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

FEB 8 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Phase IV review of Thiabendazole.

EFGWB # 90-0808, 90-0880 and 91-0213, Chemical 060101,
Rereg. Case #2670, DP BARCODE D158974

FROM: Akiva D. Abramovitch, Ph.D. *Akiva Abramovitch*
Review Section #3
Environmental Fate and Ground Water Branch/EFED

TO: Amy Rispin, Chief
Science Analysis and Coordination Staff/EFED

THRU: Henry Jacoby, Branch Chief *Henry Jacoby*
Environmental Fate and Ground Water Branch/HED

The attached EFGWB Phase IV Review and Data Tables summarize the status of the data requirements for currently registered uses of thiabendazole.

The LUIS report on the fungicide thiabendazole of January 21, 1991 lists terrestrial food and non food indoor food and non food and aquatic food crop uses.

The aquatic use on rice requires aerobic aquatic and anaerobic aquatic metabolism, aquatic field dissipation and irrigated crops data. Water solubility of thiabendazole at pH 5-9 is less than 50 mg/L at 25 C. The irrigated crop data may be waived if a restriction is placed on the label on using the water from the rice fields to irrigate other crops.

The registrant does not have to submit additional volatility data since the vapor pressure of thiabendazole is 4×10^{-9} mm Hg at 25 C.

The photodegradation on soil, anaerobic soil metabolism and fish accumulation data requirements were satisfied by the attached review and are the only data requirements satisfied to date. Hydrolysis, photodegradation in water and adsorption/desorption data were reviewed in 1990 and found unacceptable.

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR THIABENDAZOLE

Chemical Code : 060101
Pesticide Type: Fungicide

Reviewer: Akiva Abramovitch
Date: January 1991

Uses (LUIIS of January 21, 1990): Terrestrial food and non food, indoor food and non food, aquatic food (rice)

<u>Phase II</u> Submitted Studies/ Addendum	<u>Phase III</u> DER/Addendum Review/Summary Identification	<u>Phase IV</u> DER/Addendum Review/Summary Review Conclusions	<u>Additional</u> Data/Info Required?
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DEGRADATION-LAB:

161-1. Hydrolysis 41265301 Feb. 20, 1990 Unacceptable Yes

Photodegradation:

161-2. In Water 41265101 Feb. 20, 1990 Unacceptable Yes
161-3. On Soil None 41397301/phase IV Acceptable No
161-4. In Air None None No/1, 2

METABOLISM-LAB:

162-1. Aerobic Soil None None Yes
162-2. Anaerobic Soil None 41559601/phase IV No
162-3. Anaerob. Aquat. None None Yes
162-4. Aerobic Aquatic None None Yes

MOBILITY STUDIES:

163-1. Leaching and 41170102 Feb. 20, 1990 Unacceptable Yes
Adsorp./Desorp.
163-2. Volatil. (Lab) None None No/2
163-3. Volatil. (Field) None None No/2

DISSIPATION-FIELD:

164-1. Terrest. (Soil) None None Yes
164-2. Aquat. (Sediment) None None Yes
164-3. Forestry None None No/1
164-4. Combin./Tank Mix None None No/1
164-5. Long Term Terr. None None Yes/3
164-5. Long Term Aqua. None None Reserved

ACCUMULATION STUDIES:

165-1. Conf. Rot. Crops None None Yes
165-2. Field Rot. Crops None None Reserved/4
165-3. Irrigated Crops None None Yes

165-4. Fish (Lab)	None	416318/phase IV	acceptable	No
165-5. Aqua. Non-target Organ. (Field)	None	None		No/1

SPRAY DRIFT:

201-1. Droplet Spect. Evaluation	None	None		Reserved/5
202-1. Field Spray Drift	None	None		Reserved/5

ROUNDWATER MONITORING:

166-1. Small Propect.	None	None		Reserved/6
166-2. Small Retrop.	None	None		Reserved/6
166-3. Large Retrop.	None	None		Reserved/6

SURFACE WATER:

167-1. Field Runoff	None	None		Reserved/6
167-2. Surface Water Monitoring	None	None		Reserved/6

FOOTNOTES:

- 1) A LUIS report of January 21, 1991 lists terrestrial food and non food uses indoor food and nonfood and aquatic food (rice).
- 2) Thiabendazole has low volatility having vapor pressure of 4×10^{-9} .
- 3) Preliminary data suggest that thiabendazole may require long term field dissipation data.
- 4) Pending evaluation of the confined crop rotation data to be submitted.
- 5) Pending ecological issues.
- 6) Present data are insufficient to make ground water/surface water risk assessment.

