

DP Barcode : D168875 PC Code No.: 028201 EFGWB Out 1 3 1992

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Product Manager PM 71

Special Review and Reregistration Division (H7508W)

From: Akiva D. Abramovitch, Ph.D., Head

Environmental Chemistry Review Section 43

Environmental Pate & Ground Water Blanch

Thru: Heary Jacoby, Chief

Environmental Fate & Ground Maler Branch/EFED (H7507C)

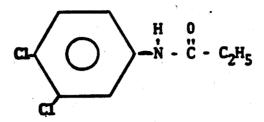
Attached, please find the EFGWB review of... Reg./File # :707-109 Chemical Name :Propanil Type Product Herbicide Product Name :Stam M-4 Company Name : Propanil Task Force Review of Confined Crop Accumulation Study Protocol for the Propanil Task Force ... Purpose EFGWB #(s): 91-0974 **Koták**w Time: 2 days Action Code :635

	EPGWB Guideline/	MRID Summary Table:	The review is this package o	cetains.
161-1	162-1	164-1	165-1 Protocc review	n 166-1
161-2	162-2	164-2	165-2	166-2
161-3	162-3	164-3	165-3	166-3
161-4	162-4	164-4	165-4	167-1
201-1	163-1	164-5	168-5	167-2
202-1	163-3			

1. CHEMICAL:

Chemical Name: 3',4'-dichloropropionanilide

CAS No.: 709-98-8
Common Name: Propanil
Trade Name: Stam M-4
Chemical Structure:



Molecular Formula: C₉H₉Cl₂NO Physical/Chemical Properties of Active Ingredient:

Molecular Weight: 218
Physical state: Crystalline
Color: Orange-yellow
Vapor pressure: 4 MPa (25 °C)

Solubility: <0.5 ppm (20 °C), 700 g/L acetone Octanol/water partition coefficient: N/A

Formulations: 4 EC

2. TEST MATERIAL: N/A

3. STUDY/ACTION TYPE:

Review of 165-1 protocol submitted by the Propanil Task Force.

4. STUDY IDENTIFICATION:

Novak, Roger A. 1991. Protocol for 165-1 study submitted by the Propanil Task Force. American Cyanamid, Princeton, New Jersey (EFGWB 91-0974).

5. REVIEWED BY:

James A. Breithaupt Agronomist, Review Section #3 OPP/EFED/EFGWB Signature: Green Bruthampt

Date: 1/1/92

6. APPROVED BY:

Akiva Abramovitch, Ph.D. Chief, Review Section #3 OPP/EFED/EFGWB

Date: JAN 7 1992

7. CONCLUSIONS:

EFGWB has the following comments on the protocol (Attachment 1):

In Attachment 2, the Propanil Task Force (PTF) was supposed to start an accumulation in confined rotational crops (165-1) study in Spring 1991. PTF was not aware of any laboratories in Arkansas, Louisiana, Mississippi, or Texas with current GLP compliance and proper 14C-licensing. Also, USDA quarantine prohibits the movement of viable Louisiana or Arkansas soil anywhere from the South due to the possible presence of fire ants and soybean cyst nematodes. In response to the letter in Attachment 2, EFGWB suggested that a California rice soil that "closely resembles" southern rice soil be used instead of a "typical California rice paddy soil." In Louisiana and Arkansas, the predominate soil that supports rice production is the Crowley silt loam (2 % sand, 79 % silt, 18 % clay, ≤1 % OM, pH 5.7). The PTF (this protocol) then suggested using a typical California rice paddy soil (16 % sand, 61 % silt, and 23 % clay, silt loam texture), which is "similar in texture" to the Crowley soil. EFGWB does not object to the use of this soil in the study, if no other rice-growing silt loam soil with closer sand, silt, and clay contents to the Crowley can be found. EFGWB needs comparison of the complete USDA classification of the California soil to the Crowley soil with the completed study.

OTHER COMMENTS

In section 3.3 of the protocol, the PTF plans to use TLC to determine the stability of the test material. If TLC is used in the study, guidelines call for TLC with 3 different solvent systems. However, EFGWB prefers to see GC/MS or HPLC/MS used in place of TLC for all analytical procedures.

In section 4.1, compositing of triplicate soil and plant samples within sampling interval with "appropriate" amounts of radioactivity was mentioned. EFGWB prefers separate analyses in place of compositing and guidelines call for identification of residues that are ≥ 10 % of applied chemical or 0.01 ppm.

