table 5). In soil columns treated with methine-labeled [^{14}C]paclobutrazol, losses of radioactivity were greater; recoveries were approximately 60% in the clay loam, 80% in the sandy loam, and ≥90% in the loamy sand and sand soils. The study authors stated that the losses of radioactivity that were observed in this mobility study reflected the relative rates of $^{14}CO_2$ evolution during the aerobic incubation period prior to leaching. However, no attempts were made to trap possible volatile degradates from the soil in this study.

2. During the 9 weeks of aerobic incubation, the treated soils were maintained at 40% of their moisture holding capacity, rather than the recommended 75% of 0.33 bar.

3. Recovery efficiencies and method detection limits were not reported.

4. EFGWB prefers that [^{14}C]residues in samples be separated by chromatographic methods (such as TLC, HPLC, or GC) with at least three solvent systems of different polarity, and that specific compounds isolated by chromatography be identified using a confirmatory method such as MS in addition to comparison to the R_f of reference standards.

   In this study, the sample extracts were analyzed using one-dimensional TLC with one solvent system. Radioactive areas on the TLC plates were identified only by comparison to the location of known reference standards chromatographed on the same plates.

5. The initial extraction of the soil, a Soxhlet-extraction for 18 hours in methanol, is extremely severe. The study authors did not provide information demonstrating that the extraction procedure did not produce artifacts or cause further degradation of compounds present in the soil.

6. EFGWB prefers that soil columns be leached continuously, rather than over an extended period of time.

10182 - EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 96 through 107 are not included in this copy.

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.

X_____ 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.

DATA EVALUATION RECORD

STUDY 8

CHEM 125601 Paclobutrazol §163-3

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID None
Hill, I.R., and S. Prashad. 1982. PP333: Leaching in soil. Report Series RJ0244B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas, Inc., Wilmington, DE.

DIRECT REVIEW TIME = 8

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

SIGNATURE:

CONCLUSIONS:

Mobility - Leaching and Adsorption/Desorption

1. This study cannot be used to fulfill data requirements.

2. These data are considered to be of uncertain value and should not be used to predict the environmental behavior of paclobutrazol and its degradates.

3. This study is unacceptable for the following reason:

   the analytical method was inadequate to accurately determine the mobility of paclobutrazol in soil (R_f values could not be calculated for the test soils because the solvent front had moved off the plates).

4. Since the soil TLC method as executed was inadequate, the problems with this study cannot be resolved with the submission of additional data. However, the mobility data requirements for unaged and aged paclobutrazol have been fulfilled.

METHODOLOGY:

Coarse sand, loamy sand, calcareous silt loam, and sandy loam soils (Table 2), were air-dried, ground to pass a 2-mm sieve, and stored in an air-dried condition in polythene bags at room temperature for an unspecified period of time. Soil TLC plates were prepared by gluing a wick made of cotton muslin and measuring approximately 5 x 6 cm to one end of an aluminum plate (5 cm wide, 0.5 cm deep, 30 cm long). Each plate was then filled to a depth of 0.5 cm with a known amount of test soil (course sand, 105 g; loamy sand, 86 g; silt loam, 60 g; and sandy loam, 61 g). A 1-cm wide band was then removed 2-3 cm from the "wick" end of each plate, using suction through a glass tube. A 2.5-g aliquot of the removed soil of each soil type was weighed into a 10-mL beaker and treated with triazole-labeled $[^{14}C]$paclobutrazol (radiochemical purity 92-98%, specific activity 3.5 mCi/mMol, ICI) at a rate equivalent to 0.125 or 1.25 g ai/ha (Table 3). Additional 2.5 g-soil samples from each soil type were treated with 0.6 kg ai/ha of [ethyl-1-^{14}C]atrazine (radiochemical purity 96%) which served as the reference standard; 2.5-g samples from each soil type were treated with 0.5 mL of solvent (unspecified) to serve as controls. The mixtures of soil and pesticide (or solvent) were left overnight at room temperature to allow the solvent to evaporate. After standing, the treated soil was thoroughly mixed and replaced on the soil plates.

The soil plates were placed at a 5-degree angle to the horizontal in a box having a water-saturated atmosphere (Figure 3a). The "wick" (uppermost) end of each plate was supported by a perspex reservoir and the lowermost end of the plate was supported by polyproplene (sic) bottles for collection of leachates (Figure 3). The plates were developed at an unspecified temperature with 80 mL of 0.01 M calcium chloride solution (equivalent to 32 cm "rain") placed in the perspex reservoir. The total amount of solution was taken up by the plates in 4-6 days.

The leached soil plates were stored at -20 C for an unspecified period of time prior to being analyzed using a TLC linear analyzer. Total radioactivity in the leachates was determined using LSC; the limit of detection for LSC was 0.002 ug/mL (less than twice background).

DATA SUMMARY:

Using modified soil TLC methods, the study authors determined that, in comparison to atrazine and based on Helling's classification system, triazole-labeled [^{14}C]paclobutrazol (radiochemical purity 92-98%), had low mobility in coarse sand, loamy sand, calcareous silt loam, and sandy loam soils. The mobility of paclobutrazol was highest in the coarse sand which had the lowest organic matter content (0.7%) and lowest clay content (6.2%), with up to 9.2% of the applied in the leachate (Table 4). Increasing the concentration of paclobutrazol appeared to increase mobility in the four soils (Table 5).

In the system used, the reference pesticide atrazine was moderately mobile, with up to 44% of the applied found in the leachate of the coarse sand (Table 4).

COMMENTS:

1. The Rf values were not calculated. However, it is not possible to calculate them from the data presented, since the test was not conducted in a similar fashion to other soil TLC studies. In TLC studies, the solvent is allowed to elute for a specified distance through the soil on the plate, the distance that the test material has moved is determined, and the Rf is calculated from the distance moved by the test substance divided by the distance moved by the solvent. In this study, the entire volume of soil was eluted with the solvent, so that the distance moved by the solvent is unknown. Volumes of leachate collected ranged from 18 to 48 mL (Table 4).

2. The reference pesticide atrazine was applied to separate plates from the test substance.

3. The temperature at which the study was conducted was not reported; it was only stated that the test was done at "room temperature".

4. In order to determine the application rates, the vessels used to mix the treated soils were washed with methanol and aliquots of the methanol washings were analyzed for total radioactivity by LSC. The actual application rates per soil type are provided in Table 3.

5. Mechanical analysis of the soils was done using the New Jersey system which identifies coarse and fine sand fractions, silt, and clay. The fine sand fraction (0.2-0.02 mm) straddles the sand and silt fractions recognized by the USDA textural classification system; therefore, soils classified under the New Jersey system cannot be readily reclassified using the USDA system.

10182 - EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 111 through 117 are not included in this copy.

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.

X______ 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.

DATA EVALUATION RECORD

STUDY 9

CHEM 125601 Paclobutrazol §164-1

FORMULATION--15--SOLUBLE CONCENTRATE

STUDY ID 40685006

Mak, C., S.J. Crook, and N.C. Atreya. 1987. Paclobutrazol: Field dissipation following subsurface applications in US orchard soils up to 12 months. Laboratory Project ID RJ0574B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

STUDY ID 40685007

Hendley, P., L.F. Davis, and B.R. Oliver. 1987a. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - California site - Report of field data. Laboratory Project ID TMU3304/B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE.

STUDY ID 40685009

Hendley, P., L.F. Davis, and B.R. Oliver. 1987b. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - Florida site - Follow-up report of field data. Laboratory Project ID TMU3303/B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE.

STUDY ID 40685010

Hendley, P., L.F. Davis, and B.R. Oliver. 1987c. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - Florida site - Second follow-up report of field data. Laboratory Project ID TMU3345B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE.

STUDY ID 40685011

Hendley, P., L.F. Davis, and B.R. Oliver. 1987d. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - West Virginia site - Follow-up report of field data. Laboratory Project ID TMU3305B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE.

STUDY ID 40685012

Hendley, P., L.F. Davis, and B.R. Oliver. 1987e. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - West Virginia site - Second follow-up report of field data. Laboratory Project ID TMU3347/B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME - 20

REVIEWED BY: C. Little TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

SIGNATURE:

CONCLUSIONS:

Field Dissipation - Terrestrial

1. This study cannot be used to fulfill data requirements at this time.

2. Paclobutrazol degraded with a half-life of 450-973 days in orchard soils from California, West Virginia, and Florida that were treated with paclobutrazol. The major degradate was the ketone metabolite of paclobutrazol.

3. This study is scientifically sound, but does not meet Subdivision N guidelines for the following reasons:

   no freezer storage stability data were provided;

   the soil was not sampled deep enough to define the extent of leaching;

   pretreatment and/or control plot data were not provided; and

   the soils and site were incompletely characterized.

4. Since the soil was not sampled deep enough at any of the test sites to define the extent of leaching, the problems with this study cannot be resolved with the submission of additional data. A new study is required.