Shaughnessy No.: 060101
Date Out of EAB: _____

To: Frank Rubis/Jay Ellenberger
Product Manager 50
Registration Division

From: A. Abramovitch, Ph.D., Supervisory Chemist *d*
Environmental Chemistry Review Section #3
Environmental Fate and Ground Water Branch/EFED

Through: Henry Jacoby, Chief
Environmental Fate and Ground Water Branch/EFED

Attached, please find the EAB review of . . .

Reg./File # : _____
Common Name : Thiabendazole
Type Product : Fungicide
Product Name : TBZ
Company Name : Merck and Company, Inc.
Purpose : Phase IV reregistration

Date Received: _____ EFGWB # (s): 900879,910213

Action Code : _____

- Deferrals to:
- _____ Ecological Effects Branch, EFED
 - _____ Science Integration and Policy Staff, EFED
 - _____ Non-Dietary Exposure Branch, HED
 - _____ Dietary Exposure Branch, HED
 - _____ Toxicology Branch I, HED
 - _____ Toxicology Branch II, HED

1. CHEMICAL: Common name:

Thiabendazole.

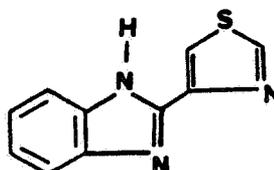
Chemical name:

2-(thiazol-4-yl)benzimidazole;
2-(1,3-thiazol-4-yl)benzimidazole.

Trade name(s):

Arbotect, Mertect, TBZ, Tecto, Thibenzole.

Structure:



Formulations:

WP (40, 60, 90%); FC.

Physical/Chemical properties:

Molecular formula: C₁₀H₇N₃S.

Molecular weight: 201.1.

Physical state: Powder.

Vapor pressure: 4x10⁻⁹

Solubility: At 25 C: c. 10g/L in water at pH 2; <50 mg/L in water at pH 5-12; >50 g/L at pH 12; 4.2 g/L acetone; 7.9 g/L ethanol; 2.1 g/L ethyl acetate. At "room temperature": 230 mg/L benzene; 80 mg/L chloroform; 39 g/L dimethylformamide; 80 g/L dimethyl sulfoxide; 9.3 g/L methanol.

2. TEST MATERIAL:

Studies 1-3: Active ingredient.

3. STUDY/ACTION TYPE:

Addendum to an application for full registration.

4. STUDY IDENTIFICATION:

Dykes, J., and K. Kabler. 1990. Determination of the photolysis rate of ¹⁴C-thiabendazole on the surface of soil. ABC Revised Final Report No. 37638. Unpublished study performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Merck & Company, Inc., Rahway, NJ. (41397301)

Dykes, J. 1990. Determination of the photolysis rate of ¹⁴C-thiabendazole on the surface of soil supplemental data. ABC Supplemental Raw Data Report No. 376381. Unpublished document prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Merck & Company, Inc., Rahway, NJ. (41397302)

Daly, D., and M. Williams. 1990. Anaerobic soil metabolism of ¹⁴C-thiabendazole. ABC Final Report No. 37640. Unpublished study performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by MSD AGVET, Division of Merck and Company, Inc., Rahway, NJ. (41559601)

M. Hirsch. 1990. Bioconcentration of ¹⁴C-thiabendazole in Bluegill Sunfish. Unpublished study performed by Environmental Science Section Health and Environment Laboratories, Eastman Kodak Company, Rochester, NY and submitted by Merck and Company, Inc., Rahway, NJ. (416318).

5. REVIEWED BY:

A. Abramovitch
Chemist
EFGWB/EFED/OPP
Review Section #2

Signature: *A. Abramovitch*
Date: FEB 6 1991

6. APPROVED BY:

A. Abramovitch
Supervisory Chemist
EFGWB/EFED/OPP
Review Section #3

Signature: *A. Abramovitch*
Date: FEB 6 1991

7. CONCLUSION:

The photodegradation on soil, the anaerobic soil metabolism and the fish accumulation data requirements were satisfied in this review.

Photodegradation on soil:

No significant degradation of thiabendazole occurred on soil when exposed to a xenon lamp simulating sunlight for 30 days.