Also in section 4.1, the PTF indicated that the equivalent rate of 6 lbs ai/A would be used in the study. According to the label dated 2/13/91 (Attachment 3) and the LOUISIANA WEED CONTROL RECOMMENDATIONS (Attachment 5), the <u>normal</u> maximum rate of propanil to be applied in one application to rice is 4 lbs ai/A <u>not to exceed</u> 8 lbs/ai/A in 2 applications. However, the label allows for application of a one-time application of 5-6 lbs ai/A as an "emergency/salvage treatment" to control larger grasses 30-40 days after planting. Use of the 6 lb ai/A rate is consistent with the label and Louisiana Weed Control Recommendations and would give concentrations of 6 ppm based on a 3-inch acre furrow slice or 3 ppm based on a 6-inch acre furrow slice.

In section 4.2.4, a comparison of the soil from the study to the Crowley silt loam is necessary.

Chemical analysis of the irrigation water (section 4.2.6) used at the beginning and end of the study should be reported.

In section 4.3.3, the protocol stated "analysis of unknown metabolites that are judged to be significant" will be conducted by mass spectrometry or other appropriate methods. EFGWB guidelines call for identification of residues that are ≥ 10 % of applied chemical or 0.01 ppm.

ENVIRONMENTAL FATE ASSESSMENT

According to EFGWB 91-0667 (Attachment 4), all data requirements are outstanding. To date, EFGWB is not aware of any detections in ground water.

8. <u>RECOMMENDATIONS</u>:

Inform the Propanil Task Force that:

- (1) the modifications to the protocol that were specified in the CONCLUSIONS section should be made,
- (2) analytical methodology validation should be provided with the results of the study. EFGWB 92-0034 called for method validation of propanil and pendimethalin in environmental media when applied as a tank mix. These data were required of American Cyanamid in EFGWB 92-0034, and may substitute for this method validation if a cost-sharing arrangement is obtained and the data are reasonable.
- (3) the status of data requirements may be seen in EFGWB 91-0667 (Attachment 4).
- 9. BACKGROUND: (from EFGWB 90-0417)

Propanil is a broad-spectrum, postemergence contact herbicide registered for use on rice, barley, oats, and wheat. The majority of domestic usage is on rice, about 70-80 %.

- 10. DISCUSSION OF INDIVIDUAL STUDIES: N/A
- 11. COMPLETION OF ONE-LINER: N/A
- 12. CBI INDEX: N/A



NPC, INCORPORATED
22636 GLENN DRIVE, SUITE 304
STERLING, VIRGINIA 22170
(703) 481-6802 VOICE • (703) 481-6806 FAX

September 5, 1991

Terri Stowe
Office of Pesticide Programs
Special Review & Reregistration Division (H7508C)
Document Processing Desk (RS-0226)
Room 266A Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22022

Dear Ms. Stowe:

RE: Propanil confined rotational crop - final protocol

On behalf of the Propanil Task Force I am submitting a copy of the final signed protocol for the propanil confined rotational crop study for agency review and comment. The agency has commented on an earlier version of this protocol. The enclosed protocol incorporates the agency comments and is the protocol under which the study was initiated earlier this summer. We would appreciate a review of this final protocol as there is still time to respond further comments.

If you have any questions, please do not hesitate to call.

Sincerely,

Roger A. Novak

Koija J. Max

Technical Director, Propanil Task Force

encl

STUDY PROTOCOL

STUDY NUMBER: XBL Study Number 91011

STUDY TITLE: Confined Rotational Crop Study with

14C-Propanil: Analysis of Soil and

Plant Samples

EPA GUIDELINE: Subdivision N (165-1)

SPONSOR: Propanil Task Force

John Wise, Chairman 1042 Linwood Lane Liberty, MO 64068

SPONSOR Roger A. Novak, Ph.D.

REPRESENTATIVE: Technical Director, Propanil Task Force

c/o NPC, Incorporated

22626 Glenn Dr. Suite 304

Sterling, VA 22071 (703) 481-6802

STUDY DIRECTOR: Robert A. Robinson, Ph.D.

XenoBiotic Laboratories, Inc.