METHODOLOGY:

Paclobutrazol (Cultar or Clipper, 2 lb/gallon SC) was applied to fruit orchards in California, West Virginia, and Florida at a nominal rate of 0.6 or 6.0 g ai/linear foot (maximum proposed application rates for fruit and amenity trees, respectively); the pesticide was injected (4- to 6-inch depth) into the soil a distance 2-6 feet from the sides of the line of trees in March/April, 1985. In California, the experimental plots were in a peach orchard located on sandy loam soil and watered using flood irrigation; the actual application rates were 0.58 and 5.41 g ai/foot. In West Virginia, the experimental plots were in an apple orchard located on clay loam soil and receiving no irrigation; the actual application rates were 0.68 and 6.49 g ai/foot. In Florida, the experimental plots were in a citrus orchard located on sand soil; the site was characterized by high air temperatures and high rainfall. The actual application rates were 0.53 and 4.86 g ai/foot.

Soil samples (10 per plot, 10 x 3 inches in 8-inch-deep increments) were collected to a depth of 48 inches in California and Florida and to a depth of 24 inches in West Virginia. The ten samples were composited at time 0 (<6 hours posttreatment) and all other sampling intervals (final sampling 356-376 days posttreatment). In addition, the ten samples/plot taken at 4 months posttreatment were analyzed separately to determine variability. The soils were stored at -20 ± 2 C for up to 9 months before analysis.

The soil samples were analyzed for total paclobutrazol residues (paclobutrazol and its ketone metabolite) and for the paclobutrazol ketone metabolite alone using Plant Protection Division Residue Analytical Method No. 79. According to the method, the samples were extracted with methanol:water (90:10) by shaking for 1 hour, then filtered. Aliquots of the extracts were transferred to a separatory funnel and partitioned with water:methylene chloride (4:1). The water fraction was discarded, and the methylene chloride fraction was evaporated to dryness on a rotary evaporator, redissolved in acetone, dried again, and redissolved in hexane. In order to clean up the samples (remove soil coextractives), the hexane solution was filtered through a silica column and the column was eluted with 70% ether:hexane. The registrant stated that for soil samples in which high concentrations of parent were expected, the partition and clean-up stages were omitted; for samples in which low concentrations were expected, only the clean-up stage was omitted. Aliquots of the soil extracts were analyzed using GLC with nitrogen-phosphorus selective detection. Recovery efficiencies from soil samples fortified with paclobutrazol at 0.1 to 200 ppm averaged 76-100% of the applied.

DATA SUMMARY:

Paclobutrazol dissipated very slowly or was stable in soil during the 356-376 days following the treatment of fruit orchards in California, West Virginia, and Florida that were treated with paclobutrazol (Cultar or Clipper, 2 lb/gallon SC) at approximately 0.6 or approximately 6.0 g ai/linear foot (Tables 8-20, Graphs 1-6). Based on concentrations of total paclobutrazol residues (paclobutrazol plus its ketone metabolite) in the upper 24 inches of soil, the registrant-calculated half-lives of the residues ranged from 450-973 days for the low-treatment-rate plots in California, West Virginia, and Florida, and the high-treatment-rate plot in California (at the high-treatment-rate sites in West Virginia and Florida, the concentration of total residues at the final sampling interval was larger than that at time 0). At 356-376 days posttreatment, the concentrations of total paclobutrazol residues in the 0- to 8-inch soil depth of plots treated at 0.6 lb ai/linear foot were 14 ppm in California, 35 ppm in West Virginia, and 11 ppm in Florida. The concentrations of total paclobutrazol residues in plots treated at 6.0 lb ai/linear foot were 177 ppm in California, 447 ppm in West Virginia, and 108 ppm in Florida. The majority of the residues were identified as paclobutrazol; the ketone metabolite of paclobutrazol was detected at a maximum mean concentration of 5.7 ppm in the 0- to 8-inch soil depth (in Florida).

Total paclobutrazol residues were detected at 0.01 to 1.9 ppm in the deepest soil samples that were collected, depths of 48 inches in California and Florida and 24 inches in West Virginia. Maximum leaching occurred at the Florida site, where at approximately 370 days posttreatment the concentrations of total paclobutrazol residues in the 40- to 48-inch depth were 0.07 and 1.8 ppm in the plots treated at 0.6 and 6.0 g ai/linear foot, respectively. In general, the paclobutrazol ketone metabolite comprised a greater percentage (up to 67%) of the total residues in the deeper soil sections than in the surface soil.

In California during the approximately 1 year study, air temperatures ranged from 25 to 105 F, precipitation totaled approximately 15.5 inches, and irrigation totaled 29.5 inches. In West Virginia, air temperatures ranged from -13 to 97 F and precipitation totaled approximately 33.5 inches. In Florida, air temperatures ranged from 19 to 100 F and precipitation totaled approximately 53 inches.

COMMENTS:

1. The soils were frozen for up to 9 months prior to analysis. The study authors stated that, based on preliminary data, paclobutrazol residues were stable for at least 9 months when stored at -20 C, and they referred to a storage stability study (N.C. Atreya and B.L. Freeman. Paclobutrazol: Storage Stability Study PP333BC02/BC03); however, this study was not provided to review. Also, it could not be determined if the concentrations of paclobutrazol and its keto analogue were stable, or only the total residues concentration was stable.

121

2. The soil was not sampled deep enough to define the extent of leaching. Total paclobutrazol residues were 0.01 to 1.9 ppm and the paclobutrazol ketone metabolite was 0.007 to 1.2 ppm in the deepest soil samples that were collected (48 inches in California and Florida and 24 inches in West Virginia).

3. The study authors reported that untreated samples were collected from all sites. It could not be determined if this referred to pretreatment samples or control (untreated) plots, and no data were provided; therefore, there was no evidence that the plots were not contaminated with paclobutrazol before or during the study.

4. Soil characteristics such as textural analysis (% sand, silt, and clay), organic matter content, pH, and CEC were not reported. The characterization of the site was incomplete; the size of the plots, slope, and depth to the water table were not reported.

5. Paclobutrazol was injected 4-6 inches below the soil surface and was, therefore, not exposed to solar irradiation.

6. Documents were provided that referred to soil samples collected at approximately 1.5 and 2 years posttreatment; however, no paclobutrazol data were provided for these intervals.

7. Routine maintenance of plots in West Virginia included applications of paraquat; in Florida, glyphosate was applied 2-3x per year. Management practices were not further characterized by the study authors.

10182-EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 123 through 146 are not included in this copy.

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.

X 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.

DATA EVALUATION RECORD

STUDY 10

CHEM 125601 Paclobutrazol §164-1

FORMULATION--06--WETTABLE POWDER

STUDY ID None
Pearson, F.J. 1985. PP333 and PP333 ketone residue dissipation in U.S. soils. Report Series TMU1760/B. Unpublished study prepared by ICI Americas Inc., Goldsboro, NC, and Analytical Biochemistry Laboratories, Columbia, MO; and submitted by ICI Americas Inc., Goldsboro, NC.

DIRECT REVIEW TIME = 20

REVIEWED BY: C. Little TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

SIGNATURE:

CONCLUSIONS:

Field Dissipation - Terrestrial

1. This study cannot be used to fulfill data requirements.

2. Paclobutrazol dissipated with half-lives of 20-26 weeks in loamy sand and silt loam soils in North Carolina, Illinois, and Mississippi. Total paclobutrazol residues [paclobutrazol and (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol)-1-yl)pentan-3-one, the ketone analogue of paclobutrazol] dissipated with half-lives of 25-32 weeks in the same soils.

3. This study is scientifically sound, but does not meet Subdivision N guidelines for the following reasons:

   freezer storage stability data were not provided; and

   the test soils were not adequately characterized.

4. In order for this study to fulfill the terrestrial field dissipation data requirements, freezer storage stability studies for both paclobutrazol and its ketone analogue must be submitted. The characteristics of the soils in the test plots must be adequately described. Also, because the soils were sampled only to a depth of 12 inches and paclobutrazol and its ketone analogue have been identified as potential groundwater contaminants in mobility (Studies 6 and 7; 40685005 and 40685004, respectively) and field dissipation studies (Study 9; 40685006, 40685007, 40685009, 40685010, 40685011, 406850120), EPA may request additional field dissipation studies.

METHODOLOGY:

Paclobutrazol (PP333; 50% WP, formulation GFU029), at 2 lb ai/A, was applied in a single application with ground spray equipment in spray volumes of 25-50 gal/A at three locations:

Norfolk sandy loam (pH 6.2, CEC 4.4 meq/100 g, 1.3% organic matter), plot size 20 x 40 feet, located in Goldsboro, North Carolina, on June 28, 1982;

Flanagan silt loam (pH 6.2, CEC 18.4 meq/100 g, 4.8% organic matter), plot size 20 x 30 feet, located in Champaign, Illinois, on July 15, 1982; and

Commerce silt loam (pH 6.2, CEC 6.6 meq/100 g, 1.8% organic matter), plot size 25 x 40 feet, located in Vicksburg, Mississippi, on July 9, 1982.