Anaerobic soil metabolism:

Thiabendazole did not undergo significant anaerobic metabolism within the 60 days anaerobic incubation period.

Bioaccumulation in Fish:

[¹⁴C]Thiabendazole did not bioaccumulate significantly in bluegill sunfish within 28 days. Bioaccumulation Factors of 86.5, 19.72 and 747 were obtained for the whole fish, edible and viscera, respectively. Within 3 depuration days, more than 96% of the material in the viscera was removed. Depuration was also significant in the edible portion.

8. RECOMMENDATIONS:

The registrant should proceed to satisfy all data requirements listed as unsatisfied in the phase IV review.

9. BACKGROUND:

A. Introduction

This review is part of the phase IV response.

B. Directions for Use

Thiabendazole is a systemic fungicide registered for use on terrestrial food crop and terrestrial nonfood crop (ornamentals, turf, and tobacco) sites. Single active ingredient formulations include wettable powder and flowable concentrate. Applications may be made during the growing season to control pathogenic fungi and postharvest to control storage diseases. Thiabendazole is slightly toxic to fish.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

Refer to attached reviews.

11. COMPLETION OF ONE-LINER: Not completed

12. CBI APPENDIX:

All data reviewed here are considered "company confidential" by the registrant and must be treated as such.

PHASE IV REVIEW OF THIABENDAZOLE

TASK 1: REVIEW AND EVALUATION OF INDIVIDUAL STUDIES

Contract No. 68D90058

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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

Table of Contents

Introduction

Scientific Studies

1. Photodegradation on Soil.
(Dykes and Kabler, 41397301; Dykes, 41397302)
2. Anaerobic Soil Metabolism.
(Daly and Williams, 41559601)
3. Bioaccumulation in Fish.
(Hirsch, 416318)

INTRODUCTION

Thiabendazole is a systemic fungicide registered for use on terrestrial food crop and terrestrial nonfood crop (ornamentals, turf, and tobacco) sites. Single active ingredient formulations include wettable powder and flowable concentrate. Applications may be made during the growing season to control pathogenic fungi and postharvest to control storage diseases. Thiabendazole is slightly toxic to fish.

DATA EVALUATION RECORD

STUDY 1

CHEM 060101
§161-3

Thiabendazole

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41397301

Dykes, J., and K. Kabler. 1990. Determination of the photolysis rate of ¹⁴C-thiabendazole on the surface of soil. ABC Revised Final Report No. 37638. Unpublished study performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Merck & Company, Inc., Rahway, NJ.

STUDY ID 41397302

Dykes, J. 1990. Determination of the photolysis rate of ¹⁴C-thiabendazole on the surface of soil supplemental data. ABC Supplemental Raw Data Report No. 376381. Unpublished document prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by Merck & Company, Inc., Rahway, NJ.

DIRECT REVIEW TIME = 15

REVIEWED BY: C. Little TITLE: Staff Scientist

EDITED BY: W. Martin TITLE: Staff Scientist
K. Patten Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager
ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: A. Abramovitch
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-1975

A. Abramovitch

SIGNATURE:

CONCLUSIONS:

Degradation - Photolysis on Soil

1. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing

information on the photodegradation of phenyl ring-labeled [¹⁴C]thiabendazole on soil.

2. Thiabendazole was stable to photolysis on sandy loam soil which was irradiated with artificial light (xenon arc lamp) at 11-41 C for 30 days.

METHODOLOGY:

Phenyl ring-labeled [¹⁴C]thiabendazole (uniformly labeled; radiochemical purity 95.4%, specific activity 3.33×10^7 dpm/mL, Merck, Sharp and Dohme Research Laboratories) was added at 48.5 ug/g to vials containing caked, air-dried sandy loam soil (58% sand, 30% silt, 12% clay, pH 7.8, 0.9% organic matter, CEC 9.2 meq/100 cm³). Methanol was added to the samples to ensure uniform distribution of the test material throughout the soil, then evaporated with a nitrogen stream. All of the vials were sealed with Teflon-lined caps. Fourteen of the vials were inverted and placed in a sealed photolysis chamber, where they were irradiated on a 12-hour photoperiod for up to 30 days with an artificial light (Atlas xenon arc lamp; Table II), positioned 32 inches above the chamber base. Wavelengths of <290 nm were filtered using a Pyrex glass sheet. A constant chamber temperature of 25 ± 2.5 C was maintained by a water flow through the chamber; however, the soil surface temperatures were 11.2-40.8 C. Two vials were designated as time zero samples; an additional 14 vials were placed in an aluminum-foil covered vessel and incubated under similar conditions to serve as dark control samples. Samples were removed for analysis at 0, 1.00, 2.98, 6.94, 10.0, 13.9, 19.0, and 30 days posttreatment.

