United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA 738-R-99-006
December 1999

Reregistration Eligibility Decision (RED)

EPTC

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-99-011 September 1999

EPA R.E.D. FACTS

EPTC

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0064, EPTC (S-Ethyl dipropylthiocarbamate).

Use Profile

The following active ingredient is covered by this Fact Sheet:

- **Common Name:** EPTC
- **Chemical Name:** S-Ethyl dipropylthiocarbamate
- **Chemical Family:** Thiocarbamate
- **Type of Chemical:** Herbicide

- **CAS Registry Number:** 759-94-4
- **OPP Chemical Code:** 041401
- **Empirical Formula:** $C_9H_{19}NOS$
- **Basic Manufacturer:** Zeneca Ag Products

EPTC is a pre-emergence and early post-emergence thiocarbamate herbicide used to control the growth of germinating annual weeds, including broadleaves, grasses, and sedges. It is used in every region of the United States in the agricultural production of a wide variety of food crops. The heaviest usage is in the Corn Belt, Northeastern and Mid-Atlantic states, Coastal and Northern Great Plains and in the Pacific Northwest. Highest use states are California, Michigan, Oregon, Pennsylvania, North Dakota, Minnesota, and Arizona. The largest markets in terms of total pounds of active ingredient are corn, potatoes, dry beans, peas, alfalfa, and snap beans. Usage ranges from about 10 to 20 million pounds a.i. annually**.** EPTC is also available to the residential home gardener for use in vegetable and ornamental gardens.

As with other thiocarbamate herbicides, EPTC exerts its herbicidal action through inhibition of cuticle formation at the early stages of seedling growth. Formulated products include emulsifiable concentrate (EC) liquids containing up to 87.8% active ingredient and granular (G) formulations containing up to 25% active ingredient. EPTC is typically applied annually in one to three applications, with each application ranging from about 2 to 6.1 lbs a.i./acre (maximum rate 7.5 to 12.2 lbs a.i./acre for alfalfa and potatoes). EPTC can either be applied by aerial or ground equipment or through chemigation. Because of its chemical properties, however it is applied, it must be incorporated into the soil immediately after application to prevent volatilization.

Regulatory History

EPTC was registered in the United States in 1958 for use as a selective preemergent herbicide, and was originally owned by Stauffer Chemical Company. Chemiolimpex, a technical EPTC (TGAI), was manufactured in Hungary, and was imported into the United States by PPG Industries of Pittsburgh, Pennsylvania. Zeneca Ag Products currently holds registrations for several end-use products, and holds the only registration for the technical product.

A Registration Standard for EPTC was issued in September 1993. The Agency determined that additional generic data would have to be submitted for evaluation in order to maintain registration. This RED reflects a reassessment of all data which were submitted in response to the Registration Standard.

Human Health Assessment

Toxicity results of acute toxicity, primary eye and dermal irritation, and dermal sensitization studies with EPTC technical material are summarized in the RED. EPTC is moderately toxic (Toxicity Category III) via the oral and dermal routes, and in a primary eye irritation study in rabbits, the technical was found to be slightly irritating (Toxicity Category III). EPTC is most toxic via the inhalation route (Toxicity Category II).

There was an increased incidence and severity of cardiomyopathy and neuronal necrosis/degeneration in studies performed in the central and peripheral nervous systems of both rats and dogs. The neurotoxic effects of EPTC are consistent with effects seen in other thiocarbamates. Because of these effects (neuronal necrosis/degeneration), and the potential for residential exposure to infants and children from use of EPTC, the Agency's FQPA Safety Factor Committee recommended that the 10x FQPA safety factor be retained for all population subgroups for acute, chronic and residential exposure assessments.

Although it appears that EPTC did not produce any significant reproductive or developmental toxicity, there is still uncertainty regarding the effects on the developing fetal nervous system This uncertainty is being addressed by the requirement of a developmental neurotoxicity study in rats. EPTC effects were also negative in two oncogenicity studies.

Occupational and Residential Exposure

Occupational and residential exposure to EPTC residues via dermal and inhalation routes can occur during handling activities such as mixing, loading, and applying; however, the potential for postapplication occupational exposure is minimal. Because EPTC is applied as a soil directed spray and immediately incorporated, or as a soil injection well before plants are mature, the potential for postapplication dermal exposure during harvest activities is minimal. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules. Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for the occupational and residential handler, and for residential postapplication inadvertent oral ingestion soil/granulars exposure to children.

Potential EPTC residential use sites may include a variety of shade trees, evergreens, and annual or perennial ornamentals. EPTC is typically applied only to bare soil once before planting or after weeding under ornamentals followed by soil incorporation. Examples of typical usage of a granular formulation in the home garden would include pre-planted application and

incorporation with a rototiller, post-plant application incorporated into the soils to a depth of 2-3 inches using a hand rake or hoe, and weed control in established trees and shrubs by incorporation into the top 6 inches of soil In contrast to occupational workers, individuals in residential settings are more likely to transplant seedlings and plant seeds by hand. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules.

Human Risk Assessment

Dietary Exposure

Risk from food and water combined are acceptable. And the Tier 1 acute dietary exposure analysis of EPTC, exposure (food consumption) was compared to an acute population adjusted dose of 0.067 mg/kg/day. The acute dietary risk analysis estimates the distribution of single day exposures for the overall U.S. population and certain subgroups. The analysis evaluates exposure to the chemical for each food commodity, and assumes uniform distribution of EPTC in the food supply.

The acute dietary residue contribution at the 95th percentile occupied less than 100% of the aPAD for any population subgroup, and therefore does not exceed the Agency's level of concern. For non-probalistic acute dietary exposure the Agency uses the 95th percentile. For the most highly exposed subgroup, children 1-6, residue contribution occupied 87.5% of the aPAD. This Tier 1 acute analysis for EPTC is a conservative upper-bound estimate with all input residues equal to the reassessed tolerance value and the assumption that 100% of the crop is treated nationwide.

Environmental Fate

The environmental fate data indicates that EPTC would not be persistent under many environmental conditions, which is supported by relatively short half-lives observed in terrestrial and low aquatic concentrations. Monitoring data suggests that concentrations of EPTC in ground water will be less than those found in surface water. However, the persistence of EPTC in ground water would probably be greater than in surface water because losses due to volatilization would be expected to be much less.

The low affinity for binding to soil and water solubility also suggest a potential to leach, but since EPTC generally does not persist long in surface soils, the potential to leach is greatly reduced.

Environmental

Ecological Effects

Assessment

EPTC is practically non-toxic to birds and bees; slightly toxic to mammals and fish, and moderately toxic to aquatic invetebrates, algae and an aquatic vascular plant. Toxicity studies are unavailable for estuarine species. Reproduction studies are not available for any species, except laboratory mammals. Due to lack of data, acute risks to estuarine species, and reproductive risks to birds, fish and aquatic invertebrates were not assessed. The registrant will be required to provide additional data in order to evaluated the potential effects of bird, aquatic and estuarine species.

EPTC is toxic to both monocot and dicot plant species. Although EPTC is a pre-emergent herbicide, it may cause some phytotoxic damage and growth effects on established plants. Risk quotients for granular and spray applications suggest that EPTC poses adverse effects on non-target plants for all uses.

Environmental Risk Characterization

Residue levels of EPTC on vegetation exceed levels of concern for high acute risks and effect on endangered species for small mammals. Soil incorporation reduces the amount of vegetation exposed, but the vegetation remaining at the surface poses a potential risk to small mammals. Given the low probability of EPTC dietary exposure to small mammals, any mortality is unlikely to have any serious effect on the local populations of small mammals, with the exception of an endangered species.

The level of concern is exceeded for endangered and terrestrial plants species such as monocots and dicots. Non-target terrestrial plants in adjacent fields or habitats are potentially at risk from spray drift from some uses and from runoff for all registered uses. EPTC also appears to have the potential to be transported off site via the vapor phase as it was one of a number of residues found in more than 25 percent of the rain samples collected in three water sheds in Minnesota. In addition, being a herbicide, EPTC may also have an indirect effect on endangered insects by adversely affecting the plants on which they depend.

The levels of EPTC that are likely to be atmospherically deposited into soils or on vegetation is uncertain. The absence of reported atmospheric deposition incidences does not preclude the occurrence of such events. The registrant will be required to provide additional data on field volatility and atmospheric dissipation in order to further evaluate the environmental fate of EPTC.

Although the EPTC data base is sufficient to render a reregistration eligibility decision, additional confirmatory data such as developmental neurotoxicity, residue analytical methods-plant, and Multiresidue method

studies are needed to further assess the chemical's toxicity. In addition, ecological effects and environmental fate studies are needed to fully assess the impact of EPTC and its primary degradates on the environment.

Risk Mitigation

To lessen the risks posed by EPTC, EPA is requiring the following risk mitigation measures:

- The exposure assessments indicate that occupational handlers are at risk to dermal and inhalation exposure, and that additional protective measures are necessary to reduce these risks. Therefore, various forms of additional personal protective equipment (PPE) (e.g., double layer clothing and respirators) and engineering controls (e.g., enclosed cockpits) are necessary for certain handler scenarios to reduce the risks to below the Agency's level of concern.

- In order to mitigate risks to homeowners, the registrant will be required to add label language which prohibit use of the belly grinder, which contributes to the highest level of exposure, for home owner products. The registrant will also be required to delete all residential emulsifiable concentrate formulation uses from the EPTAM 7E label. In addition, the registrant will be required to change the maximum rate of 15 lbs per acre for the Eptam 2.3 granular products to the typical rate of 5 lbs per acre for residential products.

- Risk quotients for granular and spray applications suggest that EPTC poses adverse effects to small herbivorous and insectivorous mammals for most uses and adverse effects on non-target terrestrial plants for all uses. EPTC use could also cause adverse effects on endangered species. As a member of the Endangered Species Task Force, the registrant will be required to obtain information which identifies endangered and threatened species of concern which may be found in areas adjacent to crops treated with EPTC.

Additional Data Required

EPA is requiring the following additional generic studies for EPTC to confirm its regulatory assessments and conclusions.

Guideline:	**Study:**
870.6300	Developmental neurotoxicity study in the rat
860.1340	Residue Analytical methods-Plant
860.1360	Multiresidue Method
860.1380	Storage Stability Data

860.1520	Processed Food/ Feed
860.1500	Crop field Trials
Guideline:	**Study:**
850.2100	Acute Avian Oral(quail/duck)
850.2300	Avian Reproduction Quail/Duck
850.1400	Fish Early Life Stage
835.4100	Aerobic Soil
835.4200	Anaerobic Soil
835.4300	Aerobic Aquatic Metabolism
835.8100	Field Volatility
835.6100	Field Dissipation
850.1730	Aquatic Organism Accumulation

Product Labeling Changes Required

Before reregistering the products containing EPTC, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF), and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration. All EPTC end-use products must comply with EPA's current pesticide product labeling requirements and. For a comprehensive list of labeling requirements, please see the EPTC RED document.

The use of currently registered products containing EPTC in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Regulatory Conclusion

EPA has determined that products containing EPTC are eligible for reregistration. The use of eligible EPTC products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to EPTC will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for EPTC during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To

obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs. Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the EPTC RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-605-6000.

For more information about EPA's pesticide reregistration program, the EPTC RED, or reregistration of individual products containing EPTC, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm, Pacific Standard Time, or 9:30 am to 7:30 pm, Eastern Standard Time, seven days a week.

Their internet address is ace.orst.edu/info/nptn.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decision on the pesticide chemical case which includes the active ingredient EPTC. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1999, contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that, in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Venus Eagle-Kunst (703) 308-8045. Address any questions on required generic data to the Special Review and Reregistration Division representative Jamil Mixon at (703) 308-8032.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number (703) 605-6000).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

EPTC (S-Ethyl dipropylthiocarbamate)

CASE # 0064

TABLE OF CONTENTS

EPTC REREGISTRATION ELIGIBILITY DECISION TEAM i

EXECUTIVE SUMMARY v

I. INTRODUCTION 1

II. CASE OVERVIEW 2
- **A. Chemical Overview** 2
- **B. Use Profile** 2
- **C. Methods and Rates of Application and Target Weeds** 3
- **D. Estimated Usage of Pesticide** 5
- **E. Data Requirements** 7
- **F. Regulatory History** 8

III. SCIENCE ASSESSMENT 8
- **A. Physical Chemistry Assessment** 8
  - **1. Chemical Profile** 8
  - **2. Environmental Fate Summary** 9
- **B. Human Health Assessment** 9
  - **1. Toxicology Assessment** 9
    - **a. Acute Toxicity** 11
    - **b. Chronic Toxicity/Carcinogenicity** 11
    - **c. Developmental & Reproductive Toxicity** 11
    - **d. Mutagenicity** 12
    - **e. Dermal Absorption** 12
    - **f. Metabolism** 12
    - **g. Other Toxicological Endpoints** 12
  - **2. Dose Response Assessment** 13
    - **a. FQPA Considerations** 13
    - **b. Cancer Classification** 14
    - **c. Reference Dose and Toxicological Endpoints** 14
  - **3. Exposure Assessment** 16
    - **a. Dietary Exposure** 16
    - **b. Dietary Exposure from Food** 18
      - **(1) Acute Dietary Exposure Assessment** 19
      - **(2) Chronic Dietary Exposure Assessment** 20
    - **c. Dietary Exposure from Drinking Water** 20
    - **d. Occupational and Non-Occupational Exposures** 23
    - **e. Occupational Exposure** 24
    - **f. Incident Reports** 25
    - **g. Residential Handler Exposure** 25

4. Risk Characterization 27
a. Dietary Risk 27
b. Occupational Handler Risk 28
c. Residential Handler Risk Characterization 35
d. Cumulative Effects 37
e. Aggregate Risk Assessment 38
C. Environmental Assessment 40
1. Ecological Toxicity Data 40
a. Toxicity to Terrestrial Animals 40
b. Toxicity to Aquatic Animals 41
c. Toxicity to Terrestrial Plants 41
2. Environmental Fate 42
a. Environmental Fate Assessment 42
b. Environmental Fate and Transport Data 44
c. Water Resources 53
3. Exposure and Risk Characterization 55
a. Ecological Exposure and Risk Characterization 56
b. Environmental Risk Characterization 64