The plots were treated with herbicides to maintain an unvegetated state throughout the study; the herbicides (paraquat, glyphosate, fluasifop-butyl) were selected so as to not interfere with the analyses of the parent compound or degradate residues. Twenty to thirty 1-inch core samples were collected to a depth of 12 inches at the NC, IL, and MS sites at pre- and post-treatment, and at intervals including 30-32, 60-69, 94-98, 123-133, 189-190, 286-287, 337-364, 533-549, 657, and 731 days posttreatment (soils were not sampled at all intervals at each site). For each site, subsamples from similar depths (0- to 6- and 6- to 12-inches) were composited and homogenized (moist) by mixing. Samples were stored frozen for up to two years until analysis.

Soil samples were broken into small clumps and air-dried by circulating air across the surface, and then homogenized using a mortar and pestle. Soil samples (100 g) were extracted by shaking with methanol:water (9:1, v:v) for 1.5 hours, then filtered and rinsed with the methanol solution. Half of the extract was then concentrated on a rotary evaporator at ≤60 C. The concentrate was adjusted to pH 11 with a 1 M sodium hydroxide solution, extracted three times with methylene chloride, dried through anhydrous sodium sulfate, rinsed with methylene chloride, and concentrated on a rotary evaporator at ≤25 C. The concentrated solution was passed through a florisil column; GLC analysis was done on the resulting residue using calibration standards of paclobutrazol and its ketone analogue in acetone. The detection limit for paclobutrazol ranged from 0.02 to 0.05 ppm; the detection limit for the ketone analogue was 0.02 ppm. Recovery efficiencies for soil samples spiked with paclobutrazol at 0.022-0.563 ug/g averaged 96.5 ± 16.9%; recovery efficiencies for 28 soil samples spiked with the ketone analogue of paclobutrazol at 0.018-0.44 ug/g was 101.3 ± 11.2%.

DATA SUMMARY:

Paclobutrazol (50% WP), at 2 lb ai/A, dissipated with registrant-calculated half-lives of 20 weeks in Commerce silt loam soil (Mississippi), 25 weeks in Norfolk loamy sand soil (North Carolina), and 26 weeks in Flanagan silt loam soil (Illinois) (Tables 3-5, Graphs 1-3). Total paclobutrazol residues (paclobutrazol plus its ketone analogue) dissipated with half-lives of 32, 25, and 29 weeks, respectively, in the same soils (Graphs 5-7). The ketone analogue was ≤0.04 ppm in the NC and IL soils, but accumulated to a maximum of 0.37 ppm in the MS soil. No downward movement of either paclobutrazol or its ketone analogue was detected.

In the 0- to 6-inch depth of the loamy sand soil at the NC site, paclobutrazol was 0.64 ppm immediately posttreatment, ranged from 0.29 to 0.40 ppm with no discernable pattern between 95 and 227 days, was 0.22 ppm at 337 days, and was 0.05 ppm at 533 days (Table 2). The ketone analogue of paclobutrazol was ≤0.03 ppm in the 0- to 6-inch depth at all sampling intervals. Neither paclobutrazol nor its ketone analogue were detected (<0.02-0.05 and <0.02 ppm, respectively) in the 6- to 12-inch depth at any sampling interval.

In the 0- to 6-inch depth of the silt loam soil at the MS site, paclobutrazol was 0.45-0.48 ppm between 0 and 62 days posttreatment, 0.10-0.16 ppm between 95 and 346 days (except for 0.26 ppm at 123 days), and 0.02 ppm at 731 days (Table 3). The ketone analogue of paclobutrazol accumulated to a maximum of 0.37 ppm at 123 days posttreatment; 0.04 ppm remained in the soil at 731 days. Neither paclobutrazol nor its ketone analogue were detected (<0.02-0.05 and <0.02 ppm, respectively) in the 6- to 12-inch depth at any sampling interval.

In the 0- to 6-inch depth of the silt loam soil at the IL site, paclobutrazol was 0.53-0.69 ppm between 0 and 69 days posttreatment, 0.38 ppm at 123 days, and 0.02 ppm at 657 days (Table 4). The ketone analogue of paclobutrazol accumulated to a maximum of 0.04 ppm at 69 days posttreatment. Neither paclobutrazol nor its ketone analogue were detected (<0.02-0.05 and <0.02 ppm, respectively) in the 6- to 12-inch depth at any sampling interval.

At the three sites, monthly rainfall ranged from 0.87 to 12.43 inches. During the first year of study, rainfall totalled 41.64 inches at the IL site, 53.92 inches at the NC site, and 86.88 inches at the MS site.

COMMENTS:

1. No freezer storage stability data were provided with the study to review. The study authors indicated that freezer storage stability data covering the two-year storage period are available for the three sites reviewed.

2. Soil properties given in the methodology were taken from the text of the study; however, due to incomplete data, the soil classifications could not be confirmed by the reviewer. In Table 1, data are given for three soil samples from each location (with several data omissions). While the table footnotes indicate that the data in Column 2 refer specifically to this study, it is obvious that in some cases averages of the data in all three columns were used; in other cases, it is unclear as to how the numbers and the classifications given in the text were obtained. For example, sand content listed in the three columns for the plot classified as Norfolk loamy sand ranged from 59 to 90%; organic matter ranged from 0.8 to 2.1%. For both the Flanagan silt loam and the Commerce silt loam, data on the soil constituents were not reported (Column 2). For the Flanagan silt loam, CEC was reported in the text as 18.4 meq/100 g, while it is reported in Column 2 as 24.4 for the soil samples used specifically for this study; the 18.4 is an average of the CEC for soils used in this study (Column 2) and a study on PF021 (Column 3). Also, the footnotes indicate that Column 1 lists previously reported data on samples collected from the Goldsboro farm; it is unclear as to why such data would be listed under the Champaign, IL, and Vicksburg, MS, sites as well.

3. The concentrations reported for total paclobutrazol residues in the 0- to 12-inch depths (Tables 2-4) appear to have been obtained by summing the concentrations of paclobutrazol in the 0- to 6- and 6- to 12-inch depths with the concentrations of its ketone analogue in the same depths. If this is true, the reported values are incorrect. The study authors failed to consider that by summing the 0- to 6- and 6- to 12-inch depths, the data are in terms of "parts per 2 million" not "parts per million"; the reported values in the 0- to 12-inch

depth are too large by a factor of two. This miscalculation does not affect the reported half-lives.

4. EFGWB recommends that, in order to define the depth of leaching of parent and degradates, soils be sampled deep enough so that no pesticide residues are detected in the two deepest soil layers analyzed. In this study, only two soil layers were analyzed (0- to 6- and 6- to 12-inches). However, since no residues were detected in the deepest layer analyzed at any sampling interval at the three sites despite yearly precipitation of approximately 42 to 87 inches, it is not logical to claim that these soils were not sampled deep enough to define the extent of leaching at these sites. In contrast to the behavior of paclobutrazol and its ketone analogue in this study, in field studies (Study 9; 40685006, 40685007, 40685009, 40685010, 40685011, 406850120) using sand and clay loam soils, total paclobutrazol residues were 0.01 to 1.9 ppm and the paclobutrazol ketone analogue was 0.007 to 1.2 ppm in the deepest soil samples that were collected (48 inches in the sand soils and 24 inches in the clay loam soil).

5. The concentrations of paclobutrazol in the soils immediately posttreatment (0.47-0.64 ppm) were lower than expected. An application rate of 2 lb ai/A should have resulted in a posttreatment concentration of approximately 1 ppm in the upper 6 inches of soil.

6. Although the original document included information on additional plots that had been tested in Visalia, CA, 3 years prior to the other three experiments discussed in this study, the study authors indicated that the CA data were included for general information only. Because of the age of the samples and the lack of long-term storage stability data, the data from CA were not included in the calculations and, therefore, are not reported in this review.

10182-EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 152 through 166 are not included in this copy.

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.

X______ 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.

DATA EVALUATION RECORD

STUDY 11

CHEM 125601 Paclobutrazol §164-1

FORMULATION--06--WETTABLE POWDER

STUDY ID 00155854
Francis, P.D. 1986. Paclobutrazol: Short-term dissipation and movement following a broadcast spray. Report Series TMU1953. Unpublished study prepared and submitted by ICI Americas Inc., Goldsboro, NC.

DIRECT REVIEW TIME = 10

REVIEWED BY: K. Patten TITLE: Staff Scientist

EDITED BY: S. Syslo TITLE: Staff Scientist

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

SIGNATURE:

This study was conducted by ICI scientists to demonstrate to EFGWB that paclobutrazol and its ketone analogue did not leach under the heavy irrigation practices used on golf courses, and that the results observed in a previous study, in which paclobutrazol residues did not leach below a depth of 6 inches, were correct.