Soil samples were extracted three times with dimethylformamide:6 N HCl (1:1). Samples were vortexed and centrifuged following each addition of solvent. The extracts were combined, brought to volume, and analyzed in duplicate for total radioactivity using LSC. The extracts were then adjusted to pH 12, partitioned with ethyl acetate, and analyzed by HPLC using an isocratic mobile phase of acetonitrile:0.001 M tetrabutyl ammonium dihydrogen phosphate in water (25:75); fractions were collected and analyzed by LSC. Additional analysis, to confirm the identity of the material as parent, was done on samples from days 0 and 30 by TLC on Merck RP-18F 254 plates developed with ethyl acetate:methanol:phosphoric acid (9:1:0.5, v:v:v). Unlabeled standards cochromatographed on the plates were visualized with UV light; radioactive zones were located with autoradiography.

DATA SUMMARY:

Phenyl ring-labeled [¹⁴C]thiabendazole (radiochemical purity 95.4%), at 48.5 ug/g, was stable to photolysis on sandy loam soil which was irradiated with artificial light (xenon arc lamp) for 30 days at 11.2-40.8 C (Tables VIII, IX). In similar, non-irradiated samples, the test compound did not degrade. Thiabendazole was the only [¹⁴C]compound detected in the soil extracts during the study (Figure 6).

Material balances were 92.4-104.2% of the applied for irradiated samples, with no discernable pattern, and ≥100% of the applied for non-irradiated samples (Tables X, XI).

COMMENTS:

1. The statistical estimation of the photolytic half-life of thiabendazole reported in this study (933 days) is of limited value because the calculations involve extrapolation beyond the experimental time limits of the study. Data are often incapable of accurately predicting trends outside of their range because differences are magnified and reactions which appear to be linear may, in fact, non linear.
2. Despite the circulation of cooling water at posttreatment 25 C through the photolysis chamber, the soil surface temperature ranged from 11.2 to 40.8 C. Normally, a high temperature variation is unacceptable since degradation increases with increased temperature. However, in this study no significant degradation occurred the temperature rise to 40 C.

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Pages 14 through 22 are not included.

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.
- FIFRA registration data.
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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 060101

Thiabendazole

§162-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41559601

Daly, D., and M. Williams. 1990. Anaerobic soil metabolism of ¹⁴C-thiabendazole. ABC Final Report No. 37640. Unpublished study performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, and submitted by MSD AGVET, Division of Merck and Company, Inc., Rahway, NJ.

DIRECT REVIEW TIME = 8

REVIEWED BY: C. Little

TITLE: Staff Scientist

EDITED BY: W. Martin
K. Patten

TITLE: Staff Scientist
Task Leader

APPROVED BY: W. Spangler

TITLE: Project Manager

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

APPROVED BY: A. Abramovitch
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-1975

A. Abramovitch

SIGNATURE:

CONCLUSIONS:

Metabolism - Anaerobic Soil

1. This study can be used to fulfill data requirements.
2. [¹⁴C]Thiabendazole was relatively stable in sandy loam soil which was anaerobically incubated in the dark for 60 days following an aerobic incubation period of 30 days. The only degradate detected throughout the study was benzimidazole.
3. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the anaerobic (nitrogen plus flooding) metabolism of phenyl ring-labeled [¹⁴C]thiabendazole in soil.

4. No additional information is needed on the anaerobic metabolism of phenyl ring-labeled thiabendazole in soil at this time.