P.O. Box 3205

Princeton, NJ 08543-3205

(609) 799-2295

TESTING FACILITY: XenoBiotic Laboratories, Inc. (XBL)

(Analytical Industrial Research Laboratory

Phase) Schalks Crossing Road

Plainsboro, NJ 08536

TESTING FACILITY: Pan-Agricultural Laboratories, Inc., (Pan-Ag)

'(In-life Phase) 32380 Avenue 10 ...

Madera, CA 93638

TEST SUBSTANCE: 14C-Propanil

PROPOSED STUDY Experimental Start Date: April 1991

SCHEDULE: Experimental Termination Date: January 1993

PROPANIL EFGWB REVVEW

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. VIFIRA registration data. The document is a duplicate of page(s) The document is not responsive to the request.	Page Pages _	is not included in this copy. through 24 are not included.
Description of the product manufacturing process. Description of quality control procedures. Identity of the source of product ingredients. Sales or other commercial/financial information. A draft product label. The product confidential statement of formula. Information about a pending registration action. FIFRA registration data. The document is a duplicate of page(s)		
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Attachment 2. Letter from the Propanil Task Force.

Attachment 3. The Latest Label for Propanil.

PROPANIL EFGINB REVIEW

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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.	
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The product confidential statement of formula.	
Information about a pending registration action.	
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Attachment 4. Copy of EFGWB 91-0667 That Contains the Current Data Requirements.

	Shaughnessy Number: 028201
	Date out of EFGWB:
To:	Product Manager 71 (Waldrop/Stowe) Reregistration Division
From:	Akiva Abramovitch, Head Environmental Fate Review Section #3 Environmental Fate and Ground Water Branch Environmental Fate and Effects Division (H7507C) Henk Jacoby Chief
Thru:	Hank Jacoby, Chief Environmental Fate and Ground Water Brankl Environmental Fate and Effects Division (H7507C)
Attac	hed, please find the EFGWB review of
Reg./	File #: n.a.
Chemi	cal Name: Propanil
Туре	Product: herbicide
Produ	ct Name: n.a.
Compa	ny Name: Rohm and Haas
Purpo	se: request for status report on data requirements; re evaluation of waiver requests
Date	Received: 06/04/91
Actio	n Code: 614
EFGWB	#(s):91-0667
Total	Reviewing Time (decimal days):
Defer	rals to:Ecological Effects Branch, EFED
	Science Integration and Policy Staff, EFED
	Non-Dietary Exposure Branch, HED
	Dietary Exposure Branch, HED

___Toxicology Branch

- photodegradation on soil -- not fulfilled
- aerobic soil metabolism -- partially fulfilled, supplemental information
 provided by MRID 415387-01, reviewed EBC 12/3/90
- <u>anaerobic soil metabolism</u> -- can be fulfilled by the anaerobic aquatic metabolism study which is to be submitted by the Propanil Task Force
- <u>leaching/adsorption/desorption</u> -- pending, will be submitted by the Propanil Task Force
- <u>field soil dissipation</u> -- pending, will be submitted by the Propanil Task Force
- long term field dissipation -- conditionally required, if the short term
 study indicates the need
- <u>accumulation in confined rotational crops</u> -- pending, will be submitted by the Propanil Task Force
- accumulation in field rotational crops -- conditionally required, if the confined study indicates uptake of residues of concern
- $\frac{\text{fish bioaccumulation}}{\text{affirmation of low accumulation in fathead minnows}} \text{waiver recommended due to low } k_{\text{ow}} \text{ and applicant's}$
- Data requirements for aquatic food use and their status is as follows:
 - hydrolysis -- pending, also required for terrestrial crop use; will be submitted by the Propanil Task Force
 - photolysis in water -- pending, will be submitted by the Propanil Task
 Force
 - <u>anaerobic aquatic metabolism</u> -- pending, will be submitted by the Propanil Task Force
 - aerobic aquatic metabolism -- pending, will be submitted by the Propanil
 Task Force
 - leaching/adsorption/desorption -- pending, also required for terrestrial
 crop use as noted above; will be submitted by the Propanil Task
 Force
 - <u>aquatic field dissipation</u> -- pending, will be submitted by the Propanil Task Force
 - long term field dissipation -- conditionally required
 - confined accumulation on rotational crops -- pending, will be submitted by
 the Propanil Task Force
 - <u>field accumulation on rotational crops</u> -- requirement reserved pending results of confined study, also required for terrestrial uses, as noted above
 - confined accumulation on irrigated rotational crops -- pending
 - $\frac{\text{fish bioaccumulation -- waiver recommended due to low } k_{\text{ow}} \text{ and applicant's}}{\text{affirmation of low accumulation in fathead minnows}}$
- Because of informal reports that propanil applied to rice subsequently reached and damaged non-target crops, especially prune trees, EFGWB also requires the following studies, which are not usually imposed for aquatic uses:
 - <u>lab volatility</u> -- the Propanil Task Force has not specifically addressed this issue

Attachment 5. The Louisiana Weed Control Recommendations on Rice.