CONCLUSIONS:

Field Dissipation - Terrestrial

1. This study cannot be used to fulfill data requirements.

2. Paclobutrazol (50% WP), at 2.25 lb ai/A, decreased from 0.98 ppm immediately posttreatment to 0.62 ppm at 30 days in the upper 6 inches of turf-covered field plots of sandy loam soil located in North Carolina. The ketone analogue of paclobutrazol was $\leq$0.02 ppm in the upper 6 inches of soil at all sampling intervals. Neither

167

paclobutrazol nor its ketone analogue were detected (<0.01 ppm) in deeper soil layers at any interval.

3. This study is scientifically sound, but does not meet Subdivision N guidelines for the following reasons:

   - the study was terminated after only 30 days, before the pattern of decline of paclobutrazol was established; and

   freezer storage stability data were not provided.

4. Because this study was terminated before the pattern of decline of paclobutrazol was established, this study cannot be amended to fulfill the terrestrial field dissipation data requirement. The study does demonstrate that paclobutrazol, applied to turf-covered plots which are heavily irrigated, does not leach during the first 30 days following treatment.

<u>METHODOLOGY</u>:

Turf-covered field plots (15 x 40 feet) of sandy loam soil (68-69% sand, 25-28% silt, 4-6% clay, 1.2% organic matter, pH 6.3-6.4, CEC 3.0-4.3 meq/100 g) located in Goldsboro, North Carolina, were treated with paclobutrazol (Parlay; 50% WP) at 2.25 lb ai/A using ground spray equipment in a single application. During the 30-day study, irrigation supplemented the natural rainfall so that the treated plot received at least 0.25 inches of water each day. Soil cores (14-21 cores/interval) were collected from the plot with a 12- or 18-inch zero contamination corer prior to treatment and at 0, 1, 3, 7, 14, and 30 days posttreatment. The cores were taken to a depth of 12 inches at 0 days, 18 inches at 14 and 30 days, and 24 inches at 1, 3, and 7 days. The cores were sectioned into 6-inch segments, and the upper 1-inch of the 12- to 18-inch segments that were collected with the 12-inch corer was discarded "to guard against contamination from material that had fallen into the core from the surface". Samples from similar depths were composited and homogenized by mixing. The samples were stored frozen at -20 C within 6 hours of collection. Samples were stored frozen for up to 3 months until analysis.

The soil samples were analyzed for total paclobutrazol residues (paclobutrazol and its ketone metabolite) and for the paclobutrazol ketone metabolite alone using Plant Protection Division Residue Analytical Method No. 79. According to the method, the samples were extracted with methanol:water (90:10) by shaking for 1 hour, then filtered. Aliquots of the extracts were transferred to a separatory funnel and partitioned with water:methylene chloride (4:1). The water fraction was discarded, and the methylene chloride fraction was evaporated to dryness on a rotary evaporator, redissolved in acetone, dried again, and redissolved in hexane. In order to clean up the samples (remove soil coextractives), the hexane solution was filtered through a silica column and the column was eluted with 70% ether:-

168

hexane. The registrant stated that for soil samples in which high concentrations of parent were expected, the partition and clean-up stages were omitted; for samples in which low concentrations were expected, only the clean-up stage was omitted. Aliquots of the soil extracts were analyzed using GLC with nitrogen-phosphorus selective detection. Recovery efficiencies from 12 soil samples fortified with paclobutrazol at 0.01 to 0.5 ppm averaged 75 ± 12% of the applied. Recovery efficiencies from 12 soil samples fortified with the ketone analogue of paclobutrazol at 0.01 to 0.5 ppm averaged 82 ± 10% of the applied.

DATA SUMMARY:

Paclobutrazol (Parlay; 50% WP), at 2.25 lb ai/A, decreased from 0.98 ppm immediately posttreatment to 0.62 ppm at 30 days in the upper 6 inches of turf-covered field plots (15 x 40 feet) of sandy loam soil located in Goldsboro, North Carolina (Table 4). Paclobutrazol was not detected (<0.01 ppm) in the 6- to 12-, 12- to 18-, or 18- to 24-inch depths at any sampling interval. The ketone analogue of paclobutrazol increased from <0.01 ppm in the upper 6 inches of soil at 0 to 7 days posttreatment to 0.02 ppm at 14 and 30 days; the ketone analogue was not detected (<0.01 ppm) in deeper soil layers at any interval.

During the 30-day study, irrigation supplemented the natural rainfall so that the treated plot received at least 0.25-inches of water each day.

COMMENTS:

1. No freezer storage stability data were provided with the study to review. The samples were stored for up to 3 months prior to analysis.

2. The study was terminated after only 30 days, before the pattern of decline of paclobutrazol and the pattern of formation and decline of its ketone analogue were clearly established; however, this study was never intended to establish a pattern of dissipation. Rather, this study was conducted by ICI scientists at the request of EFGWB to demonstrate that paclobutrazol and its ketone analogue did not leach under the heavy irrigation practices used on golf courses, and to demonstrate that the results observed in a previous study (reviewed in this report as Study 10, Pearson, 1985, No MRID), in which paclobutrazol and its ketone analogue did not leach below a depth of 6 inches, were correct.

   In contrast to the behavior of paclobutrazol and its ketone analogue in this study, in field studies (Study 9; 40685006, 40685007, 4068-5009, 40685010, 40685011, 406850120) using sand and clay loam soils, total paclobutrazol residues were 0.01 to 1.9 ppm and the paclo-

169

butrazol ketone analogue was 0.007 to 1.2 ppm in the deepest soil samples that were collected (48 inches in the sand soils and 24 inches in the clay loam soil). It may be that in this study the paclobutrazol was absorbed by the turf and so was not available to leach.

3. The concentrations reported for total paclobutrazol residues in the 0- to 12-inch depths (Table 4) appear to have been obtained by summing the concentrations of paclobutrazol in the 0- to 6-, 6- to 12-, 12- to 18-, and 18- to 24-inch depths with the concentrations of its ketone analogue in the same depths. If this is true, the reported values are incorrect. The study authors failed to consider that by summing the multiple depths, the data are in terms of "parts per 2, 3, or 4 million" (depending on whether two, three, or four 6-inch segments were summed) not "parts per million"; the reported values for the total soil column are too large.

10182-EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 171 through 173 are not included in this copy.

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.

X 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.

DATA EVALUATION RECORD

STUDY 12

CHEM 125601 Paclobutrazol §165-4

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID None
Hamer, M.J., and I.R. Hill. 1983. PP333: Accumulation in bluegill sunfish in a flow-through system. Report Series RJ0321B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE.

DIRECT REVIEW TIME = 12

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: G. Maske
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-9733

5-Feb'90

SIGNATURE:

CONCLUSIONS:

Laboratory Accumulation - Fish

1. This study cannot be used to fulfill data requirements.

2. Paclobutrazol residues accumulated in bluegill sunfish that were exposed to triazole-labeled [^{14}C]paclobutrazol at 0.5 ppm for 14 days under flow-through conditions. The maximum mean bioconcentration factors were 20x for edible tissues (day 3), 248x for nonedible tissues (day 3), and 44x for whole fish (day 10).

3. This study is scientifically sound, but does not meet Subdivision N guidelines for the following reasons:

   - the study was terminated after 14 days of exposure, before it was certain that the adsorption of [^{14}C]paclobutrazol residues by the fish had plateaued; and

   radioactive residues in the fish tissues were not characterized.

4. Since the study was terminated before it was certain that the concentration of [^{14}C]residues reached a plateau in the fish tissues, the problems with this study cannot be resolved with the submission of additional data. A new study must be conducted.

METHODOLOGY:

Bluegill sunfish (Lepomis macrochirus; mean weight and length of 0.94 g and 38 mm, respectively) were acclimated (conditions unspecified) for three weeks prior to the initiation of the study.

Flow-through aquatic exposure systems were prepared using two 80-L glass aquaria. Dechlorinated "mains" water (filtered through activated charcoal; pH 7.6-8.0, Table 2) was provided to each aquarium at a rate of 4.5 turnovers per day. One aquarium was treated with triazole-labeled [^{14}C]paclobutrazol (radiochemical purity >94%, specific activity 3.33 KBq/mg, ICI) at 0.5 ppm; the remaining aquarium contained untreated water and served as a control. The aquaria were equilibrated for 24 hours prior to the introduction of 125 bluegill sunfish to each aquarium, and were maintained at approximately 18 C. The fish were fed pelleted food daily at approximately 1% of their total body weight. During a 14-day exposure period, seven fish from both the treated and control aquaria, and water samples (500 mL) from the treated aquarium only were taken at 0, 1 (fish only), 3, 7, 10, and 14 days. Additional water samples (10 mL) were taken from both aquaria daily during the exposure period. All water samples were collected 5 cm below the water surface. Following the 14-day exposure, 60 fish from each aquarium were transferred to separate aquaria containing untreated water for a 14-day depuration period. During the depuration period, fish were sampled from the treated and control aquaria on days 1, 3, and 7; no water samples were taken from either aquarium during the depuration period.

