



2002084

File Copy
Propiconazole

DP Barcode : D198845
PC Code No : 122101
EEB Out : 04-25-94

To: Bruce Sidwell
Product Manager 53
Special Review and Reregistration Division (7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 122101-000100
Chemical Name : Propiconazole
Type Product : Fungicide
Product Name : Tilt Fungicide Products
Company Name : Ciba-Geigy Corporation
Purpose : Registrant response to Phase IV DCI Notice
for List C, Case No. 3125.

Action Code : 620 Date Due : 04/02/94
Reviewer : K. Valente Date In : 02/03/94

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed)
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

DP BARCODE: D198845

REREG CASE # 3125

CASE: 816533
SUBMISSION: S457219

DATA PACKAGE RECORD
BEAN SHEET

DATE: 02/02/94
Page 1 of 2

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 620 3(C)2(B)-90 DAY RESPONSE
CHEMICALS: 122101 Propiconazole 100.00 %

ID#: 122101-000100

COMPANY: 000100 CIBA-GEIGY CORP.

PRODUCT MANAGER: 53 BRUCE SIDWELL

703-308-8078 ROOM: CS1 3E3

PM TEAM REVIEWER: RICHARD GEBKEN

703-308-8591 ROOM: CS1 WF3145

RECEIVED DATE: 01/05/94 DUE OUT DATE: 03/21/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 198845 EXPEDITE: N DATE SENT: 02/01/94 DATE RET.: / /

CHEMICAL: 122101 Propiconazole

DP TYPE: 999 Miscellaneous Data Package

CSF: N

LABEL: N

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 04/02/94

DIV : EFED

02/03/94

/ /

NEGOT DATE: / /

BRAN: EEB

02/03/94

/ /

PROJ DATE: / /

SECT:

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/ /

REVR :

02/03/94

02/03/94

CONTR:

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* * * DATA REVIEW INSTRUCTIONS * * *

Ciba has returned the 90 day response for Propiconazole.
Please find attached the documents pertaining to EEB.

The issues Ciba has addressed are summarized below:

Ecotoxicology (72-3(a)(b)(c), 72-4(a) and 141-1):
Ciba requests altering of the classification of studies for
guidelines 72-3 (a), (b), and (c) since TEP data were
determined to be appropriate to address ecotoxicology; TEP
studies were classified as "Accept" leaving the appropriate
designation for the 72-3 series as "Accept". Ciba Plant
Protection maintains that currently available data
appropriately address guideline 72-4(a); a data volume
providing additional information on this guideline
accompanies the 90-day response. Ciba will conduct the
requested honey bee acute contact study (guideline 141-1)
and submit a report to EPA within the required time frame.
Ciba is requesting no time extensions in association with
any ecotoxicology guidelines.

The following studies were submitted by Ciba with the 90
day response

MRID GDLN
43075501 72-4(A)



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

APR 26 1994

April 25, 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Registrant Response to Propiconazole DCI (D198845)

TO: Bruce Sidwell, PM 53
Special Review and Reregistration Division (7508W)

FROM: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Ciba-Geigy has responded to the Phase IV DCI for propiconazole (Tilt) fungicide (dated 7/92). Three separate issues relating to ecological effects data are addressed in this response:

- (1) Request to waive marine-estuarine fish acute toxicity data with TGAI or accept existing core data with TEP to satisfy Guideline 72-3(a);
- (2) Request to upgrade fish early life study (MRID #417203-02), including additional data submitted; and
- (3) Agreement to perform honeybee acute contact study to satisfy Guideline 141-1.

EEB agrees to accept the existing core data with the TEP to satisfy Guideline 72-3(a) for marine-estuarine fish. Data requirements for shrimp and mollusc with the TGAI have already been waived.

EEB cannot address the request to upgrade the fish early life stage study without having the raw data with which to perform the statistical analysis; therefore, the study cannot be upgraded at this time. However, EEB records show that Guideline 72-4(a) is already fulfilled (accession no. 072210); in addition, a core higher-tier study (72-5, fish life cycle) is also available for use in a risk assessment.

The status of Guideline requirement 70-1, special study (Aquatic field residue study) was not addressed in the registrants' response. This study is required to support the rice use of propiconazole, and was first required in 1984.