CHARGESIES

CHARGE

Weed Control Performance Ratings of Selected Rice Herbicides in Trials Conducted by the Louisiana Experiment Station

Prow1 + Propan11	Modown + Propanil	Basagran	Blazer	2,4-D Dacamine	2,4-D Amine	Ordram	Propan11	Arrosolo	POSTEMERGENCE	1	Bolero (Delayed)	Modown	Ordram (PPI)	Bolero PPS		PREEMERGENCE
					*											
175	123	10	70	70	۳	င	, pa	য			. G.,	ď	R	e	1	Barnyardgrass
r o	P	P	7	ים	P	P	P	٦			r d	P.	င	. 6	2	Red Rice
E	2 12	, rp	ים	70	P		E ²	EZ			G	P	1	6	9	Sprangletop
F	les .	P	P	P	P	יש	स्य	150			न्द्र	79	F	•	ম	Signalgrass
E	চে	F		Pé	3 PJ	G	(F)	rs			1		tx.		F 3	Sedges
P	P	-	,	ေ	G	יש	₩	P			P	1	-	,	P	Alligatorweed
G	2 6	2		চ	t s	P	G,	S G	3		EI.	F	-	,	হো	Ducksalad
G	-G	2	g 1	t×	টো	70	င့	3 G	3		175	-	, ,	•	ဝ	Redstem
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	,		ا .	ı (t	; t=	1 -)) 	•			[7]		, l	a	য়ে	Waterhyssop
	₂	₂	₽ .	v	ر د) 4	, G	22	2		T-P	۱ ۱		0	দ্ব	Jointvetch
	_{C2}	₂	15	, ;	5 3 (5	5 h	a 6	2	₂		į.	, .	5	שי	Ħ	Dayflower
- 1			יסי	म्ब्र	73 C	5 7	a c	י ר	7		~	, ,	9	ا ه	۳	Texasweed

3

Weed Control Performance Ratings of Selected Rice Herbicides in Trials Conducted by the Louisiana Experiment Station

(ontinued)

see Totoowing Comments on ducksatad	5 co following com	A rew sedges are controlled See following comments	2Controlled only when small (less	Londax	Whip	Modown	Bolero + Propanil		
ments on queksal		controlled	management hen small (less		,				
20			than	P	E4	1	যে	Barnyardgrass	
			than 2 leaf)	ъ	P	1	P	Red Rice	
				P	E4	1	দ্য	Sprangletop	
				P	E4	ı	ल	Signalgrass	(or
	- nc	Good - 70 Excellent	Poor -	R	₩.		ফ	Sedges	(oncinued)
	not rated	20-	1eg	Ħ	'ਚ	G	שי	Alligatorweed	
		- 90-100 z	than 49%	E	ם ו	1	G ²	Ducksalad	
			Ñ	E	۳	1	G ²	Redstem	
				P	P	1	tes	Hemp Sesbania	
				যে	q	8	1	Waterhyssop	
				ъ	þ	1	G ²	Jointvetch	
				ဂ	P	l.	G ²	Dayflower	
				ဂ	ים	ъ	ດຸ	Texasweed	

RICE (Continued)

0	Inoredient	Active	Rate/Acre	
	Broadcast	Material for 1 Acre	Rate of Formulated	
	to Appry	Time		
	Controtter	meeus 110d	U)	
		Remarks		

3.0 to 6.0 qt
of 4.0 lb/gal
material or
3.5 to 7 lb of
85% dry flowable.
Apply 10 gal by
air, 20 by ground

seeding.