Total radioactivity in the daily water samples was quantified by LSC. The water samples taken from the treated aquarium at 0, 3, 7, 10, and 14 days were adjusted to approximately pH 1 with 10 M hydrochloric acid and partitioned twice with methylene chloride. Aliquots of the aqueous and organic fractions were analyzed for total radioactivity by LSC. The first methylene chloride extract, which contained the majority (>99%) of the extracted radioactivity, was concentrated by rotary evaporation under vacuum and the concentrate was analyzed by

175

LSC. Additional aliquots of the concentrated extracts were analyzed by one-dimensional TLC on silica gel plates developed in chloroform:ethyl acetate (1:1). The extracts were cochromatographed with unlabeled paclobutrazol as a reference standard. The location of the unlabeled paclobutrazol was determined using UV fluorescence quenching; the radioactive compounds were located and quantified using a TLC linear analyzer and autoradiography.

Three whole fish taken at each sampling interval were frozen for an unspecified period of time, and were then analyzed for total radioactivity by LSC following combustion. The remaining four fish taken at each sampling interval were dissected into edible (lateral musculature, skin, and bones) and nonedible (viscera only) tissues; the head (with gills) and fins were discarded. The edible tissues were frozen for an unspecified period of time prior to analysis. The edible and nonedible tissues were analyzed using LSC following combustion.

DATA SUMMARY:

[^{14}C]Paclobutrazol residues (uncharacterized) accumulated in bluegill sunfish that were exposed to triazole-labeled [^{14}C]paclobutrazol (radiochemical purity 92-96%) at 0.5 ppm for 14 days under flow-through conditions. The maximum mean bioconcentration factors were 20x for edible tissues (day 3), 248x for nonedible tissues (day 3), and 44x for whole fish (day 10) (Table 4). Total [^{14}C]residue concentrations in the fish tissues were variable during the study, ranging from 1.6 to 10.7 ppm in edible tissues, 61 to 131 ppm in nonedible tissues, and 11.5 to 23.2 ppm in whole fish (Table 5).

Total [^{14}C]paclobutrazol residues in the treated water during the exposure period ranged from 0.51 to 0.58 ppm, of which 77-95% was paclobutrazol (Table 3). Throughout the study, the temperature of the water in the treated aquarium ranged from 17.5 to 19.0 C, the pH ranged from 7.6 to 8.0, and the dissolved oxygen content ranged from 8.1 to 9.7 mg/L.

COMMENTS:

1. The study was terminated after only 14 days, before it was certain that the accumulation of [^{14}C]paclobutrazol in the fish had plateaued. The study authors' conclusion that the concentration of [^{14}C]-residues in the fish tissues had plateaued was contradicted by the data provided in Table 4 and Figure 3 of the original document. [^{14}C]Residues were quite variable in all of the fish tissues during the entire 14-day exposure period. The study authors did not address the issue of variability in [^{14}C]residues in the fish tissues.

2. [^{14}C]Residues in the fish tissues were not characterized. [^{14}C]Residues in the water were analyzed using TLC; however, only the concentrations of total extractable [^{14}C]residues and [^{14}C]paclobutrazol

176

were reported (Table 3). The study authors stated that no other discrete product was evident in chromatograms of the water at >5%, but no supporting data were provided.

3. Recoveries of paclobutrazol from fortified fish tissues and water samples, and method detection limits were not reported.

4. During the 3-week acclimation period, the mortality was reported as <1%, and at the time of testing, the fish were judged to be in good health. During the study period, no mortality was observed in the fish from both the treated and control aquaria.

5. The radiochemical purity of the ^{14}C-stock solution was determined by TLC using two solvent systems: hexane:acetone (2:1) and chloroform:-ethyl acetate (1:1). The radiochemical purity was reported as 95.5% for the former solvent system; the value reported in the original document was illegible for the latter solvent system, but appears to be >94%.

6. The 96-hour LC_{50} of paclobutrazol for bluegill sunfish was reported to be 23.6 mg/L; the concentration of paclobutrazol used in the present experiment (0.5 mg/L) was 2% the 96-hour LC_{50}.

7. EFGWB prefers that [^{14}C]residues in samples be separated by chromatographic methods (such as TLC, HPLC, or GC) with at least three solvent systems of different polarity, and that specific compounds isolated by chromatography be identified using a confirmatory method such as MS in addition to comparison to the R_f of reference standards.

   In this study, the water extracts were analyzed using one-dimensional TLC with a single solvent system. Radioactive areas on the TLC plates were identified only by comparison to the location of known reference standards chromatographed on the same plates. It was assumed by the study authors that the radioactive areas contained a single compound; the radioactive areas were not analyzed further to confirm the identification.

10182-EAT FATE DER ! PACLOBUTRAZOL

Page ______ is not included in this copy.

Pages 178 through 185 are not included in this copy.

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.

X______ 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.

EXECUTIVE SUMMARY

The following findings are derived from those reviewed studies which have met the requirements of 40 CFR Part 158.290 and the guidance of Subdivision N, and were also deemed acceptable.

Hydrolysis

(Woods and Leahey, 1983a, no MRID)

Triazole ring-labeled [^{14}C]paclobutrazol (radiochemical purity 98%), at 10.2 ppm, was relatively stable in sterile aqueous buffered solutions (pH 4, 7, or 9) that were incubated in the dark at 25 C for 30 days. At 30 days posttreatment, [^{14}C]paclobutrazol comprised 94.9 and 95.0% of the radioactivity recovered in duplicate pH 4 solutions, 94.2 and 95.6% in pH 7 solutions, and 96.6 and 98.9% in pH 9 solutions. Unidentified water-soluble [^{14}C]residues comprised 0.01-0.06% of the recovered radioactivity (except for 0.22% in one pH 9 solution). The material balances at day 30 ranged from 97 to 108% of the applied.

Photodegradation in water

(Woods and Leahey, 1983b, no MRID)

Triazole-labeled [^{14}C]paclobutrazol (radiochemical purity 98%), at 10.4 ug/mL, was relatively stable in a sterile aqueous pH 7 buffer solution that was continuously irradiated for 10 days with a xenon arc lamp at 29 to 40 C. The measured intensity of the xenon lamp at test distance (not specified) was 1.94-2.50 W/m^2 at 420 nm compared to measured sunlight intensity of 1.14-1.63 W/m^2 at 420 nm. At 10 days posttreatment, [^{14}C]paclobutrazol comprised 96.6 and 100% of the radioactivity recovered in duplicate irradiated solutions and 97.6% in the dark control. In the irradiated samples, unidentified water-soluble [^{14}C]residues comprised 1.2 and 1.8% of the recovered radioactivity; no unidentified [^{14}C]residues were present in the dark control. The material balances at day 10 were 93 and 94% for the irradiated samples and 98% for the dark control.

Photodegradation on soil

(Tegala et al., 40685002)

Triazole-labeled [^{14}C]paclobutrazol (radiochemical purity >99.1%), at 2.48 kg/ha, photodegraded with a half-life of >>33 "sun-equivalent days" in loam soil irradiated with a xenon arc lamp at 24-26 C for 105.24 hours (according to the study authors, 3.17 hours of irradiation was equivalent to approximately 1 Florida spring day). After 105.24 hours of irradiation, [^{14}C]paclobutrazol comprised an average 87.4% of the applied radioactivity, 1H-1,2,4-triazole comprised 4.2%, unidentified extractable compounds comprised 2.6% (four compounds, each $\leq$1.8%), other extractable radioactivity (origin material and "background") comprised 3%, and unextractable residues comprised 2.8%. No radioactivity was volatilized from the soil during the study period. In the dark control, [^{14}C]paclobutrazol did not degrade

186

during the 105-hour study period. In the irradiated samples and the dark control, the material balances ranged from 97.7 to 101.9% of the applied during the study.

Mean intensities of light measured at the soil surface during the irradiation period were: 1.65-1.80 x 10^{-4} W/cm^2 at 297 nm; 8.8-9.2 x 10^{-4} W/cm^2 at 365 nm; 1.68-1.82 x 10^{-1} W/cm^2 at 280-420 nm; and 9.0-9.5 x 10^{-3} W/cm^2 at 430-700 nm. The mean intensity of radiation received per sample was 1.72-1.77 x 10^{-1} W/cm^2.

Aerobic soil metabolism

(Harvey and Hill, 40685003)

Triazole- and methine-labeled [14C]paclobutrazol (radiochemical purities ≥92.0%), at approximately 1.5 kg ai/ha, degraded with a half-life of >1 year in loam soil incubated at 20 C and 40% of its moisture holding capacity for 1 year. At 1 year posttreatment, 54.0% of the applied triazole-labeled [^{14}C]paclobutrazol and 50.4% of the applied methine-labeled [^{14}C]paclobutrazol (60.0 and 57.9% of the recovered, respectively) remained undegraded.