IV. RISK MANAGEMENT AND REREGISTRATION DECISION 67
A. Determination of Eligibility 67
1. Eligibility Decision 67
2. Eligible and Ineligible Uses 67
B. Regulatory Position 67
1. Food Quality Protection Act Findings 69
a. Determination of Safety for U.S. Population 69
b. Determination of Safety for Infants and Children 70
2. Tolerance Reassessment Summary 70
3. Codex Harmonization 76
4. Risk Mitigation 76
a. Risk Mitigation for Occupational Handler Exposure 76
b. Risk Mitigation for Residential Handler Exposure 80
c. Ecological Risk Mitigation 82
(1) Mammalian Mitigation 82
(2) Terrestrial Plant Mitigation 82

V. Actions Required of Registrant 83
A. Data Requirements 83
B. Labeling Requirements 83
C. Existing Stocks 94

VI. APPENDICES 95
Appendix A. TABLE OF USE PATTERNS ELIGIBLE FOR REREGISTRATION 97

Appendix B. TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION 107
Appendix C. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE REREGISTRATION DECISION (BIBLIOGRAPHY) 113
Appendix D. GENERIC DATA CALL-IN 135
1. EPTC Data Call-In Chemical Status Sheet 152
2. Generic DCI Response Forms Inserts Plus Instructions 153
3. Requirements Status and Registrant' Response Forms Plus Instructions 156
Appendix E. PRODUCT SPECIFIC DATA CALL-IN 166
1. Product Specific Chemical Status Sheet 179
2. Data Call-In Response Form for the Product Specific Data Plus Instructions 180
3. Product Specific Requirement Status and Registrant's Response Forms Plus Instructions 183
4. EPA'S Batching of EPTC Products for Meeting Acute Toxicity Data Requirements for Reregistration . . . 190
5. List of All registrants sent this Data call-In 192
Appendix F. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS 195

EPTC REREGISTRATION ELIGIBILITY DECISION TEAM

Biological and Economic Analysis

Rafael Prieto	Science Information and Analysis Branch
Jihad Alsadek	Economic Analysis Branch
James Saulmon	Herbicide & Insecticide Branch

Environmental Fate and Effects Assessment

Daniel Rieder	Environmental Risk Branch III
James K. Wolf	Environmental Risk Branch III
William Rabert	Environmental Risk Branch III

Health Effects Division

Paula A. Deschamp	Reregistration Branch II
Ken W. Dockter	Reregistration Branch II
Stephen C. DeVito	Reregistration Branch II
Robert F. Fricke	Reregistration Branch II
Renee Sandvig	Reregistration Branch II
Carol Christensen	Reregistration Branch II
Jerome Blondell	Chemistry & Exposure Branch I
Monica Spann	Chemistry & Exposure Branch I

Registration Division

Jim Tompkins	Herbicide Branch
Tobi Colvin-Snyder	Herbicide Branch

Special Review & Reregistration Division

Mark Wilhite	Reregistration Branch I
Jamil Mixon	Reregistration Branch I

Non-Dietary Human Risk Management

Steve Morrill	Product Reregistration Branch
Rich Dumas	Reregistration Branch II
Deanna Scher	Reregistration Branch I
Katherine Boyle	Reregistration Branch II
Daniel Helfgott	Special Review Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
ChE	Cholinesterase
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., ppm, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
μg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure

GLOSSARY OF TERMS AND ABBREVIATIONS

MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dosage
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24c of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

EPA has completed its reregistration eligibility assessment for the pesticide S-ethyl dipropylthiocarbamate (EPTC) and determined that the data are adequate to support a reregistration eligibility decision. This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. This decision considered the requirements of the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food Drug and Cosmetic Act (FFDCA) and the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) the two Federal statutes that provide the framework for pesticide regulation in the United States.

In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residues, and to develop a screening program to determine whether pesticides produce endocrine disrupting effects.

In September 1999, the Agency presented a paper on the common mechanism of toxicity of the carbamate pesticides to the Science Advisory Panel (SAP). In that presentation, the Agency noted that although various classes of compounds may inhibit acetyl cholinesterase, the potency, reversibility, and related factors may influence whether or not related pesticides should be included in a cumulative risk assessment. The Agency is currently awaiting a report from the SAP.

At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether EPTC, a thiocarbamate, shares a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. Therefore, for the purposes of this tolerance reassessment, the Agency has assumed that EPTC does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals.

EPTC is a pre-emergence and early post-emergence thiocarbamate herbicide used to control the growth of germinating annual weeds, and grasses in a variety of food crops. The largest market in terms of total pounds active ingredient are corn, potatoes, dry beans, peas, alfalfa, and snapbeans There are also registered home garden uses in vegetable and ornamental gardens. EPTC can either be applied by ground equipment, through irrigation and aerial for granular only. Because of its chemical properties, it must be incorporated into the soil immediately after application to prevent volatilization.

EPTC is moderately toxic via the dermal and oral routes and is highly toxic via the inhalation route. Also, there was an increased incidence and severity of cardiomyopathy and neuronal necrosis/degeneration in studies performed in the central and peripheral nervous systems of both rats and dogs. The neurotoxic effects of EPTC are consistent with effects seen in other thiocarbamates.

Because of these effects (neuronal necrosis/degeneration), and the potential for residential exposure to infants and children from use of EPTC, the Agency's FQPA Safety Factor Committee recommended that the 10x FQPA safety factor be retained for all population subgroups for acute, chronic and residential exposure assessments. Although it appears that EPTC did not produce any significant reproductive or developmental toxicity, there is still uncertainty regarding the effects on the developing fetal nervous system after such exposure. This uncertainty is being addressed by the requirement of a developmental neurotoxicity study in rats. EPTC effects were also negative in two oncogenicity studies.

Several of the residential and occupational handler scenarios exceed the Agency's level of concern. These exposure risks are mitigated, as specified in Chapter IV of this Document, with additional Personal Protective Equipment (PPE), engineering controls, or in the case of residential exposure, use rate reduction and label changes. Postapplication risk estimates were conducted for only one scenario: inadvertent soil ingestion by infants/children resulting from hand-to-mouth behavior. The MOE estimated for this scenario is substantially less than the Agency's level of concern.

Acute and chronic risk from food do not exceed the Agency's level of concern. In both assessments, exposure (consumption) was compared to a population adjusted dose (PAD) reflecting retention of the FQPA 10x factor. The PAD is equal to the acute or chronic RfD divided by the FQPA Safety Factor. The Agency considers dietary residue contributions greater than 100% of the PAD to be of concern. Acute dietary exposure comprised 40.5% of the aPAD for the general population, and 87.5% of the aPAD for the most highly exposed subgroup, children (1-6 years). Chronic dietary exposure comprised 9.6% of the cPAD for the general population, and 17.4% of the cPAD for the most highly exposed subgroup, children (1-6 years).

EPTC was rarely detected in groundwater (less than 2% of samples), but more frequently detected in surface water monitoring data (4% to 25%). Established water concentrations of EPTC do not exceed any Drinking Water Level of comparison (DWLOCs). The available monitoring data support this conclusion.

Aggregate acute dietary risk estimates do not exceed the Agency's level of concern. The aggregate acute dietary risk estimates include exposure to EPTC residues in food and water. Acute dietary exposure from food was 87.5% of the acute PAD, and was not of concern. Based on the available information, the Agency concludes with reasonable certainty that no harm to any population will result from acute aggregate dietary exposure to EPTC.

Short-term aggregate and chronic aggregate risk estimates do not exceed Agency's level of concern. Short term aggregate risk estimates for **adults** include exposure to EPTC residues in food, water, and high-end non-occupational use in residential settings (applying granules by hand/spoon). Although short-term dermal and inhalation exposures are anticipated during handling and applying EPTC, the endpoint effect selected for inhalation risk differs from the endpoint effect selected for dermal and oral risk. Therefore, the inhalation route of exposure does not contribute to the aggregate risk estimate. Short-term aggregate risk estimates for **infants/children** include exposure to EPTC

residues in food, water, and from inadvertent oral soil ingestion resulting from hand-to-mouth behavior. Chronic aggregate (non-cancer) risk estimates do not exceed the Agency's level of concern. The chronic aggregate dietary risk estimates include exposure to EPTC residues in food and water.

The environmental fate data indicates that EPTC would not be persistent under many environmental conditions, which is supported by relatively short half-lives observed in terrestrial and low aquatic concentrations. Monitoring data suggests that concentrations of EPTC in ground water will be less than those found in surface water. However, the persistence of EPTC in ground water would probably be greater than in surface water because losses due to volatilization would be expected to be much less.

The low affinity for binding to soil and water solubility also suggest a potential to leach, but since EPTC generally does not persist long in surface soils, the potential to leach is greatly reduced.

EPTC is practically non-toxic to birds and bees; slightly toxic to mammals and fish, and moderately toxic to aquatic invetebrates, algae and an aquatic vascular plant. Toxicity studies are unavailable for estuarine species. Reproduction studies are not available for any species, except laboratory mammals. Due to lack of data, acute risks to estuarine species, and reproductive risks to birds, fish and aquatic invertebrates were not assessed. The registrant will be required to provide additional data in order to evaluate the potential effects of bird, aquatic and estuarine species.

Toxicity rating categories have not been established for terrestrial plants. EPTC is toxic to both monocot and dicot plant species. Although EPTC is a pre-emergent herbicide, it may cause some phytotoxic damage and growth effects on established plants. Risk quotients for granular and spray applications suggest that EPTC poses adverse effects on non-target plants for all uses.

Residue levels of EPTC on vegetation exceed levels of concern for high acute risks and effect on endangered species for small mammals. Soil incorporation reduces the amount of vegetation exposed, but the vegetation remaining at the surface poses a potential risk to small mammals. Since soil incorporation is necessary within the 24 hours specified on the label for good weed control, exposed vegetation on the field surface after soil incorporation will be sparse. The scarcity of the treated vegetation and the rapid volatilization of EPTC from the exposed vegetation in the couple days, reduces the magnitude and possibility of risks to a short time period. The scarcity of the vegetation in the field is less inviting for hungry mammals than vegetative areas surrounding the field, which also lowers the probability that many small mammals will feed in the field and will be affected by EPTC. Given the low probability of EPTC dietary exposure to small mammals, any mortality is unlikely to have any serious effect on the local populations of small mammals, with the exception of an endangered species.

Being a herbicide, EPTC may have an indirect effect on endangered insects by adversely affecting the plants on which they depend. As member of the Endangered Species Task Force, the

registrant will be required to obtain information which identifies endangered and threatened species of concern which may be found in areas adjacent to crops treated with EPTC.

Whether these levels of EPTC are likely to be atmospherically deposited into soils or on vegetation is uncertain. The absence of reported atmospheric deposition incidences does not preclude the occurrence of such events. The registrant will be required to provide additional data on field volatility and atmospheric dissipation in order to further evaluate the environmental fate of EPTC.

Although the EPTC data base is sufficient to render a reregistration eligibility decision, additional confirmatory data such as developmental neurotoxicity, residue analytical methods-plant, and Multiresidue method studies are needed. In addition, ecological effects and environmental fate studies are needed to fully assess the impact of EPTC and its primary degradates on the environment.

Before reregistering the products containing EPTC, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF), and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

The exposure assessments indicate that occupational handlers are at risk to dermal and inhalation exposure, and that additional protective measures are necessary to reduce these risks. Therefore, various forms of additional personal protective equipment (PPE), are necessary for certain handler scenarios to reduce the risks to below the Agency's level of concern. In order to mitigate risks to homeowners, the registrant will be required to add label language which prohibit the use of specific application tools, which contributes to the highest level of exposure, drop all residential emulsifiable concentrate formulation uses, and change the maximum granular application rate to the typical rate for residential products.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and the submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "The Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredients are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. As a result, EPA is embarking on an intensive process, including consultation with registrants, States tribes and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food use pesticides. The FQPA does not, however, amend any of the existing reregistration deadlines set forth in §4 of FIFRA. In addition, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of EPTC, including the risk to infants and children for any potential dietary, drinking water, dermal, or oral exposures. The document consists of six sections. Section I is the introduction. Section II describes EPTC, its uses, data requirements, and regulatory history. Section III discusses the human health and environmental assessment, based on the data available to the Agency. Section IV presents the reregistration decision for EPTC. Section V discusses the reregistration requirements for EPTC. Finally, Section VI is the Appendices which support this RED. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Document:

- Common Name: EPTC
- Chemical Name: S-Ethyl dipropylthiocarbamate
- Chemical Family: Thiocarbamate
- Type of Chemical: Herbicide
- CAS Registry Number: 759-94-4
- OPP Chemical Code: 041401
- Empirical Formula: $C_9H_{19}NOS$
- Basic Manufacturer: Zeneca Ag Products

B. Use Profile

EPTC is a pre-emergence and early post-emergence thiocarbamate herbicide used to control the growth of germinating annual weeds, including broadleaves, grasses, and sedges. It is used in every region of the United States in the agricultural production of a wide variety of food crops. The heaviest usage is in the Corn Belt, Northeastern and Mid-Atlantic states, Coastal and Northern Great Plains and in the Pacific Northwest. Highest use states are California, Michigan, Oregon, Pennsylvania, North Dakota, Minnesota, and Arizona. The largest markets in terms of total pounds of active ingredient are corn, potatoes, dry beans, peas, alfalfa, and snap beans. Usage ranges from about 10 to 20 million pounds a.i. annually**.** EPTC is also available to the residential home gardener for use in vegetable and ornamental gardens.

As with other thiocarbamate herbicides, EPTC exerts its herbicidal action through inhibition of cuticle formation at the early stages of seedling growth. Formulated products include emulsifiable concentrate (EC) liquids containing up to 87.8% active ingredient and granular (G) formulations containing up to 25% active ingredient. EPTC is typically applied annually in a single or three application process, with each application ranging from about 2 to 6.1 lbs a.i./acre (max rate 7.5 to 12.2 lbs a.i./acre for alfalfa and potatoes). EPTC can either be applied by ground equipment or through irrigation. Because of its chemical properties, however it is applied, it must be incorporated into the soil immediately after application to prevent volatilization.