propanil at 3.0 to 6.0 lb/A

Various formulations

POSTEMERGENCE

Grass prior Mos
to 4 leaf gra
stage. Usually sed
within 10-14 bro
days after in

Most annual
grasses, some
sedges and
broadleaf weeds
in the seedling

moisture and temperature above 70° F. with actively growing grass. Use 3.0 1b grass is stunted and deep-Control best with good soil tillering; control usually for larger grass that is rooted in dry soil. 5.0 lb 4 to 5 leaf stage, or when 4.0 to 4.5 lb for grass in for grass in 3 leaf stage, not entirely satisfactory. total per season. Apply to actual per single treatment Do not use more than 6 lbs. in the late tillering stage Do not apply after rice is Do not apply over 8.0 lb (45-60 days after planting)

Do not treat when temperature is below 50° F. or above 100° F. In many cases a

weather, leave unflooded 4 to 5 days if possible.

reinfestation occurs and a second application is needed.

growing actively and soil is

During cool cloudy

moist.

weather is warm, grass is

about 12 to 24 hours if

drained field and flood in

Rate/Acre Active Ingredient	Rate of Formulated Material for 1 Acre Broadcast	Time To Apply	Weeds Controlled	Remarks
propanil (continued)	•			However, the 8 lb season limitation should not be exceeded. Read and follow label directions on bird repellants concerning subsequent use of propanil. propanil should not be applied after Furadan has been used. Do not apply to second crop.
molinate at 3.0-4.0 lb/A	Ordram 15G 20-25 1b of granular material	Rice should be large enough to be flooded. Grass should be a minimum of 1" but no taller than 5".	Barnyardgrass, seedling yellow nutsedge, fimbry-stilis, and spikerush.	Grass must be at least 2/3 submerged at time of application. A flood of at least 2 inches in depth must be maintained after treatment. Drainage may result in loss of control.
molinate + propanil at 4.5 - 6.0 lb/A	Arrosolo 3-3E 3-4 qt	Apply at same time that would be suitable for propanil application.	Barnyardgrass, sprangletop and small broadleaf weeds.	Similar in control to propanil. May be more active on certain weeds when compared to equivalent rate of propanil.

Attachment 6. Administrative Materials.

DP BARCODE: D168875 REREG CASE #

CASE: 818688 DATA PACKAGE RECORD DATE: 09/18/91

SUBMISSION: S402808 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 635 PROPOSED TEST PROT SUBM

CHEMICALS: 028201 3',4'-Dichloropropionanilide

ID#: 028201 COMPANY:

PRODUCT MANAGER: 71 WALTER WALDROP 703-308-8062 ROOM: CS1 3B3
PM TEAM REVIEWER: TERRI STOWE 703-308-8043 ROOM: CS1 3D5

RECEIVED DATE: 09/16/91 DUE OUT DATE: 12/25/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 168875 EXPEDITE: Y DATE SENT: 09/18/91 DATE RET.: / /

CHEMICAL: 028201 3',4'-Dichloropropionanilide

DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 12/17/91 CSF: N LABEL: N

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN.: FOR IMMEDIATE REVIEW - PROPANIL PROTOCOL

Please review the Propanil protocol for GLN 165-1 Confined Rotational Crop study. Please send a copy of the review to:

Terri Stowe

SRRD/RB (H7508W)

Crystal Station I - 3rd fl.

THANK YOU!!!

For the attached reregistration case, please identify all applicable data requirements and note those for which adaquate data have not been submitted to the Agency.

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

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

Abramonth

	•		DP Barcode	:D <u>/6887</u> S
			PC Code No.	:
			Date Out	:
TO:		•		
	Product Manager Registration Division (H750)	5C)		
	Akiva Abramovitch, Head Chemistry Review Section a Environmental Fate and Gr			
	Hank Jacoby, Chief Environmental Fate and Gre Environmental Fate and Eff	ound Water Brancects Division (H75	ch 507C)	
Attached,	please find the EFGWB re	view of	er.	
Reg./File	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·		
Chemical	Name : \mathcal{P}	ropanil		
Type Proc	•	· •		
Product _. N	lame :	·	•	
Companý	Name :	•		
Purpose	·			
	:	4		
Date Rece	ived:/	EFGWB#: 91- <u>Ø</u>	<i>524</i> Time	(days):
Deferrals 1	o:			
	_ EEB/EFED	_ DEB/HED	· ·	TB1/HED
	_ SIPS/EFED	OREB/HED		TR2/WED

40