The major degradate of both test substances was (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one [the ketone analogue of paclobutrazol; Compound II], at a maximum concentration of 15.0 and 16.8% of the applied (17.2 and 18.7% of the recovered) at 1 year posttreatment. In the soil treated with triazole-labeled [^{14}C]paclobutrazol, 1,2,4-triazole was detected at a maximum concentration of 2.6% of the recovered at 1 year posttreatment, unidentified extractable compounds (origin and "background" on the TLC plate) were 11.6% of the recovered, a total of 1.1% of the recovered had been evolved as CO_2, and 6.0% was unextractable. In the soil treated with methine-labeled [^{14}C]paclobutrazol, unidentified extractable compounds were 8.0% of the recovered at 1 year posttreatment, a total of 12.1% of the recovered had been evolved as CO_2, and 5.0% was unextractable. The material balances during the study for the triazole label ranged from 77% (at 4 months posttreatment) to 105% (at 8 months) of the applied; material balances for the methine label ranged from 87% (at 12 months posttreatment) to 98% (at 0 months) of the applied.

Anaerobic aquatic metabolism

(Harvey and Hill, 40685003)

Triazole- and methine-labeled [14C]paclobutrazol (radiochemical purity ≥92%), at approximately 1.5 kg ai/ha, degraded with a half-life of >1 year in flooded loam and silt loam soils incubated at 20 C for 1 year. At 1 year posttreatment in the loam soil, 72.4% of the applied triazole-labeled [^{14}C]paclobutrazol and 60.5% of the applied methine-labeled [^{14}C]paclobutrazol (78.7 and 70.4% of the recovered, respectively) remained undegraded; in the silt loam soil, approximately 76% of the applied triazine-labeled [^{14}C]paclobutrazol (approximately 82% of the recovered) remained undegraded.

187

The major degradate of both test substances was (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one [the ketone analogue of paclobutrazol; Compound II], at a maximum concentration of 9.6-9.7% of the recovered in the loam soil and 1.1% in the silt loam soil at 1 year posttreatment. 1,2,4-Triazole was detected at a maximum concentration of ≤1.8% of the recovered at 1 year posttreatment in the loam and silt loam soils treated with triazole-labeled [^{14}C]paclobutrazol. CO_2 evolution was greater from the soil treated with the methine label than that treated with triazole label (5.3% versus 0.1-0.3% of the recovered at 1 year). In all samples, unidentified extractable compounds (origin and "background" on the TLC plate) were ≤10.4% of the recovered, and 2.6-4.0% was unextractable. The material balances during the study ranged from 85 to 103% of the applied.

Results from a static system (flooded silt loam soil in beakers) were similar to those reported for the flow-through system.

Leaching and adsorption/desorption

(Takacs and White, 40685005)

Based on batch equilibrium experiments, triazole-labeled [^{14}C]paclobutrazol (radiochemical purity ≥95.3%) was mobile to very mobile in nine soils ranging in texture from sand to silt loam that were equilibrated at 21 C in 4:10 soil:calcium chloride solution slurries that contained 0.026, 0.052, 0.079, 0.105, or 0.22 ug of paclobutrazol/g of moist soil. K_{ads} values (ug of pesticide per g of dry soil ÷ ug of pesticide per mL of solution) ranged from 1.3 to 23.0. In general, adsorption increased with an increase in soil organic matter content and a decrease in soil pH. An estimated 65% of the adsorbed [^{14}C]paclobutrazol desorbed from the soil during two desorption steps; K_{des} values for the nine soils ranged from 1.87 to 27.97 following the first desorption step and from 2.66 to 33.95 following the second desorption step.

(Mistry and Hill, 40685004)

Using column leaching techniques, aged (9 weeks) residues of methine-labeled [^{14}C]paclobutrazol (radiochemical purity 96%) were determined to be relatively immobile (<1% of the applied in the leachate) in 30-cm columns of sand, sandy loam, loamy sand, and clay loam soils leached with 66.1 cm (1350 mL) of 0.01 M calcium chloride solution over a 9-week period. In contrast, aged residues of triazole-labeled [^{14}C]paclobutrazol were determined to be of low mobility (2-3% of the applied in the leachate) in sand and sandy loam soils and mobile (6-13% of the applied in the leachate) in loamy sand and clay loam soils. In all cases, the majority (58.6-90.7% of the applied) of the aged [^{14}C]residues did not leach out of the upper 10 cm of the treated soil columns.

[^{14}C]Residues in the leachate were characterized as "very polar material" (they did not move from the origin using TLC). In all soil columns after leaching, [^{14}C]paclobutrazol was the major extractable degradate, ranging

188

from 17.5% of the applied (triazole-labeled) in the clay loam to 84.4% (methine-labeled) in the sand. One degradate, (2RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)-pentan-3-one, the ketone analogue of paclobutrazol, was isolated from the soil columns at up to 12.6% of the applied; the remaining radioactive residues in the columns were either unidentified extractable compounds (≤6.3% of the applied) or unextractable compounds (≤18.7%).

After 9 weeks of aging and immediately prior to leaching, parent paclobutrazol comprised 71.6-91.0% of the applied in the sandy loam, loamy sand, and sand soils; the ketone analogue comprised up to 9% of the applied in the three soils. Degradation of the parent compound was greater in the clay loam soil; paclobutrazol accounted for 49.9-55.0% of the applied and its ketone analogue was 15.9-17.6% of the applied at 9 weeks posttreatment.

Material balances after the 9-week incubation period ranged from 92.8 to 99.3%. Material balances after the leaching period were 85-112% for the triazole-labeled [^{14}C]paclobutrazol and 61-95% for the methine-labeled [^{14}C]paclobutrazol.

The following findings are derived from those reviewed studies which have <u>not</u> met the requirements of 40 CFR 158.290 and/or the Subdivision N Guidelines, but which have been deemed good studies following generally sound scientific practice. They thereby provide <u>supplemental</u> information on the fate of the pesticide.

<u>Terrestrial field dissipation</u>

(Hendley et al., 40685007, 40685009, 40685010, 40685011,and 4068512; Mak et al., 40685006)

Paclobutrazol dissipated very slowly or was stable in soil during the 356-376 days following the treatment of fruit orchards in California, West Virginia, and Florida that were treated with paclobutrazol (Cultar or Clipper, 2 lb/gallon SC) at approximately 0.6 or approximately 6.0 g ai/linear foot. Based on concentrations of total paclobutrazol residues (paclobutrazol plus its ketone metabolite) in the upper 24 inches of soil, the registrant-calculated half-lives of the residues ranged from 450-973 days for the low-treatment-rate plots in California, West Virginia, and Florida, and the high-treatment-rate plot in California (at the high-treatment-rate sites in West Virginia and Florida, the concentration of total residues at the final sampling interval was larger than that at time 0). At 356-376 days posttreatment, the concentrations of total paclobutrazol residues in the 0- to 8-inch soil depth of plots treated at 0.6 lb ai/linear foot were 14 ppm in California, 35 ppm in West Virginia, and 11 ppm in Florida. The concentrations of total paclobutrazol residues in plots treated at 6.0 lb ai/linear foot were 177 ppm in California, 447 ppm in West Virginia, and 108 ppm in Florida. The majority of the residues

189

were identified as paclobutrazol; the ketone metabolite of paclobutrazol was detected at a maximum mean concentration of 5.7 ppm in the 0- to 8-inch soil depth (in Florida).

Total paclobutrazol residues were detected at 0.01 to 1.9 ppm in the deepest soil samples that were collected, depths of 48 inches in California and Florida and 24 inches in West Virginia. Maximum leaching occurred at the Florida site, where at approximately 370 days posttreatment the concentrations of total paclobutrazol residues in the 40- to 48-inch depth were 0.07 and 1.8 ppm in the plots treated at 0.6 and 6.0 g ai/linear foot, respectively. In general, the paclobutrazol ketone metabolite comprised a greater percentage (up to 67%) of the total residues in the deeper soil sections than in the surface soil.

In California during the approximately 1-year study, air temperatures ranged from 25 to 105 F, precipitation totaled approximately 15.5 inches, and irrigation totaled 29.5 inches. In West Virginia, air temperatures ranged from -13 to 97 F and precipitation totaled approximately 33.5 inches. In Florida, air temperatures ranged from 19 to 100 F and precipitation totaled approximately 53 inches.

(Pearson, 1985, no MRID)

Paclobutrazol (50% WP), at 2 lb ai/A, dissipated with registrant-calculated half-lives of 20 weeks in Commerce silt loam soil (Mississippi), 25 weeks in Norfolk loamy sand soil (North Carolina), and 26 weeks in Flanagan silt loam soil (Illinois). Total paclobutrazol residues (paclobutrazol plus its ketone analogue) dissipated with half-lives of 32, 25, and 29 weeks, respectively, in the same soils. The ketone analogue was ≤0.04 ppm in the North Carolina and Illinois soils, but accumulated to a maximum of 0.37 ppm in the Mississippi soil. No downward movement of either paclobutrazol or its ketone analogue was detected.