The following is information on the types of formulations registered with an overview of use sites and application methods:

Types of Products	% A..I.
EMULSIFIABLE CONCENTRATE	67.8 to 76.9%
MANUFACTURING PRODUCT EMULSIFIABLE CONCENTRATE	87.8%
END USE PRODUCT EMULSIFIABLE CONCENTRATE [72.2%, 73.4%, 74.4%, 75.2%, 76.97%, 82.6%, 87.27%, 87.80%]	72.2 to 87.8%
GRANULAR [2.3%, 5.0%, 10.0%, 20.0%, 25.0%]	02.3 to 25.0%
SOLUBLE CONCENTRATE/LIQUID	92.9%
TECHNICAL GRADE/END USE	98.5%

Table 1. Use sites for EPTC

Food use sites	Non-food use sites	Residential/public use sites
Alfalfa	Citrus nursery stock	Parks
Almonds	Non-bearing Orange Orchards	Ornamentals
Beans	Non-bearing grapefruit	Shade trees
Birdsfoot trefoil	Evergreens	Evergreens
Citrus	Deciduous trees	Flower Gardens
Clover	Scrubs	Aquatics (Drainage Systems)
Corn (field and sweet)	Pine seedling nurseries	Turf (Ornamental)
Cotton	Ornamentals (plant, flowers)	Golf Course Sand traps
Garden beets		
Lespedeza		
Potatoes		
Safflower		
Sunflower		
Sugar beets		
Sweet Potatoes		
Tomatoes		
Walnuts		

C. Methods and Rates of Application and Target Weeds

EPTC may be broadcast using aerial equipment to apply premix granulars, ground boom to spray the premixed chemical, or applied through chemigation. EPTC is highly volatile, and must be soil incorporated either as soon as possible after application with ground equipment or through

irrigation to effectively control weed germination. EPTC is applied primarily as a pre-plant herbicide, but applications are also made post-plant, postemergence, and as fall fallow treatments. Other types of treatment include band treatment and soil sidedress treatment.

Labels recommend that soil incorporation occur at the same time as application, a couple of hours after application, or in the case of arid areas, such as eastern Oregon, within 36 hours. According to EPTC labels, application rates on agricultural crops range from a minimum of 1.5 to 7.4 lbs a.i./A on sweet potatoes. Application rates frequently range from 2.0 to 4.0 lbs a.i./A for most crops. However, application rates of 6.1 lbs. a.i./A are registered for use on beans, corn, non-bearing citrus, Irish potatoes, and fallow land. Labels for most uses do not indicate whether multiple applications are permitted and what maximum annual poundages are permitted, but will have to be corrected on the reregistered labels. The highest number of applications identified on a label is 4 applications on alfalfa. The maximum annual poundage limitation on labels is 15 lbs. a.i./A for use on ornamentals.

Types of Treatment

Band treatment, Broadcast, Chemigation, Directed spray, Soil band treatment, Soil broadcast treatment, Soil incorporated treatment, Soil injection treatment, Soil sidedress treatment, Soil treatment, Spray.

Equipment

Aircraft, By hand, Granule applicator, Gravity irrigation, Low pressure ground sprayer, Injection equipment, Irrigation, Package applicator, Soil incorporation equipment, Soil injector equipment, Sprayer, Spreader, Sprinkler irrigation.

Timing

At planting; Bearing; Bloom; Early postemergence; Early spring; Established plantings; Fall; Foliar; Fruiting; June; Late fall; Late summer; Layby; Nonbearing; Nursery stock; Plant bed; Post-thinning; Postemergence; Post-plant; Post-transplant; Pre-bedding; Pre-bloom; Pre-emergence; Pre-plant; Preplant (Fall); Preplant (Spring); Pretransplant; Seed Crop; Spring; When needed.

Target Weeds

BROADLEAVES: annual morningglory, black nightshade, carpetweed, chrysanthemum weed, common chickweed, common lambsquarters, common purslane, common ragweed, corn spurry, cutleaf evening primrose, cutleaf nightshade, dead nettle, fiddleneck, Florida pusley, hairy nightshade, henbit, lambsquarters, mugwort, nettleleaf goosefoot, prickly sida, prostrate pigweed, puncturevine, redroot pigweed, shepherds purse, sicklepod, smartweed, tall morningglory, tumble pigweed, velvetleaf.

GRASSES: annual bluegrass, annual ryegrass, barley (volunteer), barnyard grass, bermuda grass, bermuda grass (seedling), crabgrass, echinochloa, fall panicum, field sandbur, giant foxtail, goosegrass, green foxtail, johnson grass (seedling), junglerice, Italian ryegrass, love grass, oat (volunteer), quackgrass, red rice rescue grass, shattercane, signalgrass, stinkgrass, tall fescue, Texas panicum, yellow foxtail, watergrass, wheat (volunteer), wild proso millet, wild oat, witchgrass, wooly cupgrass; SEDGES: purple nutsedge, yellow nutsedge.

D. Estimated Usage of Pesticide

Table 2 summarizes the best available estimates of EPTC use. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Based on available pesticide survey usage information for the years of 1987 through 1996, an annual estimate of EPTC total domestic usage averaged approximately 20 million pounds a.i. for almost 6 million acres treated. EPTC is a broad spectrum herbicide with its largest markets in terms of total pounds a.i. allocated to corn (56%), corn continuous (13%), dry beans/peas (8%),and potatoes (6%). Most of the usage is in CA, MI, OR, PA, ND, MN, AZ, SC, NC, AR, MT, IL, NE, LA, TX, KY, TN, AND CO.

Crops with the highest percentage of total U.S. planted acres treated with EPTC include processed snap beans (59%), dry beans (32%), dry peas (29%), potatoes (25%), green peas (21%).

Table 2. Estimated percentage of EPTC Treated Acres

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB a.i. Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb a.i. acre/yr	#appl / yr	lb a.i. A/appl	(% of total lb a.i. used on this site)
Alfalfa	23,949	146.9	293.9	0.6%	1.2%	490	970	3.3	1.4	2.3	CA WI WA AZ MN NY 72%
Almonds	429	7.3	14.6	1.7%	3.4%	19	39	2.6	1.2	2.2	CA 100%
Apples	572	0.7	1.5	0.1%	0.3%	3	7	4.8	2.2	2.2	WA 82%
Barley	7,505	3.3	14.0	0.04%	0.2%	8	26	2.4	1.1	2.2	ND ID 91%
Beans, Dry	1,802	574.3	794.7	32%	44%	430	866	0.7	1.0	0.7	NE MI ID CO NY 85%
Beans, Snap, Fresh	81	5.9	9.5	7.3%	12%	14	23	2.4	1.0	2.3	FL NY 81%
Beans, Snap, Proc.	228	135.6	184.2	59.4%	81%	450	608	3.3	1.0	3.3	WI OR 87%
Peas/Dry	2,181	637.9	837.3	29.2%	38%	1,520	2,156	2.4	1.0	2.3	MI NE CO ID WA 82%
Peas, Green	723	148.4	209.4	20.5%	29%	470	626	3.2	1.0	3.1	WI OR NY MI FL 82%
Beets	12	0.04	0.6	0.4%	4.8%	0.1	2	3.0	1.0	3.0	CA 100%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB a.i. Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb a.i. acre/yr	#appl / yr	lb a.i. A/appl	(% of total lb a.i. used on this site)
Berries	161	0.1	3.3	0.04%	2.1%	0.3	13	4.0	1.0	4.0	MI 100%
Cherries	128	0.1	0.2	0.04%	0.2%	0.1	0.2	1.0	1.0	1.0	OR 100%
Cole Crops	313	0.02	0.03	0.01%	0.01%	0.1	0.2	1.0	1.0	1.0	PA 100%
Corn	72,284	2,664	5,328	3.7%	7.4%	11,070	22,136	4.2	1.1	3.9	MN IA IL SD ND WI 80%
Corn Continuous	27,111	629	1,259	2.3%	4.6%	2,560	5,116	4.1	1.0	4.0	IA MN WI IL NE KS 61%
Cotton	12,689	4.2	8.4	0.03%	0.1%	16	32	3.8	2.2	1.7	AZ 92%
Cucurbits	285	0.1	0.3	0.04%	0.1%	0.3	1	2.9	1.0	2.9	MI 86%
Flax	188	0.8	2.0	0.4%	1.1%	3	14	3.3	1.0	3.3	ND MN 100%
Hay, Other	33,427	5.2	16.5	0.02%	0.05%	22	78	4.2	1.0	4.2	OK TX ID IL 82%
Idle Cropland	7,461	1.8	151.6	0.02%	2.0%	6	466	3.1	1.0	3.1	CA MI 98%
Lemons	63	0.4	0.8	0.6%	1.2%	1	3	3.7	2.2	1.7	AZ 100%
Lettuce	268	1.5	3.0	0.6%	1.1%	8	16	5.4	1.0	5.4	AZ 100%
Lots/Farmsteads /etc	24,815	0.5	1.0	0.002%	0.004%	2	4	4.3	1.4	3.1	OR IA WI LA 88%
Melons	368	0.2	0.4	0.1%	0.1%	1	2	3.7	1.0	3.7	CA MI 100%
Oats/Rye	6,133	0.4	2.5	0.01%	0.04%	1	3	1.7	1.0	1.7	MN 88%
Oranges	867	0.3	0.6	0.04%	0.1%	3	5	8.5	3.5	2.4	AZ 98%
Other Crops	2,515	151.9	284.8	6.0%	11.3%	320	617	2.1	1.0	2.0	MN CA LA ID MT 83%
Peaches	212	0.2	1.3	0.1%	0.6%	0.4	2	1.7	1.0	1.7	CA SC 100%
Peanuts	1,610	0.3	1.6	0.02%	0.1%	1	7	4.5	1.0	4.5	NC 100%
Pecans	488	0.02	0.04	0.004%	0.01%	0.1	0.2	1.0	1.0	1.0	CA 100%
Potatoes	1,421	358.0	439.7	25.2%	30.9%	1,190	2,251	3.3	1.0	3.3	ID CO WA CA OR 80%
Rice	2,921	0.1	0.2	0.004%	0.01%	1	2	9.5	1.5	6.3	AR 100%
Roots/ Tubers	244	1.2	6.5	0.5%	2.7%	2	12	1.8	1.3	1.4	CA MI OR 92%
Seed Crops	1,516	35.3	129.8	2.3%	8.6%	97	357	2.7	1.0	2.7	MT IL OR 95%
Seaside Acres	21,802	2.0	4.0	0.01%	0.02%	6	16	3.0	1.0	3.0	NY UT CA SD NE 80%
Sorghum	11,280	0.1	0.2	0.001%	0.002%	0	1	2.5	1.0	2.5	NE 100%
Soybeans	62,879	13.6	42.0	0.02%	0.1%	37	73	2.7	1.1	2.6	MN NC NE ND TN WY 70%
Sugar Beets	1,415	149.9	273.0	10.6%	19.3%	290	599	1.9	1.0	1.9	MN CA ID 82%
Sugarcane	852	2.5	11.5	0.3%	1.4%	10	46	4.0	1.0	4.0	LA 100%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB a.i. Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb a.i. acre/yr	#appl / yr	lb a.i. A/appl	(% of total lb a.i. used on this site)
Summer Fallow	29,040	5.8	880.7	0.02%	3.0%	18	2,690	3.1	1.0	3.1	CA TX 99%
Sunflower	2,745	9.1	21.0	0.3%	0.8%	33	83	3.6	1.0	3.6	ND OH WI SD PA 85%
Sweet Corn, Fresh	233	1.0	6.0	0.4%	2.6%	8	48	7.9	1.0	7.9	81%
Sweet Corn, Proc.	544	51.9	79.5	9.5%	14.6%	230	347	4.4	1.0	4.4	WI MN OR 90%
Sweet Potatoes	85	0.8	5.0	1.0%	6.0%	2	15	3.0	1.0	3.0	TX 100%
Tobacco	695	0.0	0.0	0.002%	0.004%	0.1	0.2	6.0	1.0	6.0	KY TN 100%
Tomatoes	500	36.0	74.7	7.2%	14.9%	83	199	2.3	1.0	2.3	CA 96%
Vegetables, Bulb	198	2.5	8.0	1.3%	4.0%	5	15	1.9	1.0	1.9	OR CO 100%
Vegetables, Other	286	140.7	240.8	49.2%	84.2%	400	700	2.8	1.0	2.8	WI OR NY MI AZ FL 81%
Walnuts	205	1.8	3.3	0.9%	1.46%	5	9	2.9	1.0	2.8	CA 100%
Wheat, Spring	20,799	7.0	18.0	0.03%	0.1%	12	48	1.7	1.1	1.5	ID CO ND 94%
Wheat, Winter	45,854	8.6	26.8	0.02%	0.1%	21	76	2.5	1.0	2.5	OR NC NY 85%
Total		5,950	8,823			19,869	30,647				

COLUMN HEADINGS

Wtd Avg = Weighted average--the most recent years and more reliable data are weighted more heavily.
Est Max = Estimated maximum, which is estimated from available data.
Average application rates are calculated from the weighted averages

NOTES ON TABLE DATA

Usage data primarily covers 1987 - 1996. Calculations of the above numbers may not appear to agree because they are displayed as rounded to the nearest 1000 for acres treated or lb. a.i. (Therefore 0 = < 500) to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)

0* = Available EPA sources indicate that no usage is observed in the reported data for this site,
which implies that there is little or no usage.
A dash (-) indicates that information on this site is NOT available in EPA sources or is insufficient.

* Other/Crop Groups

Cole Crops includes broccoli, Brussels sprouts, cabbage, cauliflower, mustard greens, collards, bok choy, and chard.
Cucurbits includes cucumber, squash, and pumpkin. Melons include cantaloupe, watermelon, honeydew, muskmelon, and winter melon.
Root and Tuber Crops include red beets, carrots, horseradish, parsnips, radish, rutabagas, sweet potatoes, turnips, and yams.
Vegetables, Other includes, artichokes, asparagus, okra, oriental vegetables, rhubarb, and truck garden.
Other Crops include ornamentals, popcorn, rapeseed/canola, and safflower.
Vegetable, bulb includes onions, leeks, and garlic.

SOURCES: EPA data (1987-96), USDA/NASS (1990-96), and National Center for Food and Agricultural Policy, 1992.

E. Data Requirements

The Agency requires the registrant to submit additional confirmatory studies as specified in 40 CFR Section 158. Data from these studies are necessary to further characterize the risks associated with the uses described in this document and to confirm assumptions made in estimating risks. Refer to section IV of this document for a complete list.

F. Regulatory History

EPTC was registered in the United States in 1958 for use as a selective preemergent herbicide, and was originally owned by Stauffer Chemical Company. Chemiolimpex, a technical EPTC (TGAI), was manufactured in Hungary, and was imported into the United States by PPG Industries of Pittsburgh, Pennsylvania. Zeneca Ag Products currently holds registrations for several end-use products, and holds the only registration for the technical product.

