

US EPA ARCHIVE DOCUMENT

Shaughnessy No.: 060101

Date Out of EFGWB:

FEB 2 1989

To: G. Werdig/R. Whitters  
Product Manager # 50  
Registration Division (TS-767)

From: Paul Mastradone, Ph.D., Acting Chief *PM*  
Environmental Chemistry Review Section 1  
Environmental Fate and Ground Water Branch  
Environmental Fate and Effects Division (TS-769-C)

THRU: Henry Jacoby, Acting Chief *Henry Jacoby*  
Environmental Fate and Ground Water Branch/EFED (TS-769C)

Attached, please find the EAB review of...

Reg./File # : 060101  
Chemical Name: Thiobendazole  
Type Product : Fungicide  
Product Name : MERTECT fungicide products  
Company Name : MERCK & Co.  
Purpose : Review request for 9-month extension to submit reports on  
three fate studies for Comprehensive Data Call In.

Date Received: 1/4/89 Action Code: 495

Date Completed: 2/2/89 EFGWB#(s): 90256

Total Reviewing Time (decimal days): 0.5

Deferrals to: \_\_\_\_\_ Ecological Effects Branch, EFED  
\_\_\_\_\_ Science Integration & Policy Staff, EFED  
\_\_\_\_\_ Non-Dietary Exposure Branch, HED  
\_\_\_\_\_ Dietary Exposure Branch, HED  
\_\_\_\_\_ Toxicology Branch, HED

MERCK SHARP & DOHME RESEARCH LABORATORIES

DIVISION OF MERCK & CO., INC.

HILLSBOROUGH ROAD, THREE BRIDGES, NEW JERSEY 08867

SAMUEL F. RICKARD, Ph.D.  
ASSOCIATE DIRECTOR, REGULATORY AFFAIRS  
AGRICULTURAL RESEARCH & DEVELOPMENT

(201) 389-3031

December 19, 1988

Office of Pesticide Programs  
OPP Mailroom (TS-767C)  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460

Attn: Thiabendazole Data Call In

Dear Ms. Werdig:

Thiabendazole Data Call In: Request for 9-Month Time Extension

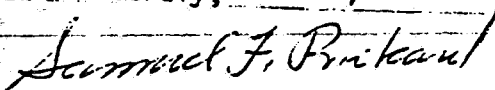
This is to request a 9-month extension for submission of reports on the following studies required to be submitted to EPA by 12/31/88 (9 months from our receipt date of 3/31/88 of the data call in notice) to partially fulfill the data requirements of the subject comprehensive generic data call in for thiabendazole.

<u>Guideline Number</u>	<u>Data Requirement</u>
161-1	Hydrolysis
161-2	Photodegradation - Water
161-3	Photodegradation - Soil

Because of conflict with other company projects and laboratory overload, it has become necessary to contract these studies to an outside laboratory. These studies are scheduled to be initiated in January, 1989, with final reports projected to be available for submission to EPA by September 30, 1989. Studies are to be conducted by Analytical Bio-Chemistry Laboratories, Inc. (P.O. Box 1097, Columbia, Missouri 65205). A copy of the laboratory invoice of 12/15/88 for the initial payment for these and several other studies is attached.

Should there be questions about this request, please contact me at the letterhead address and telephone number.

Sincerely,



Samuel F. Rickard

:cg

Attachment

OFFICE OF PESTICIDE PROGRAMS DATA REVIEW RECORD

ATTACHMENT 1

Confidential Business Information-Does Not Contain National Security Information(E.O. 12065)  
 This form is to be used for individual studies and for submission of pesticide applications

1. PRODUCT NAME		CHEMICAL NAME	
2. IDENTIFYING NUMBER	3. RECORD NUMBER	4. ACTION CODE	5. MRID/ACCESSION NUMBER
060101	237401	4951	Thiabendazole
			6. STUDY GUIDELINE OR NARRATIVE
			161-1
			161-2
			161-3
7. REFERENCE NUMBER	8. DATE RECEIVED (EPA)	9. PRODUCT/REVIEW MANAGER/DCI	10. PM/RM TEAM NUMBER
5	12/20/88	G. Werda/R. White	50
11. DATE SENT TO (HED/EFED/RD/BEAD)	13. DATE RETURNED TO (RD/SRRD)	INSTRUCTIONS:	
01/04/89		March + (random request) 9-mo. time extension for the above guidelines not done to coincide with other company projects, etc. (500 lbs)	