In the 0- to 6- inch depth of the loamy sand soil at the North Carolina site, paclobutrazol was 0.64 ppm immediately posttreatment, ranged from 0.29 to 0.40 ppm with no discernable pattern between 95 and 227 days, was 0.22 ppm at 337 days, and was 0.05 ppm at 533 days. The ketone analogue of paclobutrazol was ≤0.03 ppm in the 0- to 6-inch depth at all sampling intervals. Neither paclobutrazol nor its ketone analogue were detected (<0.02-0.05 and <0.02 ppm, respectively) in the 6- to 12-inch depth at any sampling interval.

In the 0- to 6- inch depth of the silt loam soil at the Mississippi site, paclobutrazol was 0.45-0.48 ppm between 0 and 62 days posttreatment, 0.10-0.16 ppm between 95 and 346 days (except for 0.26 ppm at 123 days), and 0.02 ppm at 731 days. The ketone analogue of paclobutrazol accumulated to a maximum of 0.37 ppm at 123 days posttreatment; 0.04 ppm remained in the soil at 731 days. Neither paclobutrazol nor its ketone analogue were detected (<0.02-0.05 and <0.02 ppm, respectively) in the 6- to 12-inch depth at any sampling interval.

190

In the 0- to 6- inch depth of the silt loam soil at the Illinois site, paclobutrazol was 0.53-0.69 ppm between 0 and 69 days posttreatment, 0.38 ppm at 123 days, and 0.02 ppm at 657 days. The ketone analogue of paclobutrazol accumulated to a maximum of 0.04 ppm at 69 days posttreatment. Neither paclobutrazol nor its ketone analogue were detected (<0.02-0.05 and <0.02 ppm, respectively) in the 6- to 12-inch depth at any sampling interval.

At the three sites, monthly rainfall ranged from 0.87 to 12.43 inches. During the first year of study, rainfall totalled 41.64 inches at the Illinois site, 53.92 inches at the North Carolina site, and 86.88 inches at the Mississippi site.

(Francis, 00155854)

Paclobutrazol (Parlay; 50% WP), at 2.25 lb ai/A, decreased from 0.98 ppm immediately posttreatment to 0.62 ppm at 30 days in the upper 6 inches of turf-covered field plots (15 x 40 feet) of sandy loam soil located in Goldsboro, North Carolina. Paclobutrazol was not detected (<0.01 ppm) in the 6- to 12-, 12- to 18-, or 18- to 24-inch depths at any sampling interval. The ketone analogue of paclobutrazol increased from <0.01 ppm in the upper 6 inches of soil at 0 to 7 days posttreatment to 0.02 ppm at 14 and 30 days; the ketone analogue was not detected (<0.01 ppm) in deeper soil layers at any interval.

During the 30-day study, irrigation supplemented the natural rainfall so that the treated plot received at least 0.25-inches of water each day.

Accumulation in laboratory fish

(Hamer and Hill, 1983, no MRID)

[^{14}C]Paclobutrazol residues (uncharacterized) accumulated in bluegill sunfish that were exposed to triazole-labeled [^{14}C]paclobutrazol (radiochemical purity 92-96%) at 0.5 ppm for 14 days under flow-through conditions. The maximum mean bioconcentration factors were 20x for edible tissues (day 3), 248x for nonedible tissues (day 3), and 44x for whole fish (day 10). Total [^{14}C]residue concentrations in the fish tissues were variable during the study, ranging from 1.6 to 10.7 ppm in edible tissues, 61 to 131 ppm in nonedible tissues, and 11.5 to 23.2 ppm in whole fish.

Total [^{14}C]paclobutrazol residues in the treated water during the exposure period ranged from 0.51 to 0.58 ppm, of which 77-95% was paclobutrazol. Throughout the study, the temperature of the water in the treated aquarium ranged from 17.5 to 19.0 C, the pH ranged from 7.6 to 8.0, and the dissolved oxygen content ranged from 8.1 to 9.7 mg/L.

RECOMMENDATIONS

Available data are insufficient to fully assess the environmental fate of paclobutrazol. The submission of data required for full registration of paclobutrazol on terrestrial food crop (orchards and greenhouse ornamentals) and terrestrial nonfood (turf grown for seed, trees in nonfood areas) use sites is summarized below:

The following data are required:

Laboratory volatility studies: No data were reviewed.

Terrestrial field dissipation studies: Three studies were reviewed; all three provide supplemental information only towards the registration of paclobutrazol. One study (Hendley et al., 40685007, 40685009, 40685010, 40685011, and 4068512; Mak et al., 40685006) is scientifically sound, but does not meet Subdivision N guidelines because no freezer storage stability data were provided; the soil was not sampled deep enough to define the extent of leaching; pretreatment and/or control plot data were not provided; and the soils and site were incompletely characterized. A second study (Pearson, 1985, no MRID) is scientifically sound, but does not meet Subdivision N guidelines because freezer storage stability data were not provided; and the test soils were not adequately characterized. A third study (Francis, 00155854) is scientifically sound, but does not meet Subdivision N guidelines because the study was terminated after only 30 days, before the pattern of decline of paclobutrazol was established; and freezer storage stability data were not provided.

Laboratory studies of pesticide accumulation in fish: One study (Hamer and Hill, 1983) was reviewed. This study is scientifically sound, but does not meet Subdivision N guidelines because the study was terminated after 14 days of exposure, before it was certain that the adsorption of [^{14}C]paclobutrazol residues by the fish had plateaued; and radioactive residues in the fish tissues were not characterized.

The following data requirements are fulfilled:

Hydrolysis studies: One study (Woods and Leahey, 1983a, no MRID) was reviewed. This study is acceptable and fulfills data requirements by providing information on the hydrolysis of triazole ring-labeled [^{14}C]paclobutrazol in sterile aqueous solutions at pH 4, 7, and 9.

Photodegradation studies in water: One study (Woods and Leahey, 1983b, no MRID) was reviewed. This study is acceptable and fulfills data requirements by providing information on the photodegradation of triazole-labeled [^{14}C]paclobutrazol in water.

Photodegradation studies on soil: One study (Tegala et al., 40685002) was reviewed. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the photodegradation of triazole-labeled [^{14}C]paclobutrazol on loam soil.

Aerobic soil metabolism studies: Two studies were reviewed. One study (Harvey et al., 1982, no MRID) was unacceptable. A second study (Harvey and Hill, 40685003) is acceptable and fulfills data requirements by provid-

192

ing information on the aerobic metabolism of triazole- and methine-labeled [^{14}C]paclobutrazol in loam soil.

Leaching and adsorption/desorption studies: Three studies were reviewed. One study (Hill and Prashad, 1982) was unacceptable. A second study (Takacs and White, 40685005) is acceptable and partially fulfills data requirements by providing information on the mobility (batch equilibrium) of unaged triazole-labeled [^{14}C]paclobutrazol in nine soils ranging in texture from sand to silt loam. A third study (Mistry and Hill, 40685004) is acceptable and partially fulfills data requirements by providing information on the mobility (column leaching) of aged methine- and triazole-labeled [^{14}C]paclobutrazol residues in sandy loam, loamy sand, clay loam, and sand soils. Together, the acceptable studies fulfill the mobility data requirement.

The following data requirements are deferred or are not required for presently registered uses:

Photodegradation in air studies: No data were reviewed. The data requirement is deferred pending the receipt of acceptable laboratory volatility studies.

Anaerobic soil metabolism studies: No data were reviewed. No data are required because paclobutrazol has no field and vegetable crop uses.

Anaerobic aquatic metabolism studies: One study (Harvey and Hill, 40685003) was reviewed. This study is acceptable and provides information on the anaerobic metabolism of triazole- and methine-labeled [^{14}C]paclobutrazol in flooded loam soil, and triazole-labeled [^{14}C]paclobutrazol in silt loam soil. However, no data are required because paclobutrazol has no aquatic uses, forestry uses, or any aquatic impact uses involving direct discharges of treated water into outdoor aquatic sites.

Aerobic aquatic metabolism studies: No data were reviewed. No data are required because paclobutrazol has no aquatic uses or any aquatic impact uses involving direct discharges of treated water into outdoor aquatic sites.

Field volatility studies: No data were reviewed. The data requirement is deferred pending the receipt of acceptable laboratory volatility studies.

Aquatic field dissipation studies: No data were reviewed. No data are required because paclobutrazol has no aquatic food crop, aquatic nonfood, or aquatic impact uses involving direct discharge of treated water into outdoor aquatic sites.

Forestry dissipation studies: No data were reviewed. No data are required because the pesticide has no forestry use.

Dissipation studies for combination products and tank mix uses: No data were reviewed; however, no data are required because data requirements for combination products and tank mix uses are currently not being imposed.

Long-term field dissipation studies: No data were reviewed, but all data may be required if the results from the field dissipation/aerobic soil metabolism studies demonstrate that residues do not reach 50% dissipation in soil prior to the recommended subsequent application.

Confined accumulation studies on rotational crops: No data were reviewed. No data are required because paclobutrazol has no field and vegetable crop or aquatic crop uses and is unlikely to be used on an area which may be rotated to a food crop after pesticide use.