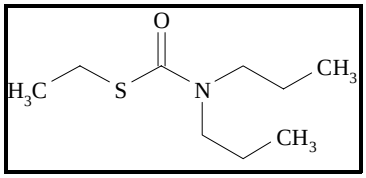
A Registration Standard for the EPTC was issued in September 1983. The Agency determined that additional generic data would have to be submitted for evaluation in order to maintain registration. This RED reflects a reassessment of all data which were submitted in response to the Registration Standard.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Chemical Profile

EPTC is the common name and Eptam is the Trade name for S-Ethyl di propyl thiocarbamate. The empirical formula of EPTC is $C_9H_{19}NOS$ and the chemical structure is shown in the figure below. Other thiocarbamate herbicides include tri-alate, di-alate, vernolate, pebulate, molinate, butylate, and cycloate.



Selected physical and chemical properties of EPTC are presented in the table below. When more than one value was available, it is presented to provided an indication of the range and variability under different temperatures, different formulations, or from different studies (or sources).

Table 3. Selected Physical and Chemical Properties of EPTC.

Property	Value
Empirical Formula	$C_9H_{19}NOS$[1]
Molecular Weight	189.32[1]
Density (Pure Active Ingredient, PAI) (Technical Grade A.I., TGAI)	0.9633 g/mL[1] 0.9639 g/mL[1]
Aqueous Solubility PAI	344 $\pm$ 5 ppm @25/°C[1] 344 ppm[1] 370 ppm @20°C[2]
Vapor Pressure	2.4×10^{-2} mm Hg @25°C[1] 1.60×10^{-2} mm Hg @20°C[2]
Dissociation Constant	not applicable
Octanol/Water Partition coefficient (PAI)	K_{ow}: $2.2 \times 10^3 \pm 0.1 \times 10^3$ @25°C or Log K_{ow}: 3.34[1]
Henry's Law Constant	1.7×10^{-5} m^3 - atm/g-mol @25°C[1] 2.29×10^{-5} m^3 - atm/g-mol @25°C[2] 6.25×10^{-4} (unitless)

1. MRID 42120801
2. EFED One-liner Database (11/15/94)

Possible soil and water degradates including EPTC sulfoxide (ESO), EPTC sulfone, N,N-dipropylformamide, dipropylamine, and ethanesulfonic acid were identified in a photolysis study. In terrestrial field dissipation studies only two degradates were detected in soil samples: ESO, and di-N-propylamine. Only ESO was identified in an aerobic soil metabolism study.

2. Environmental Fate Summary

The environmental fate data base is incomplete, but is sufficient to allow for an environmental fate assessment of parent EPTC that generally fits the pattern suggested by the monitoring data which are available.

Soil metabolism and volatilization from soil are the most important dissipation pathways, for EPTC in the environment. EPTC does not appear to be persistent under most conditions, but where microbial degradation is inhibited or volatilization is restricted EPTC could be persistent. EPTC is highly volatile (vapor pressure 1.60×10^{-2} mm Hg @20°C, Henry's Law Constant ~1.7 x 10-5 m^3 - atm/g-mol @ 25°C).

B. Human Health Assessment

1. Toxicology Assessment

Cardiomyopathy and neuronal cell necrosis were observed in studies of varying length of treatment and in different species using EPTC. EPTC did not produce any significant reproductive and developmental toxicity, and was negative in two oncogenicity studies.

EPTC is a reversible inhibitor of Cholinesterase (ChE). Toxicology studies with EPTC did not show any consistent pattern of ChE inhibition among different species, lengths of treatment, or the type of ChE enzyme measured. Inhibition of plasma ChE with dose-related increases in red blood cells and brain ChE inhibition are the typically expected results. In some studies, brain ChE activity was inhibited without any effect on either plasma or erythrocyte ChE activities. In other studies, erythrocyte ChE was inhibited with no inhibition of either plasma or brain ChE. Two studies which yielded commonly expected results were a chronic dog oral dosing (capsule), study in which plasma only was ChE inhibited, and a rabbit developmental study, in which plasma and erythrocyte ChE were inhibited. As a class of compounds, thiocarbamates do not produce consistent ChE inhibition profiles. A study with rats measured the inhibition of ChE by EPTC and other thiocarbamates-cycloate, butylate, pebulate, or vernolate at doses at or near the acute median lethal doses. While vernolate, pebulate and cycloate inhibited plasma, erythrocyte, and brain ChE to varying degrees, butylate inhibited plasma ChE only, and EPTC inhibited only erythrocyte and brain ChE, but not plasma ChE.

Cardiotoxicity was observed in subchronic and long-term studies, and, in general, the severity and incidence of the lesion increased with increasing dose of EPTC. In 90-day feeding and inhalation studies and in two chronic feeding/oncogenicity studies, all in rats histopathological evaluations revealed myocardial degeneration. Additional studies in rats, revealed myocardial degeneration in adult animals in two separate two-generation reproduction studies. In two chronic oral dosing studies in the dog, degenerative changes in the cardiac muscle were observed when EPTC was administered in a capsule, but not when administered at comparable doses in the diet. In both of the dog studies, electrocardiograms were taken, but only one high-dose male in the capsule study had changes which were described as "potentially" treatment-related.

EPTC, as well as other thiocarbamates (molinate, cycloate, pebulate, vernolate, and butylate), has toxic effects on the central and peripheral nervous systems. With EPTC, there was an increased incidence and severity of neuronal necrosis/degeneration in both the central and peripheral nervous systems in rats and dogs. In the neurotoxicity studies in rats, dose-related increases in the incidence of neuronal necrosis were observed in the brains after acute and subchronic exposure to EPTC. The acute delayed neurotoxicity study in hens, however, did not reveal any delayed neurotoxicity. In both combined chronic toxicity/oncogenicity studies in rats and in the chronic (capsule) study in dogs, treatment-related neuromuscular lesions were observed. In all of these studies, hindquarter weakness was observed, and at necropsy evaluation, atrophy and degeneration of the skeletal muscle was observed. In the dog study, the lesions were described as Wallerian-type degeneration in the spinal cords and various peripheral nerves.

Because of the neurotoxic effects (neuronal necrosis/degeneration), the Hazard Identification Assessment Review Committee (HIARC) recommended that a developmental neurotoxicity study in the rat be performed, and recommended that the 10X uncertainty factor, as required by FQPA, be retained.

a. Acute Toxicity

Results of acute toxicity, primary eye and dermal irritation, and dermal sensitization studies with EPTC technical material are summarized in the following table. EPTC is moderately toxic (Toxicity Category III) via the oral and dermal routes, and in a primary eye irritation study in rabbits, the technical was found to be slightly irritating (Toxicity Category III). EPTC is most toxic via the inhalation route (Toxicity Category II).

Table 4. Acute Toxicity of EPTC Technical Material.

Study Type	Animal	Results			Tox Cat	MRID No
81-1: Acute Oral	Rat	LD_{50}	Male Female Combined	1465 (1290-1663) mg/kg 1712 (1324-2214) mg/kg 1599 (1294-1976) mg/kg	III	00 157868
81-2: Acute Dermal	Rabbit	LD_{50}	Male Female	> 2000 mg/kg > 2000 mg/kg	III	00 157869
81-3: Acute Inhalation	Rat	LC_{50}	Combined	1.39 (0.97-2.00) ppm	II	00 157870
81-4: Primary Eye Irritation	Rabbit	PIS (24hr) = 2.2 Reversed within 3 days			III	00 157871
81-5: Primary Dermal Irritation	Rabbit	PII = 1.4			IV	00 157872
81-6: Dermal Sensitization	Guinea Pig	Very slight sensitizer			N/A	00 157873
		Weak sensitizer (Magnus son-Kligman)			N/A	41709201

The acute toxicity category, listed above, are for informational purposes only. The data supporting these category may or may not meet current acceptability criteria. The acceptability status of these data may be reassessed during product reregistration.

b. Chronic Toxicity/Carcinogenicity

EPTC is not carcinogenic. Oncogenicity studies in both rat and mice did not indicate that exposure to EPTC resulted in an increased incidence of neoplastic lesions. This is supported by lack of a carcinogenic effect in other long-term studies and no genetic component in reproduction and developmental studies.

c. Developmental & Reproductive Toxicity

The developmental and reproductive toxicity of EPTC was evaluated. Studies in rat and rabbits showed developmental and reproductive toxicity only in the presence of maternal or parental toxicity. In a prenatal developmental toxicity study in rats, developmental toxicity (in part, decreased fetal body weight and decreased litter size, but effects were attributed to maternal stress) was seen in the presence of marked maternal toxicity (increased mortality and decreased body weight). In a developmental toxicity study in rabbits, developmental toxicity (decreased fetal body weight) was again seen in the presence of marked maternal toxicity (in part, decreased body weight and increased mortality).

In a two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in parental toxicity. However, even though there does not appear to be any concern about the reproductive or developmental toxicity of EPTC, based on studies available, the neurotoxic effects (neuronal necrosis and degeneration) warrant the need for a developmental neurotoxicity study, and therefore the retention of the 10X safety factor, as required by the Food Quality Protection Act (FQPA).

d. Mutagenicity

EPTC has intrinsic genotoxicity which was not expressed in either the *in vivo* micro nucleus test or the Drosophila sex-linked recessive lethal mutation assay.

e. Dermal Absorption

In dermal absorption studies with EPTC and other thiocarbamates, EPTC was found to rapidly evaporate (volatilize) from warm skin. Based on a dermal absorption study in the rat which utilized a charcoal impregnated filter to capture vapors lost from the skin, absorption of EPTC was determined to be 5% at 10 hours.

f. Metabolism

The metabolism of EPTC was evaluated in rats using ^{14}C-labeled EPTC. EPTC was rapidly absorbed and excreted; there was very little bioaccumulation. Most of the radioactivity appeared in urine, with markedly lower amounts in the feces and exhaled air. No sex differences were noted in the absorption, tissue distribution, and excretion of EPTC.

g. Other Toxicological Endpoints

Endocrine Disrupter Effects

FQPA requires EPA to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...". EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry, and research scientists, to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disrupter Screening Program was published in the Federal Register of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of EPTC and end-use products for endocrine effects may be required.

2. Dose Response Assessment

a. FQPA Considerations

The Agency's FQPA Safety Factor Committee met on November 2, 1998 to evaluate the hazard and exposure data for EPTC and recommended that the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be retained in assessing the risk posed by this chemical due to concern for:

> A data gap for a developmental neurotoxicity study in rats which was identified by the HIARC. A developmental neurotoxicity study will provide additional data regarding functional parameter development, potential increased susceptibility, and the effects of EPTC on the development of the fetal nervous system.
>
> The requirement for a developmental neurotoxicity study is supported by the following:
>
> the severe neuropathology exhibited in acute, subchronic, and chronic studies with adult animals (acute, subchronic, and chronic exposure to EPTC produced neuronal cell necrosis of the brain in adult rats and dogs; and axonal degeneration of the spinal cord in the adult rat); the structure activity relationship to molinate and other thiocarbamates known to produce neurotoxicity/neuropathology; molinate induces neurotoxicity/neuropathology after single and multiple exposures *via* the oral, dermal, and inhalation routes across species. There is clear evidence of increased susceptibility in rat fetuses following *in utero* exposure to molinate in the prenatal developmental study. Increased susceptibility was demonstrated in the developmental neurotoxicity study in rats. Molinate was also found to be a reproductive toxicant (mice, rats, and dogs);

The Committee determined that the 10x FQPA safety factor is applicable for the following subpopulations:

Acute Dietary Assessment: All populations which include infants and children. The FQPA factor is appropriate for these populations due to the uncertainty regarding the effects on the developing fetal nervous system after a single exposure to EPTC. This uncertainty is also being addressed by the requirement of a developmental neurotoxicity study in rats.

Chronic Dietary Assessment: All populations which include infants and children. The FQPA factor is appropriate for these populations due to the uncertainty regarding the effects on the developing fetal nervous system after repeated exposures to EPTC. This uncertainty is being addressed by the requirement of a developmental neurotoxicity study in rats.

Residential (Short-, Intermediate- and/or Long-Term) Assessment(s): All populations which include Infants and Children. The FQPA factor is appropriate for these populations since the potential for residential exposure to infants and children resulting from the use of EPTC exists and

there is uncertainty regarding the effects on the developing fetal nervous system after such exposure. Again, this uncertainty is being addressed by the requirement of a developmental neurotoxicity study in rats.

b. Cancer Classification

EPTC is not carcinogenic. Oncogenicity studies in both the rat and mouse did not indicate that exposure to EPTC resulted in an increased incidence of neoplastic lesions. EPTC has intrinsic genotoxicity which was not expressed in either the *in vivo* micro nucleus test or the Drosophila sex-linked recessive lethal mutation assay. This is supported by lack of a carcinogenic effect in long-term studies, and no genetic component in reproduction and developmental studies.

c. Reference Dose and Toxicological Endpoints

On September 17, 1998, the Agency's Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicological endpoints selected for acute and chronic dietary, as well as for occupational and residential (dermal and inhalation) exposure risk assessments for EPTC. On July 29, 1999, the HIARC reconsidered the short and intermediate-term inhalation endpoints selected for occupational and residential risk assessments based on the re-evaluation of the 90-day inhalation toxicity study in rats. The doses and toxicological endpoints selected for various exposure scenarios are summarized in the following table.

The Reference Dose (RfD) is derived from an exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control, along with the application of uncertainty factors. The percent of the RfD is calculated as the ratio of the exposure value to the RfD (exposure/RfD x 100 = % RfD).

Table 5. Summary of Doses and Endpoints Selected for EPTC Risk Assessments.