METHODOLOGY:

Phenyl ring-labeled [¹⁴C]thiabendazole (radiochemical purity 98.6%, specific activity 24.77 uCi/mg; MSD AGVET) was applied at 1 ug/g to sandy loam soil (58% sand, 30% silt, 12% clay, pH 7.8, 0.9% organic matter, CEC 9.2 meq/100 g) which had been air-dried, sieved through a 2-mm mesh screen, and stored in a plastic bag in the dark at room temperature for 58 days prior to use. After treatment, the soil was moistened to 70-75% of field capacity, placed in a sealed chamber (Figure 1), and aerobically incubated for 1 month in the dark at 24-26 C. Humidified air was drawn through the system and vented through ethylene glycol, sulfuric acid and KOH traps. Following the aerobic aging period, glucose (1%) was added to the test soils, which were then flooded with well water. The chamber was flushed with nitrogen and incubated for an additional 60 days under the conditions described above. (It was unclear if the humidified air that had been continuously drawn through the system was replaced with nitrogen gas.) Duplicate samples were collected at 0, 1, 3, 7 and 14, and 30 days posttreatment, and at 15, 30, 45 and 60 days after the establishment of anaerobic conditions (45, 60, 75 and 90 days posttreatment).

Soils were extracted by the procedure shown in Figure 3. Samples were centrifuged and the water layer was decanted; aliquots of the water were analyzed by LSC. The samples were mixed with 1 N methanolic KOH, placed on a mechanical shaker for 2 hours, and centrifuged for 10 minutes. The extract was decanted and the soil was rinsed twice with methanolic KOH; the rinsates were combined (Soil Extract I) and analyzed by LSC. A single aliquot of the extract was concentrated under nitrogen and neutralized with HCl; the mixture was centrifuged and the supernatant was analyzed by reverse-phase HPLC using a mobile phase of water:acetonitrile:H₃PO₄ (75:25:0.04, v:v:v) with UV-detection; fractions were collected and analyzed by LSC. Identification of compounds was done by comparison of the retention times of the parent and degradates with those of reference standards (Figure 2). The extracted soil was further extracted with 6 N HCL:dimethylformamide (1:1, v:v; Soil Extract II). Soil samples were shaken, centrifuged, and rinsed as described above; an aliquot of the extract was analyzed by LSC. An additional aliquot of the extract was adjusted to pH 12.0. The extract was then partitioned twice with ethyl acetate, and triplicate aliquots of the aqueous and organic phases were analyzed by LSC. An aliquot of the organic phase was reduced to dryness under nitrogen and the residues were redissolved in methanol. The mixture was vortexed and analyzed by reverse-phase HPLC as described above. To confirm the presence of the parent compound and the degradate benzimidazole, selected extracts were analyzed using two-dimensional TLC on silica gel plates

developed in the first direction with dioxane:toluene:ammonium hydroxide (8:1:1, v:v:v) and in the second direction with butanol:water:acetic acid (65:25:10, v:v:v). Non-radiolabeled standards were cochromatographed with the soil extracts and visualized under UV light. Radioactive areas on the plates were located by autoradiography and were scraped from the plates and analyzed by LSC.

To quantify non-extractable residues, the soil was dried under nitrogen and combusted in triplicate; the evolved $^{14}\text{CO}_2$ was quantified by LSC. Trapping solutions were also analyzed in triplicate to quantify volatile [^{14}C]residues.

DATA SUMMARY:

Phenyl ring-labeled [^{14}C]thiabendazole (radiochemical purity 98.6%), at 1.04 ug/g, was relatively stable in sandy loam soil incubated in the dark at 25 C under anaerobic conditions (nitrogen and flooding) for 60 days following a 30-day aerobic incubation period under similar conditions. Parent thiabendazole was 88.3% of the applied immediately posttreatment, 74.0% at day 30, and 78.0% at day 90 (day 60 post-flooding; Table V). The degradate

benzimidazole

was present at a maximum of 13.7% of the applied at day 1 posttreatment, decreasing to 8.3% by 30 days posttreatment and 5.5% by 90 days (60 days post-flooding, Table VI). Non-extractable residues increased from 0.62 to 5.8% of the applied during the first 30 days posttreatment, and were 5.5-6.2% throughout the remainder (anaerobic portion) of the study. At 90 days posttreatment, cumulative volatiles accounted for 0.820% of the applied. Material balances were 95.3-102.9% of the applied.

COMMENTS:

1. The study authors calculated a half-life for thiabendazole of 211 days for the aerobic-incubation portion of the study. The statistical estimations of the anaerobic soil metabolic half-life of thiabendazole reported in this experiment are of limited value because the calculations involve extrapolation considerably beyond the experimental time limits of the study. Data are often incapable of accurately predicting trends outside of their range because small differences are magnified and reactions which appear to be linear may, in fact, be curvilinear.
2. The study authors did not clearly indicate whether the flow of air through the system was replaced with nitrogen after the nitrogen purge of the system when the tubes were flooded, or if the air flow through the system was resumed.