Field accumulation studies on rotational crops: No data were reviewed. No data are required because paclobutrazol has no field and vegetable crop or aquatic crop uses and is unlikely to be used on an area which may be rotated to a food crop after pesticide use.

Accumulation studies on irrigated crops: No data were reviewed; however, no data are required because the test substance is not intended for aquatic food crop or aquatic nonfood uses, for uses in and around holding ponds used for irrigation purposes, or for uses involving effluents or discharges to water used for crop irrigation.

Field accumulation studies on aquatic nontarget organisms: No data were reviewed; however, no data are currently required because the accumulation in laboratory fish study demonstrated that paclobutrazol has a low potential to accumulate in fish and that what does accumulate is rapidly eliminated from the fish tissue.

REFERENCES

Francis, P.D. 1986. Paclobutrazol: Short-term dissipation and movement following a broadcast spray. Report Series TMU1953. Unpublished study prepared and submitted by ICI Americas Inc., Goldsboro, NC. (00155854)

Hamer, M.J., and I.R. Hill. 1983. PP333: Accumulation in bluegill sunfish in a flow-through system. Report Series RJ0321B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (No MRID available)

Harvey, B.R., and I.R. Hill. 1985. Paclobutrazol: Degradation in aerobic and flooded soils. Report Series RJ0370B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (40685003)

Harvey, B., M. Weissler, C. Zinner, and I. Hill. 1982. PP333: Degradation in Soil. Report Series RJ0256B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (No MRID available)

Hendley, P., L.F. Davis, and B.R. Oliver. 1987a. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - California site - Report of field data. Laboratory Project ID TMU3304/B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE. (40685007)

Hendley, P., L.F. Davis, and B.R. Oliver. 1987b. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - Florida site - Follow-up report of field data. Laboratory Project ID TMU3303/B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE. (40685009)

Hendley, P., L.F. Davis, and B.R. Oliver. 1987c. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - Florida site - Second follow-up report of field data. Laboratory Project ID TMU3345B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE. (40685010)

Hendley, P., L.F. Davis, and B.R. Oliver. 1987d. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - West Virginia site - Follow-up report of field data. Laboratory Project ID TMU3305B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE. (40685011)

Hendley, P., L.F. Davis, and B.R. Oliver. 1987e. Paclobutrazol: Field dissipation and leaching following subsurface application in orchard soils - West Virginia site - Second follow-up report of field data. Laboratory Project ID TMU3347/B. Unpublished study performed by ICI Biological Research Center, Goldsboro, NC, and submitted by ICI Americas Inc., Wilmington, DE. (40685012)

Hill, I.R., and S. Prashad. 1982. PP333: Leaching in soil. Report Series RJ0244B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas, Inc., Wilmington, DE. (No MRID available)

Mak, C., S.J. Crook, and N.C. Atreya. 1987. Paclobutrazol: Field dissipation following subsurface applications in US orchard soils up to 12 months. Laboratory Project ID RJ0574B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (40685006)

Mistry, R., and I.R. Hill. 1986. Paclobutrazol: Mobility of paclobutrazol and its degradation products in soil columns. Laboratory Project ID RJ0495B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (40685004)

Pearson, F.J. 1985. PP333 and PP333 ketone residue dissipation in U.S. soils. Report Series TMU1760/B. Unpublished study prepared by ICI Americas Inc., Goldsboro, NC, and Analytical Biochemistry Laboratories, Columbia, MO; and submitted by ICI Americas Inc., Goldsboro, NC. (No MRID available)

Takacs, M.G., and B.G. White. 1986. Paclobutrazol: Adsorption and desorption equilibria in soils. Laboratory Project ID TMJ2377B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (40685005)

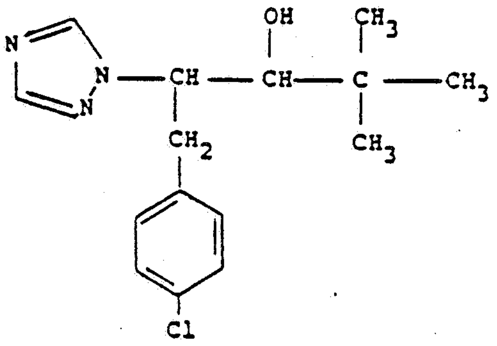
Tegala, B., C.B. Clements, and M.W. Skidmore. 1987. Paclobutrazol: Photolytic stability on a soil surface. Report Series RJ0601B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (40685002)

Woods, T.M., and J.P. Leahey. 1983a. PP333: Hydrolysis in water at pH 4, 7 and 9. Report Series RJ0216B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (No MRID available)

Woods, T.M., and J.P. Leahey. 1983b. PP333: Photolysis in aqueous solution. Report Series RJ0317B. Unpublished study performed by ICI Plant Protection Division, Berkshire, UK, and submitted by ICI Americas Inc., Wilmington, DE. (No MRID available)

APPENDIX

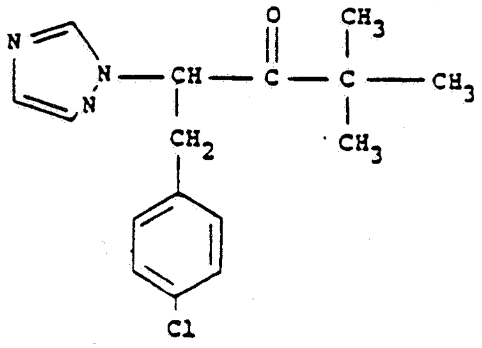
PACLOBUTRAZOL AND ITS DEGRADATES



Paclobutrazol

(2RS,3RS)-1-(4-Chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)pentan-3-ol.

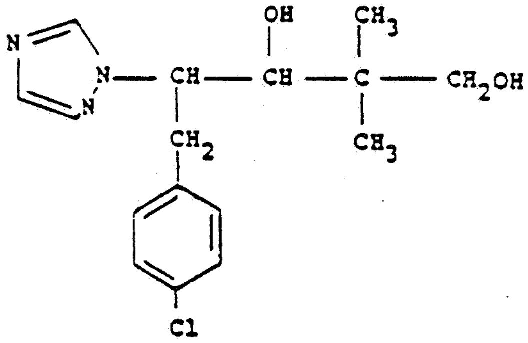
(PP333)



Ketone analogue of paclobutrazol

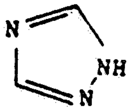
(2RS)-1-(4-Chlorophenyl)-4,4-dimethyl-2-(1,2,4-triazol-1-yl)pentan-3-one.

Compound II



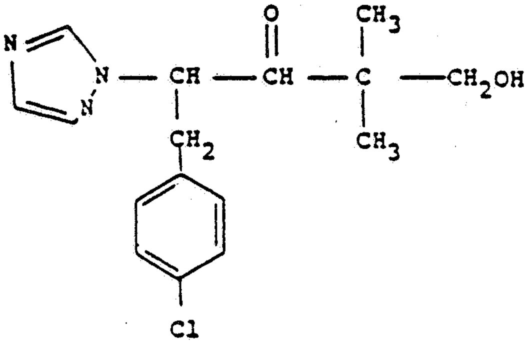
5-(4-Chlorophenyl)-2,2-dimethyl-4-(1,2,4-triazol-1-yl)-pentan-1,3-diol.

Compound III



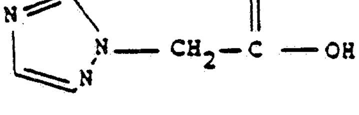
1,2,4-Triazole

Compound V



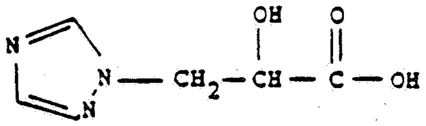
5-(4-Chlorophenyl)-2,2-dimethyl-3-oxo-4-(1,2,4-triazol-1-yl)pentanol

Compound VI



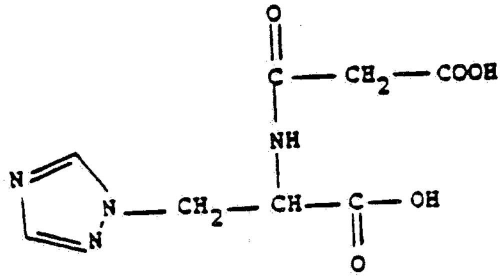
2-(1,2,4-Triazol-1-yl)acetic acid

Compound VII



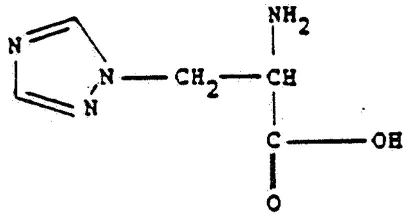
3-(1,2,4-Triazol-1-yl) lactic acid

Compound VIII



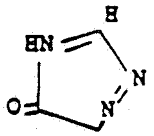
2-Malonyl-3(1,2,4-triazol-1-yl)alanine

Compound IX



3-(1,2,4-Triazol-1-yl)alanine

Compound X



4,5-Dihydrotriazol-3-one

Compound XI