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	LOAEL=200 (LDT)	Neuronal necrosis in the brain	Acute Neurotoxicity in Rat
	UF=300 (10x,10x, 3x for lack of NOAEL)	**Acute RfD = 0.67 mg/kg/day**	
	FQPA Safety Factor Retained (10x)	**Acute PAD = 0.067 mg/kg/day**	
Chronic Dietary	NOAEL=2.5	Parental toxicity, dose-related increase in degenerative cardiomyopathy	Two-Generation Reproduction Study in Rat
	UF=100 (10X10)	**Chronic RfD = 0.025 mg/kg/day**	
	FQPA Safety Factor Retained (10x)	**Chronic PAD = 0.0025mg/kg/day**	
Carcinogenicity (Dietary)	Not required. EPTC was not mutagenic and did not exhibit any oncogenic potential in a mouse oncogenicity study, and two combined chronic toxicity/oncogenicity studies in rat.		
Short-Term (Dermal) [a]	Oral LOAEL=200	Neuronal necrosis in the brain.	Acute Neurotoxicity in Rat
	UF = 300 (10x, 10x, 3x for lack of a NOEL) (5.0% dermal absorption) UF = 3000 for all non-occupational residential populations which include infants and children (FQPA Safety Factor Retained (10x)		
Intermediate-term (Dermal)	Oral NOAEL = 9	Decreased body weight and relative brain weight and neuronal necrosis	90-Day Neurotoxicity Study in Rat
	UF = 100 (10x10) (5.0% dermal absorption)		
Long-Term (Dermal)	The use pattern does not indicate the need for long-term dermal risk assessment.		
Inhalation (Short Term)	NOAEL 58 μg/L	Myocardial degeneration observed at 21 days in a 90-day inhalation study	90-day Inhalation Study in Rat
	UF = 100 (10x10)(100% inhalation absorption); UF = 1000 for all non-occupational populations		
Inhalation (Intermediate Term less than 21 days)	NOAEL 58 μg/L	Myocardial degeneration observed at 21 days in a 90-day inhalation study	90-day Inhalation Study in Rat
	UF = 100 (10x10) (100% inhalation absorption); UF = 1000 for all non-occupational populations		
Inhalation (Intermediate Term greater than 21 days)	NOAEL = 8.3 μg/L	Clinical signs, decreased food consumption, brain ChEI in males, and increased prothrombin times in females.	90-day Inhalation Study in Rat
	UF = 100 (10x10) (100% inhalation absorption); UF = 1000 for all non-occupational populations (FQPA Safety Factor Retained) (10x)		
Long-Term (Inhalation)	The use pattern does not indicate the need for long-term inhalation risk assessment.		

a = The use of a 5% dermal absorption rate is required for dermal risk assessments.

The population adjusted dose (PAD) is an adjusted RfD reflecting the retention or reduction of the FQPA safety factor for all populations which include infants and children. For EPTC, the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD) is 0.067 mg/kg/day and 0.0025 mg/kg/day, respectively.

Because different toxic effects were observed for dermal and inhalation dose routes, a separate margin of exposure (MOE) will be used for dermal and inhalation risk assessments.

For the short, intermediate and long term dermal, as-well-as short, intermediate and long term inhalation, the FQPA 10x safety factor was retained for non-occupational, but not occupational handlers.

3. Exposure Assessment

a. Dietary Exposure

In plants, EPTC is metabolized to a variety of products via several different metabolic pathways. The major metabolic pathway of EPTC involves initial oxidation of the sulfur atom to a sulfoxide, which is oxidized further to a sulfone. The sulfone metabolite is then conjugated with glutathione and the resultant glutathione conjugate is sequentially metabolized to the following cysteine; N-malonyl cysteine; S-lactic acid; and O-malonyl-S-lactic acid-conjugates: The second metabolic pathway of EPTC is hydroxylation of the alkyl yielding the following: N-(2-hydroxy)propyl-N-(3-hydroxy)propyl-and S-(2-hydroxy)ethyl-metabolites.

The Agency has concluded that the EPTC plant residues of toxicological concern are: EPTC, EPTC sulfoxide; EPTC sulfone; and the EPTC conjugates (i.e. glutathione-; cysteine-N-malonyl cysteine-S-lactic acid, and O-malonyl-S-lactic acid-conjugates). The basis for the toxicological concern of these substances is the presence of the thiocarbamate moiety. The hydroxylated EPTC plant metabolites also contain the thiocarbamate moiety. However, these metabolites are formed only in low concentrations and, as such, the Agency believes these residues do not contribute significantly to the total toxicity of EPTC.

Because of the diverse structural and physiocochemical differences between these compounds, the Agency concurred with the registrant's position that development of a single enforcement analytical method that can detect each of these residues was not feasible. Because development of an enforcement analytical method for the hydroxylated metabolites was feasible, the Agency concurred with the registrant's recommendation that EPTC and its hydroxylated metabolites be used as marker residues of EPTC residues of toxicological concern (i.e., markers of EPTC, EPTC sulfoxide, EPTC sulfone, and the EPTC conjugates resulting from the glutathione-S-transferase pathway).

Therefore, tolerances for EPTC residues in or on plants represent the presence of EPTC and its hydroxylated metabolites (free or conjugated). The ratio formed in plants of EPTC residues of

toxicological concern to EPTC residues that will be used as markers varies from 1.5:1 (potatoes) to 13.2:1 (bean vines). The Agency decided that, for purposes of assessing the risks posed by EPTC, the concentration of any marker compound residues will be multiplied by 15 to estimate the concentration of residues of concern. This factor was selected to cover the high-end of the range of metabolite ratios. The tolerance expression, therefore, will now consist of residues of EPTC *per se* and the EPTC hydroxylated metabolites mentioned above. Hence, all EPTC tolerances have been reassessed based on residue data for the combined residues of EPTC and its hydroxylated metabolites.

For the determination of residues of EPTC *per se* in or on plant commodities, the Pesticide Analytical Manual (PAM, Vol. II, Section 180.117) lists Methods A (GLC/MC (micro colorimetric) Method RR-50; level of detection (LOD) = 0.02-0.04 ppm, depending on the matrix) and B (a confirmatory colorimetric procedure). The EPTC Reregistration Standard Guidance Document of 1983 concluded that the GLC/MC method is adequate for data collection and corresponding tolerance enforcement. Hence, an enforcement analytical method for detecting EPTC *per se* is available.

For the determination of hydroxylated metabolites (free or conjugated) of EPTC in or on plant commodities, the registrant has proposed a GC/NPD method as an enforcement method. (The level of quantification (LOQ) of each hydroxylated metabolite is 0.01 ppm.) The registrant recently submitted to the Agency a description of the proposed method, along with preliminary recovery data. The proposed method was reviewed by the Agency, and determined to be adequate. The Agency has required an independent laboratory validation (ILV) of the proposed method in accordance with PR Notice 96-1. When a successful ILV has been received and evaluated, an Agency method trial will be conducted at the EPA Analytical Chemistry Laboratory.

For purposes of tolerance enforcement in accordance with the revised tolerance expression (the combined residues of EPTC and its hydroxylated metabolites as markers), confirmatory data are required to validate the proposed enforcement method for determination of the hydroxylated metabolites. An enforcement analytical method for EPTC is currently available. The Agency believes that field trial consistently demonstrate that residues of EPTC and the hydroxylated metabolites present on treated commodities are non-detectable. The existing enforcement method for the parent will be revised when the new method is available.

In animals, only a single EPTC residue of toxicological concern was found, in goats, (EPTC-cysteine conjugate) and hens (unmetabolized EPTC) fed highly exaggerated doses of EPTC, and in both cases the residue was formed in low concentration only. The Agency concludes, therefore, that residues of EPTC in animal commodities represent a Category 3 situation under 40 CFR §180.6(a): i.e., situations in which it is not possible to establish with certainty whether finite residues will be incurred under reasonable worst-case exposure scenarios, but there is no reasonable expectation of the occurrence of finite residues in animal commodities. Therefore, tolerances for residues of EPTC in animal commodities need not be established.

Residue data from crop field trials, processing studies, and livestock feeding studies have been reviewed for the purpose of tolerance reassessment. Submitted residue data from field trial and processing studies depict combined residues of EPTC and its three hydroxylated metabolites. These data were obtained using analytical methods adequately validated for data collection. Storage stability data support the integrity of the residue data for EPTC, but no data are currently available to delineate the stability of the hydroxy metabolites in frozen plant matrices; these data have been required. In general, field trials met the criteria for the required number of samples, and were conducted in locations representative of the major growing regions specific to the crop tested. The test systems utilized representative product formulations, applied at maximum rates, using application equipment in accordance with label specifications. Residues of EPTC and its three hydroxylated metabolites were nondetectable (<0.05 ppm) in the majority of samples of raw and processed commodities from the submitted field trials.

The Agency is recommending revocation of tolerances for certain commodities for one or more of the following reasons:

(1) crop groupings are obsolete or no longer applicable, thus warranting revocation of certain crop group tolerances concomitant with establishment of tolerances for individual commodities.

(2) there are no longer significant livestock feed items for the commodity.

(3) currently there are no registered uses. Insufficient field trial data are available to reassess the tolerances for flaxseed, citrus, and strawberries. Existing tolerances for these commodities have been used for dietary exposure estimates.

b. Dietary Exposure from Food

The acute and chronic dietary exposure assessments were conducted using the Dietary Exposure and Evaluation Model (DEEM^{TM}) system. DEEM can be used to estimate exposure to constituents in foods comprising the diets of the U.S. population, including population subgroups. The software contains food consumption data from the USDA Continuing Survey of Food Intake by Individuals (CFSII) from 1989-1992.

For EPTC, inputs to the DEEM^{TM} analysis include reassessed tolerances and percent crop treated data. Tolerances published for EPTC under 40 CFR 180.117 have been reassessed (HED Residue Chemistry Chapter, dated 9/25/98). The reassessed tolerance residue values, adjusted by a factor of 15 to estimate the residues of concern, have been used as the basis for a DEEM^{TM} Tier 1 analysis for acute dietary exposure, and a DEEM^{TM} Tier 3 analysis for chronic dietary exposure. The Tier 3 analysis used average field trial residue values (adjusted for marker compounds) and also incorporated percent of crop treated data (BEAD Quantitative Usage Analysis for EPTC, dated 3/10/98). Where percent crop treated estimates indicated no EPTC use, a default minimum assumption of 1% crop treated was applied.

Where residues were nondetectable, one-half LOD (limit of detection) was assumed. Data from processing studies indicate that residues of EPTC and its hydroxylated metabolites do not concentrate in the processed fractions of the tested crops except sugar beet molasses (4x concentration factor) and potato granules (1.4x). The residue file created using the DEEM ™ software for these dietary exposure analyses reflects these processing factors using a value of 1 for adjustment factor #1 (adjustment for concentration/reduction of residues in processed commodities) for commodities with no concentration. However, the concentration factor is reflected in the reassessed tolerances for sugar beet molasses (*e.g.*, the reassessed tolerance value for sugar beets is 0.1 ppm, and the reassessed tolerance value for sugar beet molasses, the processed commodity, is 0.4 ppm). Also, there is a citrus processing study that is outstanding. Because the processing study for citrus has not been performed, all default concentration factors in the DEEM ™ software have been retained for citrus food items.

(1) Acute Dietary Exposure Assessment

For the Tier 1 acute dietary exposure analysis of EPTC, exposure (food consumption) was compared to an acute population adjusted dose of 0.067 mg/kg/day (FQPA Safety Factor Committee Report, 11/18/98). The acute dietary risk analysis estimates the distribution of single day exposures for the overall U.S. population and certain subgroups. The analysis evaluates exposure to the chemical for each food commodity, and assumes uniform distribution of EPTC in the food supply.

As shown in Table 6, the acute dietary residue contribution at the 95th percentile occupied less than 100% of the aPAD for any population subgroup, and therefore does not exceed the Agency's level of concern. For non-probalistic acute dietary exposure the Agency uses the 95th percentile. For the most highly exposed subgroup, children 1-6, residue contribution occupied 87.5% of the aPAD. This Tier 1 acute analysis for EPTC is a conservative upper-bound estimate with all input residues equal to the reassessed tolerance value and the assumption that 100% of the crop is treated nationwide.

Table 6. Summary of Tier 1 EPTC Acute Dietary Exposure Analysis by DEEM.

Population	95th Percentile	
	Exposure	% aPAD
U.S. Population	0.027156	40.53
All Infants <1 year	0.034682	51.76
Nursing Infants <1 year	0.012725	18.99
Non-nursing Infants <1 year	0.041815	62.41
Children 1-6 years	0.058633	87.51
Children 7-12 years	0.037088	55.36

(2) Chronic Dietary Exposure Assessment

A chronic exposure analysis was performed using the DEEM ™ exposure modeling software. Input values for the Tier 3 analysis include average residues from field trials and incorporated percent of the crop treated information. Largest markets in terms of total pounds active ingredient are allocated to corn (56%), dry beans/peas (8%), and potatoes (6%). Exposure (consumption) was compared to the chronic population adjusted dose of 0.0025 mg/kg/day (FQPA Safety Factor Committee Report, 11/18/98).

As shown in Table 7, the chronic dietary residue contribution occupies less than 100% of the cPAD for all population subgroups, and therefore does not exceed the Agency's level of concern. For the most highly exposed subgroup, children 1-6, the residue contribution occupies 17.4% of the cPAD. This Tier 3 chronic analysis for EPTC is a refined estimate where average residues from crop field trials and percent of crop treated data were used as inputs. For the majority of collected samples, residues of EPTC and its hydroxylated metabolites were less than the detection limit of 0.02 or 0.04 ppm, depending on the matrix. Where residues were nondetectable, one-half the LOD was assumed.

Table 7. Summary of Tier 3 EPTC Chronic Dietary Exposure Analysis by DEEM

Population Subgroup	Anticipated Residue Concentration (mg/kg/day)	Percent of Chronic PAD
U.S. Population	0.000277	9.6
All Infants (<1 year)	0.000281	11.3
Nursing Infants (<1 year)	0.000072	2.9
Non-nursing Infants (<1 year)	0.000369	14.8
Children (1-6 years)	0.000435	17.4
Children (7-12 years)	0.000340	13.6

c. Dietary Exposure from Drinking Water

The Agency has completed an analysis of available monitoring data and conducted a Tier I screening level assessment for ground water and a Tier II assessment of surface water to estimate the potential EPTC concentrations in ground water and surface water. Tier II modeling was used for surface water, because the Agency's Tier I surface-water and ground-water models do not consider volatilization. EPTC is volatile and mobile in soil and does not appear to be persistent under most conditions. The metabolites of EPTC were not considered in the screening-level assessment due to a lack of environmental fate data. Although limited, there are acceptable data available indicating that metabolites of EPTC are less persistent than the parent compound.

Surface Water Modeling:

Tier II surface water modeling was conducted for EPTC, on several major crops at high exposure sites, using the EPA's PRZM and EXAMS models. The crops modeled were alfalfa, beans, citrus, corn, and potatoes. They were selected, from label information, because they generally represent the maximum application rates, number of applications, and the maximum total amount applied. Lower concentrations were predicted for those scenarios having the lowest application rates and the fewest number of applications.