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The following data requirements are **outstanding** for propiconazole:

- 70-1: Aquatic field residue monitoring--rice use
- 141-1: Honeybee acute contact study (TGAI)

The following data requirements are **reserved** for propiconazole:

- 141-2: Honeybee toxicity of residues (TEP) (pending results of acute contact study).

If you have any questions on the above, please contact Kathryn Valente Montague (308-2804).

*File copy
Propiconazole*

Generic Data Requirements for Propiconazole as of 4/25/94

Data Requirement	Composition	Use Pattern ¹	Does EPA Have Data to Satisfy Data Req.	Citation	More Data Submitted Under FIFRA 3(c) (2) (B)?
158.490 Wildlife and Aquatic Organisms					
70-1 Special Study: Aquatic residue monitoring on rice (TEP)			No		Yes
AVIAN AND MAMMALIAN TESTING					
71-1 Avian oral LD ₅₀ TGAI		A, B, C, D, J	Yes	00079689, 00067926	No
71-2 Avian dietary LC ₅₀					
a. upland gamebird TGAI		A, B, C, D, J	Yes	00079690	No
b. waterfowl TGAI		A, B, C, D, J	Yes	00067927	No
71-3 Wild Mammal Toxicity TGAI			No		No
71-4 Avian Reproduction TGAI		A, B, J	Yes	133369, 134502	No
71-5 Simulated and actual field testing-mammals and birds TEP			No		No
AQUATIC ORGANISM TESTING					
72-1 Freshwater fish LC ₅₀					
a. Coldwater TGAI		A, B, C, D, J	Yes	00067923	No
b. Warmwater TGAI		A, B, C, D, J	Yes	00067922	No
c. Warmwater TEP		D	Yes	0013295	No

¹A=Terrestrial food, B=Terrestrial nonfood, C=Aquatic food, D=Aquatic nonfood, G=Aquatic nonfood, J=forestry.

d. Coldwater	TEP	D	Yes	00132928	No
72-2 Freshwater Invertebrate					
EC ₅₀	TGAI	A,B,C,D,J	Yes	00067295	No
	TEP	D	Yes	00132932	No
72-3 Marine/Estuarine					
Acute LC ₅₀					
a: fish	TGAI	C,D	Partial ²	00132921	No
b: mysid	TGAI	C,D	N/A ²		
c: oyster	TGAI	C,D	N/A ²		
d: fish	TEP	C,D	Yes	00132924	No
e: mysid	TEP	C,D	Yes	00132933	No
f: oyster	TEP	C,D	Yes	00132934	No
72-4 Fish early life stage and aquatic invert. life cycle	TGAI	C,D	Yes	00163165,417203-02, 072210	No
72-5 Fish Life Cycle	TGAI	C,D	Yes	408820-01	No
72-6 Aquatic organism accumulation	TGAI		Yes ³		No
72-7 Simulated or actual field testing - aquatic organisms	TEP	D	No		No
158.150 PLANT PROTECTION					
121-1 Target area phytotoxicity	TEP		No		No

²This requirement has been waived.

³EFGWB has data on bioaccumulation in fish indicating that propiconazole has little tendency to bioaccumulate; therefore, 72-6 is not required.

Nontarget Area Phytotoxicity

TIER I

122-1	Seed germ./ seedling emergence	TGAI		No		No
122-1	Vegetative vigor	TGAI		No		No
122-2	Aquatic plant growth	TGAI		No		No

TIER II

123-1	Seed germ./ seedling emergence	TGAI	A, B, C, D, J	Yes	416732-02, -03	No
123-1	Vegetative vigor	TGAI	A, B, C, D, J	Yes	416732-01	No
123-2	Aquatic plant growth	TGAI	A, B, C, D, J	Yes	00132937, 00132938, 00133363, 00132939, 00133362	No

TIER III

124-1	Terrestrial plant field testing	TEP	A, B, C, D, J	No		No
124-2	Aquatic plant field testing	TEP	A, B, C, D, J	No		No

158.590 NONTARGET INSECT TESTING - POLLINATORS

141-1	Honeybee acute contact toxicity	TGAI	A, B	No		Yes
141-2	Honeybee toxicity of residues	TEP	A, B	No		Reserved ⁴
141-5	Field testing for pollinators	TEP	A, B	No		No

⁴Reserved pending results of acute contact study.