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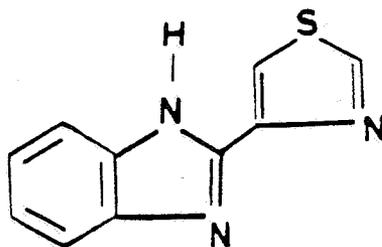
Pages 26 through 38 are not included.

The material not included contains the following type of information:

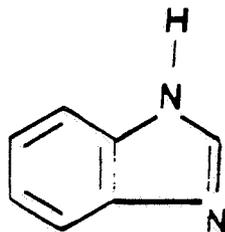
- Identity of product inert ingredients.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

APPENDIX
THIABENDAZOLE AND ITS DEGRADATES



Thiabenzidole



Benzimidazole

DATA EVALUATION RECORD

STUDY 3

CHEM 060101

Thiabendazole

§162-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 416318

M. Hirsch. 1990. Bioconcentration of ¹⁴C-thiabendazole in Bluegill Sunfish. Unpublished study performed by Environmental Science Section Health and Environment Laboratories, Eastman Kodak Company, Rochester, NY and submitted by Merck and Company, Inc., Rahway, NJ.

DIRECT REVIEW TIME = 8

REVIEWED BY: A. Abramovitch
ORG: US EPA

TITLE: Section Chief

APPROVED BY: A. Abramovitch
TITLE: Section Chief
ORG: EFGWB/EFED/OPP
TEL: 557-1975

A. Abramovitch

SIGNATURE:

CONCLUSIONS:

Bioaccumulation in Fish:

1. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the bioaccumulation in fish of phenyl ring-labeled [¹⁴C]thiabendazole.
2. [¹⁴C]Thiabendazole did not bioaccumulate significantly in bluegill sunfish within 28 days. Bioaccumulation Factors of 86.5, 19.72 and 747 were obtained for the whole fish, edible and viscera, respectively. Within 3 depuration days, more than 96% of the material in the viscera was removed. Depuration was also significant in the edible portion.

METHODOLOGY:

Phenyl ring-labeled [¹⁴C]thiabendazole (radiochemical purity 98.6%, specific activity 57.4 uCi/mg) was delivered to an aquarium containing filtered lake water to maintain a concentration of 2.32±0.13 ug/L (1/10 the LC/50). The flow rate was 26.7 ml/min and the water temperature was 20 C. 80 bluegill sunfish of 4 gram average

weight were held in test and control aquaria and observed for mortality, behavior, etc. Five fish were collected randomly at 0, 1, 3, 7 and 14, and 28 days and 3 fish were dissected and analyzed for whole fish, viscera and edible portion. Triplicate homogenized fish samples were analyzed by combustion for total radioactivity. Fish samples collected on days 21 and 28 were also homogenized, extracted and analyzed by HPLC in reference to authentic samples of parent and metabolites to identify accumulated residues. Water samples were analyzed by LSC.

DATA SUMMARY:

Bioaccumulation Factors of 86.5, 19.72 and 747 were obtained for the whole fish, edible and viscera, respectively. Samples from days 21 and 28 were analyzed to determine the identity of the accumulated residues. Between 62-77% of the residues in the edible portion were thiabendazole and 18-31% was associated with the 5-hydroxy metabolite. In the viscera, over 80% of the accumulated residues were the 5 hydroxy thiabendazole. Within 3 depuration days, more than 96% of the material in the viscera was removed. Depuration was also significant in the edible portion. Samples in the depuration phase were taken on days 1,3,7,10,12 and 14.

COMMENTS:

1. The study was well conducted, documented and presented. However, a graphical presentation of the accumulation and depuration data should have been made to assist in determining whether an steady state equilibrium was reached in the accumulation phase.
2. Discharge of accumulated material was faster in the viscera than in the edible portion.

Page _____ is not included in this copy.