PRZM/EXAMS output consists of estimated daily concentration in a standard water body for the length of the simulation (typically 36 years). For each scenario, the annual peak value is the highest daily concentration in a year, thus, there are 36 peak values. These values are sorted (maximum to minimum) and the 90^{th} percentile value is selected (i.e., 1-in-10-year). The range of the 90^{th} percentile peak EECs for the 10 scenarios was 3.67 to 41.69 µg/L. Maximum peak concentrations ranged from 6.35 to 57.35 µg/L. The mean of the annual means ranged from 0.16 to 3.44 µg/L. In general the lowest EECs were generated for beans and corn whereas the highest EECs were for citrus. The peak (57.35 µg/L) and mean (3.44 µg/L) of the annual means of the citrus scenario were used in the drinking water risk assessment.

The maximum concentrations were generated by the citrus scenario using an application rate of 3.1 lb/a.i. A applied three times per year with a 30 day interval between applications. Aquatic degradation rates had to be estimated because data were not available. Agency guidance suggests that the aquatic metabolism rate can be estimated by multiplying the aerobic soil metabolism rate by 0.5 (multiplying the half-life by 2). As noted in the environmental fate assessment, EPTC did not follow first-order decline so half-lives were estimated by using transformed linear regression and non-transformed linear regression. The 90th percent upper bound on the mean aerobic soil metabolism half-lives were 37 and 77 days for the linear and non-linear regression, respectively.

The aerobic aquatic metabolism half-lives thus were assumed to be 74 and 154 days (2 times the aerobic soil half-life) for linear and non-linear regression, respectively. The EPTC surface water concentrations presented above used the more conservative 154 day half-life. The half-life selected made very little difference between the surface water concentrations for EPTC. The loss of EPTC through volatilization was the dominant route of dissipation of EPTC in the surface water environment. EPTC was assumed to be applied as a ground spray followed by a 2-inch soil incorporation. Spray drift was assumed to be 1% of the pesticide applied for ground spray and zero for granular application.

Ground Water Modeling:

The SCI-GROW (Screening Concentration in Ground Water) model was used to conduct a Tier I ground-water assessment, although the concentration is probably over-predicted because SCI-GROW does not consider volatilization as a route of dissipation. SCI-GROW was developed to estimate potential ground-water concentrations for parent EPTC under hydrologically vulnerable

conditions. The maximum EPTC concentration in ground water predicted by the SCI-GROW using the maximum rate 6.1 lb. a.i./ac and 2 applications was 5.89 µg/L and an average half-life of 58.5 days (ln-transformed) and median K_{OC} of 144.5. Using the average non-linear estimated half-life of 24 days, rather than 58.5 days, and with all other inputs remaining the same resulted in an estimated ground water concentration of 1.84 µg/L.

The persistence of EPTC in ground water would probably be greater than in surface water since losses due to volatilization would be expected to be much less. EPTC is mobile in soil as indicated by K_{oc}s ranging from 136 to 266 mL/g. EPTC does not appear to be persistent, under most conditions, but where microbial degradation is inhibited or volatilization is restricted EPTC could be persistent (leached below the most microbially active zone).

Ground and surface water monitoring data from at least thirty states indicate that EPTC has the potential to contaminate both ground and surface waters. Peak concentrations of EPTC in surface water estimated by PRZM/EXAMS (6.35 to 57.35 μg/L) corresponds reasonably well with the range of the highest surface water concentrations of EPTC observed in monitoring data (10 to 40 μg/L) although the 40 μg/L value is outside the range of the method calibration. The concentration of EPTC in ground water estimated by SCI-GROW (1.84 μg/L) also corresponds reasonably well with the range of the highest ground water concentrations of EPTC observed in monitoring data (0.5 to 2.7 μg/L).

A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. OPP uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide through drinking water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

DWLOCs for Chronic (Non-Cancer) Exposure

Chronic DWLOCs were calculated based on the chronic dietary (food) exposure, default body weights ,and water consumption figures. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70/kg/2/L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child). To calculate the DWLOC, the chronic dietary food exposure was subtracted from the chronic PAD using the equation

$$DWLOC_{chronic} = \frac{\text{[chronic water exposure (mg/kg/day) x (body weight)]}}{\text{[consumption (L) x } 10^{-3} \text{ mg/}\mu\text{g]}}$$

where chronic water exposure (mg/kg/day) = [cPAD - (chronic food (mg/kg/day)]

As shown in Table 8, the drinking water estimated concentrations from modeling in ground water (1.84 μg/L),and surface water (3.44 μg/L), are all below the Agency's DWLOCs for EPTC for all population subgroups. Based on the available information, residues of EPTC in drinking water do not result in an unacceptable contribution to chronic dietary exposure at this time.

Table 8. Drinking Water Levels of Comparison for Chronic Dietary Exposure.

Population Subgroup	Chronic PAD(mg/ kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	$DWLOC_{chronic}$ (μg/L)	PRZM-EXAMS (μg/L)	SCI-GROW (μg/L)
Adult male	0.0025	0.000231	0.00227	78	2 .44	1.84
Adult Female	0.0025	0.000229	0.00227	68	3.44	1.84
Infants <1 yr	0.0025	0.000281	0.00222	20	3.44	1.84
Children 1-6	0.0025	0.000435	0.00207	20	3.44	1.84
Non-Hispanic Black	0.0025	0.000271	0.00223	76	3.44	1.84

DWLOCs for Acute Exposure

Acute DWLOCs were calculated based on the acute dietary (food) exposure, default body weights, and water consumption figures. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70/kg/2 L (adult male), 60 kg/2 L (adult female), and 10 kg/1L (child). To calculate the acute DWLOC, the acute dietary food exposure was subtracted from the acute PAD using the equation

$$DWLOC_{acute} = \frac{\text{[acute water exposure (mg/kg/day) x (body weight)]}}{\text{[consumption (L) x } 10^{-3} \text{ mg/}\mu\text{g]}}$$

where acute water exposure (mg/kg/day) = [aPAD - acute food (mg/kg/day)].

As shown in Table 9, the drinking water estimated concentrations in ground water (1.84 μg/L) and surface water (57.35 μg/L) are below the Agency's DWLOCs for EPTC. The Agency concludes that based on the available information, modeled residues in drinking water do not exceed the Agency's level of concern for contribution to acute dietary exposure at this time.

Table 9. Drinking Water Levels of Comparison for Acute Dietary Exposure.

Population Subgroup	Acute PAD	Food Exposure (mg/kg/day)	Water Exposure mg/kg/day	$DWLOC_{acute}$ (μg/L)	PRZM EXAMS (μg/L)	SCI-GROW (μg/L)
Adult Male	0.067	0.027156	0.039844	1395	57	2.00
Adult Female	0.067	0.027156	0.039844	1195	57	2.00
Infants <1 yr	0.067	0.041815	0.025185	252	57	2.00
Children 1-6	0.067	0.058633	0.0084	84	57	2.00

d. Occupational and Non-Occupational Exposures

Occupational and residential exposure to EPTC residues via dermal and inhalation routes can occur during handling activities such as mixing, loading, and applying; however, the potential for postapplication occupational exposure is minimal. Because EPTC is applied as a soil directed spray and immediately incorporated, or as a soil injection well before plants are mature, the potential for post-application dermal exposure during harvest activities is minimal. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules. Based on

toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for the occupational and residential handler, and for residential postapplication inadvertent oral ingestion soil/granulars exposure to children.

e. Occupational Exposure

Occupational Handler Exposure Scenarios

The Agency has identified 12 major exposure scenarios for which there is potential for occupational handler exposure during mixing, loading, and applying products containing EPTC to agricultural crops and to non-agricultural use sites. These occupational scenarios reflect a broad range of application equipment, application methods, and use sites. The scenarios were classified as short-term (1-7 days) and intermediate-term (1 week to several months) based primarily on the frequency of exposure. A long term exposure duration is not expected, because applications are typically made only once per year or for application well spaced in time. The estimated exposures considered baseline protection (long pants and a long-sleeved shirt, shoes and socks, no gloves, and an open cab or tractor), additional personal protective equipment (PPE, which includes a double layer of clothing and gloves and/or a dust/mist respirator), and engineering controls (closed mixing/loading systems for liquids and granulars and enclosed cabs/trucks).

Occupational Handler Exposure Data Sources and Assumptions

The registrant submitted a biological monitoring study conducted with cycloate. Although the Agency agreed that acceptable data from monitoring studies conducted with cycloate could be used to estimate exposure of other thiocarbamates, data from the submitted study were not used in this risk assessment. In the study, an EC formulation was mixed, loaded and applied using groundboom spray equipment mounted on either open- or closed-cab equipment. The study was not used in this assessment because an inadequate number of replicates were completed for each exposure scenario and replicates used varying PPE, equipment and/or engineering controls and the subjects wore a varying range of protective clothing during handling and application activities. Data on upper arms, forearms, thighs, lower legs, and hands are missing and would have to be extrapolated from other scenarios in the study. PHED mixer/loader/applicator data sets for ground application of liquid formulations better represents the registered EPTC uses and the resulting scenario-specific handler exposures.

Occupational Postapplication Exposure

The current restricted entry interval (REI) for EPTC is 12 hours, with the exception that if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

EPTC is applied is a soil-directed herbicide that must be thoroughly incorporated immediately following application through mechanical means or watering-in. It is applied as a pre-plant application

and as a post-emergent application to established plants. Post-emergent applications include crops such as tomatoes and beans, where hand labor activities involving contact with the soil subsurface such as staking are common. For post-emergent applications to ornamentals in nurseries, there are no restrictions on the timing of transplanting/harvesting the ornamentals following application. For all crops, labeling instructions direct users to use shallow cultivation (i.e., mechanical or hand raking/hoeing) after application to control weeds that escape control.

No product-specific postapplication exposure data were available for EPTC, therefore a surrogate range-finder postapplication assessment was conducted. The surrogate assessment assumed that 20 percent of the EPTC applied was available for transfer (i.e., dislodgeable) at 12 hours following application/incorporation. A transfer coefficient of 1000 cm^2/hr would be appropriate for tasks that would involve contact with the soil subsurface, such as hoeing, raking, staking, thinning, irrigating, and transplanting (ornamentals). An eight hour work day and the maximum EPTC application rate of 15 pounds active ingredient per acre was used. Using the high end assumptions in this surrogate assessment, the margin of exposure at 12 hours after application/incorporation was over a thousand.

Therefore, the EPA is establishing a 12-hour restricted-entry interval for all uses of EPTC. The labeling should state that the REI does not begin until EPTC has been appropriately incorporated as directed. The WPS exception allowing unrestricted entry to treated areas following application and appropriate incorporation provided the soil subsurface will not be contacted should be cited on the labeling using the standard language for soil incorporation.

f. Incident Reports

The Agency has reviewed the OPP Incident Data System (IDS), the Poison Control Center, the California Department of Food and Agriculture (Department of Pesticide Regulation), and the National Pesticide Telecommunications Network (NPTN) data bases for reported incident information for EPTC. Of the 19 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995), 17 involved use of EPTC alone and were judged to be responsible for the health effects. When the acute toxicity data for individual products are reviewed, the Agency will impose the appropriate eyewear based on the toxicity category. Additional dermal protective equipment, such as double layers or chemical resistant aprons, will be required based on the EPTC risk assessment, for some handler and applicator scenarios as discussed in section IV of this document.

g. Residential Handler Exposure

Potential EPTC residential use sites may include a variety of shade trees, evergreens, and annual or perennial ornamentals. EPTC is typically applied only to bare soil once before planting or after weeding under ornamentals followed by soil incorporation. Examples of typical usage of a granular formulation in the home garden would include pre-planted application and incorporation with a rototiller, post-plant application incorporated into the soils to a depth of 2-3 inches using a hand rake or hoe, and weed control in established trees and shrubs by incorporation into the top 6

inches of soil In contrast to occupational workers, individuals in residential settings are more likely to transplant seedlings and plant seeds by hand. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules.

Residential handler exposure to EPTC residues via dermal and inhalation routes can occur during handling, mixing, loading, and applying activities. The exposure duration of these activities was classified as short-term (1-7 days), because EPTC is usually applied only once per year up to 3 applications well-spaced in time.

Residential Handler Exposure Scenarios

The Agency has determined that there is potential exposure to residential mixer, loader, and applicators during the usual use patterns associated with EPTC. Based on the use patterns, four major residential exposure scenarios were identified for EPTC. These involve loading/applying granulars with a push-type spreader, a belly grinder spreader, by hand/spoon, or applying granulars with a shaker can.

Residential Handler Exposure Data Sources and Assumptions

Residential handler exposure assessments were completed by the Agency assuming an exposure scenario for homeowners wearing the following attire: short sleeved shirt, short pants, shoes and socks, and no gloves or respirator. PHED values used to estimate daily unit exposure values were taken from the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 1997).

The area treated per day was assumed to be 10,000 square feet for a push type spreader, 1,000 square foot for belly grinder spreader, and 15lbs 10oz for shaker can and hand/spoon application. Calculations were made using the maximum application rates for crops as stated on the available EPTC labels. Application rates represent the range of exposure levels associated with the various use patterns.

Because no exposure data sets for application with a granular shaker can are available in PHED, the unit exposure data for granular application using a belly grinder was utilized for the granular shaker can scenario. Exposure estimates for the belly grinder is considered representative of shaker can because both are held at approximately the same height during application. The entire container (15 lb. 10 oz.) is assumed to be applied in one day.

Residential Postapplication Exposure Scenarios

The Agency has determined that there is a potential for non-occupational postapplication exposure from use by the residential handler, and from commercial use of EPTC in parks, recreational areas, and golf courses (sand traps). The Agency believes that postapplication dermal exposure at these sites is minimal for the following reasons: 1) use on golf courses is limited to sand traps, 2)

EPTC is volatile and dissipates quickly; and 3) it is soil incorporated, making very little available at upper soil layers. Thus, a quantitative assessment of the potential exposure to adults and children from these sources is not needed.

The Agency has also determined that there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules. Although there is little exposure potential for children's ingestion of EPTC granules, it is the Agency's policy to routinely conduct screening level assessments for this scenario, when a granular pesticide may be applied in residential settings.

The scenarios likely to result in postapplication exposures are as follows:

A. Ingestion of granules in treated areas (toddler);

B. Incidental ingestion of soil from pesticide-treated residential areas (toddler);

Data Sources and Assumptions for Postapplication Exposure Calculations.

The equations and assumptions used for each of the scenarios were taken from the *Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments* guidance document, and are given below. The following general assumptions were made for all scenarios:

- On the day of application, it was assumed that 100 percent of the application rate is available from the soil as dislodgeable residue.