(THIS SECTION APPLIES TO REVIEW OF STUDIES ONLY)

CHECK APPLICABLE BOX:

- ADVERSE 6(a)(2) DATA (405)
- SPECIAL REVIEW DATA (870)
- GENERIC DATA (REREGISTRATION) (660)
- PRODUCT SPECIFIC DATA (REREGISTRATION) (655)
- 15. NUMBER OF INDIVIDUAL STUDIES SUBMITTED

HAVE ANY OF THE ABOVE STUDIES (in whole or in part) BEEN PREVIOUSLY SUBMITTED FOR REVIEW? (circle: yes or no) IF YES, PLEASE IDENTIFY THE STUDY(IES):

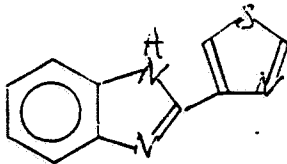
TO	TYPE OF REVIEW	19. REVIEWERS ALSO SENT TO	20. DATA REVIEW CRITERIA
	SCIENCE ANALYSIS & COORD. TOXICOLOGY/HFA TOXICOLOGY/IR DIETARY EXPOSURE NON-DIETARY EXPOSURE ECOLOGICAL EFFECTS <input checked="" type="checkbox"/> ENVIRONMENTAL FATE & GROUND H2O SPECIAL REVIEW REREGISTRATION GENERIC CHEMICAL SUPPORT INSECTICIDE-RODENTICIDE FUNGICIDE-HERBICIDE ANTIMICROBIAL PRODUCT CHEMISTRY PRECAUTIONARY LABELING ECONOMIC ANALYSIS ANALYTICAL CHEMISTRY BIOLOGICAL ANALYSIS	SAC TOX/HFA TOX/IR DEB NDE EEB EFGWB SR RER GSC IR FH AM	PC PL EA AC BA
CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS)			A. Policy Note #31 <input type="checkbox"/> 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria <input type="checkbox"/> 2 = data of particular concern from registration standard <input type="checkbox"/> 3 = data necessary to determine tiered testing requirements B. Section 18 <input type="checkbox"/> 1 = data in support of section 3 in lieu of section 18 C. Inert Ingredients <input checked="" type="checkbox"/> 1 = data in support of continued use of List 1 inert

CONFIDENTIAL STATEMENT OF FORMULA (TRADE SECRETS)

LABEL ATTACHED

- Data Coordinator  
 Yellow - Data Review Section  
 Green - Return with completed review  
 Pink - PM/RM/DCI

1. CHEMICAL:                    Common Name- thiabendazole  
                                          Chemical Name- 2-(4-thiazolyl)benzimidazole  
                                          Trade Name- MERTECT products  
                                          Chemical Structure-



2. TEST MATERIAL: Not applicable.
3. STUDY/ACTION TYPE: Merck & Co. is requesting a 9-month extension to submit reports on three fate studies required for the thiabendazole Comprehensive Data Call In; the studies are hydrolysis and photodegradation in water and on soil.
4. STUDY IDENTIFICATION: Not applicable.

5. REVIEWED BY:

Herbert L. Manning, Ph.D.  
 Microbiologist  
 EFGWB/EFED

Signature: *Herbert L. Manning*

Date: FEB 2 1989

6. APPROVED BY:

paul J. Mastradone, Ph.D.  
 Acting Chief, Section 1, EFGWB/EFED

Signature: *Paul J. Mastradone*

Date: FEB 2 1989

7. CONCLUSION:

EFGWB (Environmental Fate and Ground Water Branch) does not object to Merck & Co. being given a 9-month extension to report data for hydrolysis and photodegradation in water/soil, as required by the thiabendazole Comprehensive Data Call In.

8. RECOMMENDATION:

There are no specific recommendations.

9. BACKGROUND:

A. Introduction- Merck & Co. is requesting the 9-month extension because company projects and laboratory overload necessitated contracting the three fate studies to an outside laboratory. The studies are scheduled to start Jan. 1989; final reports are expected to be submitted by 30 Sep 1989. Analytical Bio-Chemistry Labs is the contracting laboratory.

B. Direction for Use- Not applicable.

10. DISCUSSION OF INDIVIDUAL STUDY:

Not applicable.

11. COMPLETION OF ONE-LINER:

Not applicable.

12. CBI APPENDIX:

There is no CBI in this review.