Pages 43 through 44 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
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 - FIFRA registration data.
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 - The document is not responsive to the request.
-

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165-4. Fish (Lab)	None	416318/phase IV	acceptable	No
165-5. Aqua. Non-target Organ. (Field)	None	None		No/1

SPRAY DRIFT:

201-1. Droplet Spect.	None	None		Yes
202-1. Field Spray Drift Evaluation	None	None		Yes

ROUNDWATER MONITORING:

166-1. Small Propect.	None	None		Reserved/5
166-2. Small Retrop.	None	None		Reserved/5
166-3. Large Retrop.	None	None		Reserved/5

SURFACE WATER:

167-1. Field Runoff	None	None		Reserved/5
167-2. Surface Water Monitoring	None	None		Reserved/5

FOOTNOTES:

- 1) A LUIS report was not available as of January 31, 1991. The data table is for terrestrial food and feed uses listed by the registrant.
- 2) Thiabendazole has low volatility having vapor pressure of 4×10^{-9} .
- 3) Preliminary data suggest that thiabendazole may require long term field dissipation data.
- 4) Pending evaluation of the confined crop rotation data to be submitted.
- 5) Present data are insufficient to make ground water/surface water risk assessment.

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR THIABENDAZOLE

Chemical Code : 060101
 Pesticide Type: Fungicide

Reviewer: Akiya Abramovitch
 Date: January 1991

Uses (LUIS Not available): Indoor food and non food , indoor medical outdoor residential

	<u>Phase II</u> Submitted Studies/ Addendum	<u>Phase III</u> DER/Addendum Review/Summary Identification	<u>Phase IV</u> DER/Addendum Review/Summary Review Conclusions	<u>Additional</u> Data/Info Required?
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DEGRADATION-LAB:

161-1. Hydrolysis 41265301 Feb. 20, 1990 Unacceptable Yes

Photodegradation:

161-2. In Water 41265101 Feb. 20, 1990 Unacceptable Yes
 161-3. On Soil None 41397301/phase IV Acceptable No
 161-4. In Air None None No/1, 2

METABOLISM-LAB:

162-1. Aerobic Soil None None Yes
 162-2. Anaerobic Soil None 41559601/phase IV No
 162-3. Anaerob. Aquat. None None No/1
 162-4. Aerobic Aquatic None None No/1

MOBILITY STUDIES:

163-1. Leaching and Adsorp./Desorp. 41170102 Feb. 20, 1990 Unacceptable Yes
 163-2. Volatil. (Lab) None None No/2
 163-3. Volatil. (Field) None None No/2

DISSIPATION-FIELD:

164-1. Terrest. (Soil) None None Yes
 164-2. Aquat. (Sediment) None None No/1
 164-3. Forestry None None No/1
 164-4. Combin./Tank Mix None None No/1
 164-5. Long Term Terr. None None Yes/3
 164-5. Long Term Aqua. None None No/1

ACCUMULATION STUDIES:

165-1. Conf. Rot. Crops None None Yes
 165-2. Field Rot. Crops None None Reserved/4
 165-3. Irrigated Crops None None No/1

DP BARCODE: D158710

REREG CASE # 2670

CASE: 807285
SUBMISSION: S386522

DATA PACKAGE RECORD
BEAN SHEET

DATE: 11/28/90
Page 1 of 1

*** CASE/SUBMISSION INFORMATION ***

CASE TYPE: REREGISTRATION ACTION: 603 PHASE 3 INITIAL SUB
CHEMICAL: 060101 Thiabendazole
ID#: 060101-000618
COMPANY: 000618 MERCK & CO INC
PRODUCT MANAGER: 50 JAY ELLENBERGER 703-308-8085 ROOM: CST 4J1
PM TEAM REVIEWER: FRANKLIN RUBIS 703-308-8184 ROOM: CST 4J6
RECEIVED DATE: 09/19/90 DUE OUT DATE: / /

*** DATA PACKAGE INFORMATION ***

DP BARCODE: 158710 EXPEDITE: N DATE SENT: 11/28/90 DATE RET.: / /
DP TYPE: 101 Phase IV Review
ADMIN DUE DATE: 12/19/90 CSF: N LABEL: N
ASSIGNED TO DATE IN ASSIGNED TO DATE IN
DIV : EFED / / REVR : / /
BRAN: EFGB / / CONTR: / /
SECT: / /

*** DATA PACKAGE REVIEW INSTRUCTIONS ***

Review guideline 165-4. MRID416318

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

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

90- 6808
0880
91 0213

DP BARCODE: D158710

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SUBMISSION: S386522

DATA PACKAGE RECORD
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Review guideline 165-4. MRID416318

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

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

91-0213

Akiva 3/13 (?)

New Study

Phase 5 review