- For children ages 1-6 the assumed soil ingestion rate is 100 mg/day.

- The assumed ingestion rate for dry pesticide formulations (i.e., granules) is 0.23 grams/day for toddlers age 3 years. This is based on the assumption that if 5.0 pounds of product were applied to a 1,000 square feet of land, the amount of product per square foot would be 2.3 g/ft^2. The toddler would consume one-tenth of the product available in a square foot.
- Toddlers (age 3 years), representing the 1 to 6 year old age group, are assumed to weigh 15 kg.

4. Risk Characterization

a. Dietary Risk

The aggregate acute dietary risk estimates include exposure to EPTC residues in food and water. Exposure (food only) to combined residues of EPTC and its metabolites of toxicological concern based on an upper-bound analysis using tolerance-level residues, and assuming 100% of crop treated, represents 87.5% of the acute PAD for the most highly exposed population subgroup (children 1-6 years). Exposure to all other groups represents less than 62.4% of the acute PAD.

Using conservative screening-level models, the estimated maximum peak concentrations of EPTC in surface water is 57 μg/L. This estimated peak concentration is slightly less than the Agency's drinking water level of comparison for exposure to EPTC in drinking water as a contribution to aggregate acute dietary risk. Based on the available information, the Agency concludes that acute dietary exposure to EPTC does not exceed the Agency's level of concern.

Chronic (non-cancer) aggregate risk estimates also do not exceed the Agency's level of concern. The aggregate chronic dietary risk estimates include exposure to EPTC residues in food and water. No chronic residential use scenarios were identified. Exposure (food only) to combined residues of EPTC and its metabolites of toxicological concern based on a Tier 3 refinement using average residues from field trial and percent of crop treated data, represents 17.4% of the chronic PAD for the most highly exposed population subgroup (children 1-6 years). Exposure to each of the other groups represents less than 14.8% of the chronic PAD for that group. Using conservative screening-level models, the estimated maximum of EPTC in surface water is 3 μg/L.* This estimated average concentration is less than the Agency's drinking water level of comparison for exposure to EPTC in drinking water as a contribution to aggregate chronic dietary risk. Based on the available information, the Agency concludes that chronic dietary exposure to EPTC does not exceed the Agency's level of concern for any population.

b. Occupational Handler Risk

Because different endpoint effects were selected for the assessment of dermal and inhalation risks, separate risk assessments were conducted for dermal and inhalation exposures. MOEs for occupational handlers were derived based upon comparison of dermal exposure estimates against either a LOAEL of 200 mg/kg/day for short-term exposure or a NOAEL of 9 mg/kg/day for intermediate-term exposure (table 4). Both the short and intermediate-term LOAEL/NOAELs were from neurotoxicity studies in the rat (oral administration). A dermal absorption factor of 5% was applied to dermal exposure estimates. MOEs were also derived based upon comparison of inhalation exposure estimates against a NOAEL of 58 mg/m^3 (15.1 mg/kg/day) for exposure from 1 to 21 days in duration (table 4), and against a NOAEL of 8.3 mg/m^3 (1.26 mg/kg/day) for exposures greater than 21 days in duration. The uncertainty factors and target MOEs for occupational workers are 300 for short-term dermal risk, 100 for intermediate-term dermal risk, and 100 for short- and intermediate-term inhalation risk. MOEs below this level would represent a risk concern for the Agency.

A summary of the short-term and intermediate-term risk estimates for baseline, additional PPE, and engineering controls is presented in Tables 9, 10, and 11. Except for scenario 9, which include chemical resistant gloves, baseline dermal unit exposure represents long pants, long sleeved shirt, shoe and sock, no gloves, open mixing/loading, open cab tractor. Additional PPE for all dermal scenarios includes double layer of clothing (50% protection factor for clothing) and chemical resistant gloves. Depending on the scenario, engineering controls include closed mixing/loading, single layer clothing, chemical resistant gloves, chemical resistant apron, respirator, closed cockpit.

Three short-term and seven intermediate-term scenarios require PPE to mitigate dermal and inhalation risks from handling and/or applying EPTC-containing products. PPE is required to mitigate risk from dermal exposure during mixing/loading EC formulations for chemigation and ground application, and for mixing/loading/applying EC formulations using hand-held equipment (a low pressure handwand).

Short-Term Risk Characterization

The estimates for short-term dermal and inhalation risks have not been combined because dermal and inhalation endpoint effects are different. Target MOE's for short term occupational dermal risk equals 300, and MOE's for intermediate dermal risk equal 100. Target MOE's for short and intermediate occupational inhalation risk both equal 100.

Dermal exposures reflecting baseline protective clothing result in MOEs that exceed the Agency's level of concern for only three of 12 short-term scenarios, in which MOEs ranged from 69 to 190, Table 4). For these three scenarios, (1a) mixing/loading EC formulations for chemigation; (1b) mixing/loading EC formulations for ground application; and (8) mixing/loading/applying EC formulations to the soil with a low pressure handwand, additional PPE (double layer of clothing and chemical resistant gloves) are required to mitigate exposure/risk. Baseline and/or PPE exposure assessments were not performed for two scenarios because methodologies other than mechanical mixing/loading/applying are not feasible. Engineering controls are required to mitigate dermal exposure for scenarios (1c) mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system) and (7) applying granular with aerial equipment. Provided that EPTC short-term dermal exposures are mitigated for the above specified exposure scenarios with PPE and/or engineering controls, MOEs for dermal exposure/risk do not exceed Agency's level of concern.

Inhalation exposures reflecting baseline protective clothing for all assessed exposure scenarios do not exceed the Agency's level of risk concern; MOEs were greater than 290 (Table 10). Short-term baseline and/or PPE exposure assessments were not performed for two scenarios, because application methodologies other than mechanical mixing/loading/applying are not feasible. Therefore, engineering controls, which include closed system or enclosed airplane cockpit, are required to mitigate inhalation exposure for these two scenarios (1c) mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system), and (7) applying granular with aerial equipment. MOEs with engineering controls are greater than 520.

Intermediate-Term Risk Characterization

The estimates for intermediate-term dermal and inhalation risks have not been not combined because dermal and inhalation endpoint effects are different. Target MOE for dermal and inhalation is 100.

Dermal exposures reflecting baseline protective clothing result in MOEs that exceed the Agency's level of concern for seven of 12 scenarios. For these seven scenarios, (1a) intermediate-term, (1b), (1d), (5), (8), (11), and the MOEs ranging from 3 to 84 require additional PPE (double

layer of clothing and chemical resistant gloves) to mitigate exposure/risk. Provided that EPTC intermediate-term dermal exposures are mitigated for the above specified exposure scenarios with PPE, MOEs ranging from 150 to 5,600 do not exceed the Agency's level of concern. Baseline and/or PPE exposure assessments were not performed for two scenarios, because application methodologies other than mechanical mixing/loading/applying are not feasible. Therefore, engineering controls are required to mitigate dermal exposure for scenarios: (1c) mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system), and (7) applying granular with aerial equipment. Although engineering controls for these two scenarios decrease dermal exposure, the estimated MOE of 60 for mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system) exceeds the Agency's level of concern.

Inhalation exposures reflecting baseline protective clothing result in MOEs that exceed the Agency's level of concern for only three of 12 intermediate scenarios, in which MOEs ranged from 40 to 90. For these three scenarios [(1a) mixing/loading emulsifiable concentrate for chemigation; (2b) loading granular for aerial application; and (4) applying dry bulk fertilizer in drop type tractor drawn spreaders at 500 acres per day for all application rates], additional PPE (organic vapor respirator) are required to mitigate exposure/risk. Provided that EPTC intermediate-term inhalation exposures are mitigated for the above specified exposure scenarios with PPE, MOEs ranging from 210 to 320 do not exceed the Agency's level of concern. Baseline and/or PPE exposure assessments were not performed for two scenarios because application methodologies other than mechanical mixing/loading/applying are not feasible. Therefore, engineering controls are required to mitigate inhalation exposure for these two scenarios, (1c) mixing/loading EC formulation for impregnation of dry bulk fertilizer (closed system), and (7) applying granular with aerial equipment. Although engineering controls for these two scenarios decrease inhalation exposure, estimated MOEs are 75 or 83 still exceed the Agency's level of concern.

A number of issues must be considered when interpreting the results of the occupational short- and intermediate-term risk assessment. For example, the acres treated per day may vary depending on the crop and application equipment as follows:

10 acres for commercial ornamental settings using mechanical applications, and 1 acre for hand held equipment, except the push type granular spreader that cover 5 acres;

40 acres for citrus groves rights-of-way sprayer application;
80 acres for drop-type tractor drawn spreader and groundboom applications in an agricultural setting;

350 acres for non-forestry aerial and chemigation applications (including flaggers supporting aerial applications).

For impregnation of dry bulk fertilizer, the total amount of treated fertilizer that can be applied in one day is constant (i.e. the application rate and the area treated vary inversely). For example, 500 acres per day can be treated when fertilizer is applied at a rate of 200 lbs per acre. At a rate of 700 lbs of fertilizer per acre, only 143 acres can be treated in one work day. The number of pounds that

can be mixed and loaded in one day was estimated by the number of 10-ton trucks that can be loaded per hour by one individual. Assuming that five, 10-ton trucks could be filled with treated fertilizer per hour, and that an individual works for eight hours, then 40 trucks (400 tons, or 800,000 lbs) could be loaded per work day.

It must be noted that the unit exposure values for mixing/loading emulsifiable concentrate for impregnation on dry fertilizer were taken from PHED and do not reflect the actual use of the pesticide. The PHED data was determined by loading and mixing fertilizer from bags, not mechanically mixing and loading fertilizer into trucks. For non-agricultural uses, if more than an acre is being treated, the Agency assumes that a push type spreader is typically used for applying a granular or that a rights-of-way sprayer is typically used for applying a liquid. For application to golf course sandtraps, which are believed to occupy an area equivalent to the area of greens, the treated area is assumed to be about 125,000 sq. ft. using a push type spreader, and 43,560 sq. ft. using a belly grinder spreader.

Table 10. Summary of Occupational Handler Dermal Risk for EPTC at Baseline, with PPE, and Engineering Controls

Exposure Scenario (Scenario #)	Short-Term MOE = 300			Intermediate Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	Baseline	PPE	Engineering Controls	
MIXER/LOADER EXPOSURE							
Mixing/Loading Emulsifiable Concentrate for Chemigation (1a)	69	12,000	N/A	3	529	N/A	The number of acres treated/day (350) is a major driver for this exposure
Mixing/Loading Emulsifiable Concentrate for Ground Application (1b)	200-1,600	34,000	N/A	9-72	1,500	N/A	A 6 lb a.i./A max rate and the number of acre treated/day (80) for ag crops (other than citrus, cotton, ornamentals) results in the highest exposures.
Mixing/Loading Emulsifiable Concentrate for Impregnation on Dry Bulk Fertilizer (Closed System) (1c)	N/A	N/A	68,000	N/A	N/A	60-430	Additional mitigation can be achieved by reduction in the amount handled/day or additional information on this use.
Mixing/Loading Emulsifiable Concentrate for Handgun (Hydraulic Sprayer) Application (1d)	400	N/A	N/A	18-72	3,100	N/A	A 6 lb a.i./A max rate and the number of acres treated (40) for non-bearing citrus results in the highest exposures.
Loading Granular in Drop-Type Tractor Drawn Spreader (2a)	69,000	N/A	N/A	3,100	N/A	N/A	N/A
Loading Granular with Aerial Equipment (2b)	24,000	N/A	N/A	1,100	N/A	N/A	N/A
APPLICATOR EXPOSURE							
Applying Spray to the Soil with a Groundboom Sprayer (3)	42,000	N/A	N/A	2,000	N/A	N/A	N/A
Applying Dry Bulk Fertilizer in Drop Type Tractor Drawn Spreader (4)	9,000	N/A	N/A	420	N/A	N/A	N/A
Applying Spray to the Soil with Handgun (Rights-of-Way Sprayer) Application (5)	900	N/A	N/A	40-160	180-720	N/A	A 6 lb a.i./A max rate and the number of acres treated (40) for non-bearing citrus results in the highest exposures.
Applying Granular with a Drop-Type Tractor Drawn Spreader (6)	59,000	N/A	N/A	2,700	N/A	N/A	N/A
Applying Granular with Aerial Equipment (7)	N/A	N/A	125,000	N/A	N/A	5,600	N/A
MIXER/LOADER/APPLICATOR EXPOSURES							
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Low Pressure Hand Wand (8)	190-470	50,000	N/A	8-21	2,300	N/A	Exposure is activity driven; the unit exposure value for handheld equipment is high. Low confidence in hand/dermal baseline and PPE data; no PF applied.
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Backpack Sprayer (9)	7,500	N/A	N/A	340	N/A	N/A	N/A

Exposure Scenario (Scenario #)	Short-Term MOE = 300			Intermediate Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	Baseline	PPE	Engineering Controls	
Loading/Applying Granular with a Push-Type Spreader (10)	1,300	N/A	N/A	58-300	230	N/A	A 15 lb a.i./A max rate on ornamentals results in the highest exposures.
Loading/Applying Granular with a Belly Grinder Spreader (11)	1,900	N/A	N/A	84-250	150	N/A	A 15 lb a.i./A max rate on ornamentals results in the highest exposures.
FLAGGER EXPOSURE							
Flagging Granular Applications (12)	72,000	N/A	N/A	3,200	N/A	N/A	N/A

Table 11. Summary of Short-Term Occupational Handler Inhalation Risk for EPTC at Baseline, with PPE, and Engineering Controls

Exposure Scenario (Scenario #)	Short Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	
MIXER/LOADER EXPOSURE				
Mixing/Loading Emulsifiable Concentrate for Chemigation (1a)	630	N/A	N/A	Exposure is driven by the amount handled; more acreage can be treated by chemigation than with vehicles.
Mixing/Loading Emulsifiable Concentrate for Ground Application (1b)	1,800	N/A	N/A	
Mixing/Loading Emulsifiable Concentrate for Impregnation on Dry Bulk Fertilizer (Closed System) (1c)	N/A	N/A	520	The highest application rate and 200 lb fertilizer/day results in the highest exposure.
Mixing/Loading Emulsifiable Concentrate for Handgun (Hydraulic Sprayer) Application (1d)	3,700	N/A	N/A	
Loading Granular in Drop-Type tractor Drawn Spreader (2a)	1,300	N/A	N/A	
Loading Granular with Aerial Equipment (2b)	440	N/A	N/A	Exposure is driven by the amount handled; more acreage can be treated via aircraft than with ground vehicles.
APPLICATOR EXPOSURES				
Applying Spray to the Soil with a Groundboom Sprayer (3)	3,000	N/A	N/A	
Applying Dry Bulk Fertilizer in Drop Type Tractor Drawn Spreader (4)	290	N/A	N/A	The 6 lb/A rate results in the greatest exposure.
Applying Spray to the Soil with Handgun (Rights-of-Way Sprayer) Application (5)	1,100	N/A	N/A	
Applying Granular with a Drop-Type Tractor Drawn Spreader (6)	1,600	N/A	N/A	
Applying Granular with Aerial Equipment (7)	N/A	N/A	580	Alfalfa 350A - low confidence in hand/dermal & inhalation data.
MIXER/LOADER/APPLICATOR EXPOSURES				
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Low Pressure Hand Wand (8)	2,300	N/A	N/A	

Exposure Scenario (Scenario #)	Short Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Backpack Sprayer (9)	2,300	N/A	N/A	
Loading/Applying Granular with a Push-Type Spreader (10)	2,200	N/A	N/A	
Loading/Applying Granular with a Belly Grinder Spreader (11)	1,100	N/A	N/A	
FLAGGER EXPOSURE				
Flagging Granular Applications (12)	5000	N/A	N/A	

Baseline inhalation unit exposure represents no respirator. Application rates are based on the maximum application rates listed on the EPTC labels. Amount handled per day are from EPA estimates of acres treated, or square feet treated in a 8-hour work day

Table 12. Summary of Intermediate-Term Occupational Handler Inhalation Risk for EPTC at Baseline, with PPE, and Engineering Controls.

