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.  
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  
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 the since the vapor pressure of thiabendazole is 4x10^-7 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.
Table: Monitoring

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<tr>
<th>Parameter</th>
<th>167-2: Surface Water</th>
<th>167-1: Field Runoff</th>
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<tr>
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Table: Surface Water Monitoring

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

From: A. Abramovitch, Ph.D., Supervisory Chemist  
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:**

   Thiaabendazole.

   **Chemical name:**

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

   **Trade name(s):**

   Arbotect, Mertect, TBZ, Tecto, Thibenzoze.

   **Structure:**

   ![Chemical Structure]

   **Formulations:**

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

   **Physical/Chemical properties:**

   Molecular formula: C_{10}H_{12}N_{3}S.
   Molecular weight: 201.1.
   Physical state: Powder.
   Vapor pressure: 4\times 10^{-8}.
   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:**


5. REVIEWED BY:
A. Abramovitch
Chemist
EFGWB/EFED/OPP
Review Section #2
Signature: [Signature]
Date: FEB 6 1991

6. APPROVED BY:
A. Abramovitch
Supervisory Chemist
EFGWB/EFED/OPP
Review Section #3
Signature: [Signature]
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:

$[^{14}]C$Thiabendazole did not bioaccumulate significantly in bluegill sunfish within 28 days. Bioaccumulation Factors of 86.5, 19.72 and 74.7 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
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  Thiabendazole
§161-3

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41397301

STUDY ID 41397302

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

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 x 10⁶ dpm/mL, Merck, Sharp and Dohme Research Laboratories) was added at 48.5 µg/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 LS.C. 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 LS.C. 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 $[^{14}C]$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 $[^{14}C]$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.
Page_____ is not included in this copy.
Pages ____ through ____ 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.
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 060101  Thiabendazole §162-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41559601

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

SIGNATURE:

CONCLUSIONS:

Metabolism - Anaerobic Soil

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

2. [¹³C]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 [¹³C]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 ["C]thiabendazole (radiochemical purity 98.6%, specific activity 24.77 µCi/mg; MSD AGVET) was applied at 1 µg/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:H₂PO₄ (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 "CO₂ was quantified by LSC. Trapping solutions were also analyzed in triplicate to quantify volatile ["C]residues.

DATA SUMMARY:

Phenyl ring-labeled ["C]thiabendazole (radiochemical purity 98.6%), at 1.04 µg/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 degrade

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.
Page is not included in this copy.
Pages through 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.
- The document is a duplicate of page(s).
- The document is not responsive to the request.

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APPENDIX

THIABENDAZOLE AND ITS DEGRADATES
Thiabenzidole

Benzimidazole
DATA EVALUATION RECORD

STUDY 3

CHEM 060101 Thiabendazole §162-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 416318

DIRECT REVIEW TIME = 8

REVIEWED BY: A. Abramovitch
ORG: US EPA

APPROVED BY: [Signature]
TITLE: Section Chief
ORG: EFGWB/EFED/OPP
TEL: 557-1975

SIGNATURE: [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 \(^{14}\)C thiabendazole.

2. \(^{14}\)C 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 \(^{14}\)C 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.
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.
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____ The product confidential statement of formula.
____ Information about a pending registration action.
\[\times\] FIFRA registration data.
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Uses (LIDS not available): Indoor Food and non-food, indoor medical, outdoor residential.

Date: January 1991
Reviewer: Akiva Abramovitz
Chemical Code: 060101

Phase I: Environmental Fate Summary Table for Thiabendazole
CASE: 807285  
SUBMISSION: S386522  

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION  
ACTION: 603 PHASE 3 INITIAL SUB  
CHEMICAL: 060101 Thiaabendazole  
ID#: 060101-000618  
COMPANY: 000618 MERCK & CO INC  
PRODUCT MANAGER: 50 JAY ELLENBERGER  
PM TEAM REVIEWER: FRANKLIN RUBIS  
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  
REVR :  
CONTR:  

* * * 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  
91-0213
CASE: 807285
SUBMISSION: S386522

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGRISTRATION  ACTION: 603 PHASE 3 INITIAL SUB
CHEMICAL: 060101 Thiabendazole
ID#: 060101-000618
COMPANY: 000618 MERCK & CO INC
PRODUCT MANAGER: 50 JAY ELLEMBERGER 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 TYPE: 101 Phase IV Review
ADMIN DUE DATE: 12/19/90  CSF: N  LABEL: N
ASSIGNED TO DATE IN
DIV: EFED 12/03/90
BRAN: EFGB / /
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

LIST B

91-0213

Akina 3/13(2)  New Study

Phase 5 review