Exposure Scenario (Scenario #)	Intermediate Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	
MIXER/LOADER EXPOSURE				
Mixing/Loading Emulsifiable Concentrate for Chemigation (1a)	90	450	N/A	Exposure is driven by the amount handled; more acreage can be treated by chemigation than with vehicles.
Mixing/Loading Emulsifiable Concentrate for Ground Application (1b)	260	N/A	N/A	
Mixing/Loading Emulsifiable Concentrate for Impregnation on Dry Bulk Fertilizer (Closed System) (1c)	N/A	N/A	75-350	The highest application rate and 200 lb fertilizer/day results in the highest exposure.
Mixing/Loading Emulsifiable Concentrate for Handgun (Hydraulic Sprayer) Application (1d)	530	N/A	N/A	
Loading Granular in Drop-Type tractor Drawn Spreader (2a)	170	N/A	N/A	
Loading Granular with Aerial Equipment (2b)	64	320	N/A	Exposure is driven by the amount handled; more acreage can be treated via aircraft than with ground vehicles.
APPLICATOR EXPOSURES				
Applying Spray to the Soil with a Groundboom Sprayer (3)	430	N/A	N/A	
Applying Dry Bulk Fertilizer in Drop Type Tractor Drawn Spreader (4)	40-300	210	N/A	The 6 lb/A rate results in the greatest exposure.
Applying Spray to the Soil with Handgun (Rights-of-Way Sprayer) Application (5)	160	N/A	N/A	
Applying Granular with a Drop-Type Tractor Drawn Spreader (6)	230	N/A	N/A	

Exposure Scenario (Scenario #)	Intermediate Term MOE = 100			Input Parameters and Potential Mitigation Measures
	Baseline	PPE	Engineering Controls	
Applying Granular with Aerial Equipment (7)	N/A	N/A	83	Alfalfa 350A - low confidence in hand/dermal & inhalation data.
MIXER/LOADER/APPLICATOR EXPOSURES				
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Low Pressure Hand Wand (8)	340	N/A	N/A	
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil a with Backpack Sprayer (9)	340	N/A	N/A	
Loading/Applying Granular with a Push-Type Spreader (10)	320	N/A	N/A	
Loading/Applying Granular with a Belly grinder Spreader (11)	160	N/A	N/A	
FLAGGER EXPOSURE				
Flagging Granular Applications (12)	720	N/A	N/A	

Baseline inhalation unit exposure represents no respirator. Application rates are based on the maximum application rates listed on the EPTC labels. Amount handled per day are from EPA estimates of acres treated, or square feet treated in a 8-hour work day.

c. Residential Handler Risk Characterization

Because different endpoint effects were selected for the assessment of residential dermal and inhalation risks, separate risk assessments were conducted for dermal and inhalation exposures. MOEs for residential handlers were derived based upon comparison of dermal exposure estimates against a LOAEL of 200 mg/kg/day for short-term exposure. The short-term LOAEL is from a neurotoxicity study in the rat (oral administration). Therefore, the absorbed fraction of each dose was calculated in order to convert to an equivalent oral dose using a dermal absorption factor of 5%. MOEs were also derived based upon comparison of inhalation exposure estimates against a NOAEL of 58 mg/m^3 which translates to 15.1 mg/kg/day. The uncertainty factors and target MOEs for residential populations (including the 10x FQPA safety factor) are 3000 for short-term dermal risk and 1000 for short-term inhalation risk.

Details of the residential handler short-term dermal and inhalation risk estimates are shown in th following table. **Dermal** exposures do not exceed the Agency's level of concern for three of the four residential handler scenarios. Application of granular formulations with a push-type spreader, by hand/spoon, and by shaker can result in margins of exposure (MOEs) ranging from **5,700 to 81,000.** Application with a belly grinder spreader, however, results in an MOE of **2,200** which exceeds the Agency's level of concern. In order to be eligible for reregistration the registrant will be required to drop the residential handler use of the belly grinder spreader. **Inhalation** exposures do not exceed the Agency's level of concern for any residential handler scenario; MOEs ranged from **15,000 to 150,000.**

Table 13. Residential Handler Short-term Dermal and Inhalation Risk to EPTC at Baseline.

Exposure Scenario (Scenario. #)	Crop/Use	Baseline Dermal		Baseline Inhalation	
		Daily Dose (mg/kg/day)[a]	Short-term MOE[b]	Daily Dose (mg/kg/day)[c]	Short-term MOE[d]
MIXER/LOADER/APPLICATOR EXPOSURE					
Loading/Applying Granular with a Push-Type Spreader (1)	Ornamentals	0.0025	81,000	0.00010	150,000
Loading/Applying Granular with a Belly grinder Spreader (2)	Ornamentals	0.090	2,200	0.0010	15,000
Loading/Applying Granular by Hand/Spoon (3)	Ornamentals	0.040	5,700	0.0008	20,000
Applying Granular Shaker Can (4)	Ornamentals	0.03	7,100	0.0003	47,000

[a] Daily Dermal Dose (mg/kg/day) = (Daily Dermal Exposure (mg/day) / Body Weight (70 kg)) x Absorption Factor (5%).
[b] Short-term Dermal MOE = LOAEL (200 mg/kg/day) / Daily Dermal Dose (mg/kg/day) . The acceptable MOE value is 3000.
[c] Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day) / Body weight (70kg).
[d] Short-term Inhalation MOE = NOAEL (15.1 mg/kg/day) / Daily Inhalation Dose (mg/kg/day). The acceptable value is 1000.

Residential Postapplication Risk Characterization

Details of the postapplication risk estimates are presented in the following table. Incidental ingestion of EPTC treated soil is not a risk concern for toddlers playing in treated areas. However, the estimated ingestion of granules in treated areas by a toddler based on standard assumptions from the Draft Residential SOPs results in an MOE of 570 which greatly exceeds the Agency's level of concern. While it is the Agency's policy to routinely conduct screening level assessments for incidental ingestion of granules from treated areas, the Agency believes a toddler's exposure to EPTC granules may be outside the scope of concern because of the small formulation particle size.

Based on information provided by the registrant on the particle density of the 2.3% a.i. granular EPTC formulation, the Agency believes that there is little exposure potential for children's ingestion of EPTC granules. The particle size is relatively small and if used according to label directions and soil incorporated, it is unlikely that EPTC granules would be accessible to a child. The Agency estimates that fewer than 50 EPTC granules, if eaten, would result in adverse effects. However, the Agency also recommends that the potential for children's exposure to EPTC granules be further minimized by an additional labeling which states, " Keep off sidewalks, driveways, patios, or similar surfaces.

Table 14. EPTC Residential Post-Application Scenarios and Estimated Risks.

Exposure Scenario (Scenario #)	Receptor	Application Rate Per Treatment (AR) (lbs a.i./A)	SR_t (μg/g)[a]	IgR (g/day) or (mg/day)[b]	F (a.i.)	BW (kg)	ADD (mg/kg/day)[c]	MOE[d]
Eating Granules in Treated Areas	Toddler	5.0	_	0.23	0.023	15	0.35	570
Soil Ingestion in Treated Areas	Toddler	5.0	38	100	_	15	0.00025	790,000

[a] Soil residue (μg/g) = [AR (lbs a.i./A) * fraction a.i. retained on soil (1.0/cm) * 4.54E+8 μg/lb * 2.47E-8 A/cm^2 * 0.67 cm^3/g soil]

[b] Ingestion rate: g/day for granular ingestion, and mg/day for incidental soil ingestion.

[c] Average daily dose (ADD) (mg/kg/day)

Granular ingestion: = [F * IgR (g/day) * 1,000 mg/g] / [BW (kg)]; and

Incidental soil ingestion: = [SRt (μg/g) * IgR (mg/day) * g/1,000,000 μg] / [BW (kg)].

[d] MOE = LOAEL (200 mg/kg/day) / ADD.

d. Cumulative Effects

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information that may be used for determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be available at present.

The Agency is examining whether and to what extent some or all organophosphate and carbamate (including, but not limited to, methyl carbamate, N-methyl carbamate, thiocarbamate, and di thiocarbamate) pesticides may share acetyl cholinesterase inhibition as a common mechanism of toxicity. In contrast to the methyl and N-methyl carbamates, the Agency has a less fully developed understanding of whether the thiocarbamates share acetyl cholinesterase inhibition as a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. While current data are limited, the thiocarbamates appear to be comparatively weak cholinesterase-inhibitors and are generally regulated based on other toxic endpoints. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other such chemicals (e.g., the organophosphate and carbamate pesticides) [see the August 31, 1999, EPA Memorandum entitled *September 1999 Meeting of the FIFRA Science Advisory Panel: Working Documents for the Session: "Proposed Guidance for Conducing Cumulative Hazard Assessments for Pesticides that Have a*

Common Mechanism of Toxicity" and "*The Carbamate Pesticides and the Grouping of Carbamate with the Organophosphate Pesticides*"]. Also see 40 CFR section 180.3(e)(5), which presents the Agency's initial grouping of chemicals that would be considered together for the purpose of tolerance reassessment. This grouping includes some carbamate pesticides but not thiocarbamate pesticides as members of the class of acetyl cholinesterase-inhibiting compounds.

In September 1999, the Agency presented a paper (cited above) on the common mechanism of toxicity of the carbamate pesticides to the SAP. In that presentation, the Agency noted that although various classes of compounds may inhibit acetyl cholinesterase, the potency, reversibility, and related factors may influence whether or not related pesticides should be included in a cumulative risk assessment. The Agency is currently awaiting a report from the SAP.

At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether EPTC, a thiocarbamate, shares a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. Therefore, for the purposes of this tolerance reassessment, the Agency has assumed that EPTC does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals.

e. Aggregate Risk Assessment

Aggregate exposure assessments for EPTC consist of dietary exposure (food and drinking water routes) and residential exposure (dermal for homeowner applicators, and incidental oral exposure for toddlers resulting from hand-to-mouth behavior.) Aggregate risk assessments were conducted for acute (1 day), short-term (1-7 days), and chronic (lifetime) exposure.

Acute Aggregate Risk

Acute aggregate risk estimates do not exceed the Agency's level of concern. The aggregate acute dietary risk estimates include exposure to EPTC residues in food and water and does not include dermal and incidental oral exposure. Exposure (food only) to combined residues of EPTC and its metabolites of toxicological concern based on an upper-bound analysis using tolerance-level residues and assuming 100% of crop treated, represents 87.5% of the acute PAD for the most highly exposed population subgroup (children 1-6 years). Exposure to all other groups represents less than 62.4% of the acute PAD. Using conservative screening-level models, the estimated maximum peak concentrations of EPTC in surface water is 57 μg/L. This estimated peak concentration is less than the Agency's drinking water level of comparison for exposure to EPTC in drinking water as a contribution to aggregate acute dietary risk. Based on the available information, the Agency concludes with reasonable certainty that no harm to any population will result from acute dietary exposure to EPTC.

Short-Term Aggregate Risks

Short-term aggregate risk estimates do not exceed Agency's level of concern. Short term aggregate risk estimates for adults include exposure to EPTC residues in food, water, and high-end

exposure estimates for non-occupational use in residential settings (applying granules by hand/spoon). Although short-term dermal and inhalation exposures are anticipated during handling and applying EPTC, the endpoint effect selected for inhalation risk differs from the endpoint effect selected for dermal and oral risk. Therefore, the inhalation route of exposure does not contribute to the aggregate risk estimate. Short-term aggregate risk estimates for infants/children include exposure to EPTC residues in food, water, and from inadvertent oral soil ingestion resulting from hand-to-mouth behavior.

In the case of EPTC, the doses, endpoints, and uncertainty factors selected for short-term dermal and non-dietary inadvertent oral exposure are the same as those selected for the acute dietary oral (food and water) exposures. Thus, calculation of the short-term DWLOC is as follows:

Solving for the short-term (ST) water exposure and the $_{DWLOCs}$ for infants/children and adults, we have:

Where, the Acute PAD = 0.067 mg/kg/day, given the information above on exposure, then

Adult Male Short-term water exposure = 0.067 mg/kg/day - [(0.00026769 + 0.04) mg/kg/day] = 0.026731 mg/kg/day

$_{DWLOCS}$ = [0.026731 mg/kg/day x 70 kg bwt] ÷ [2 L/day x 1 E-3 mg/μg] = 937 μg/L (ppb)

Children 1-6 Short-term water exposure = 0.067 mg/kg/day - [0.000516 +0.0003 mg/kg/day = 0.066315 mg/kg/day

$_{DWLOCS}$ = [0.066234 mg/kg/day x 10 kg bwt] ÷ [1 L/day x 1 E-3 mg/μg] = 663 μg/L (ppb)

As shown in the following table, the drinking water estimated concentrations in both ground water (Sci-Grow estimated 1.84 μg/L) and surface water (PRZM-EXAMS estimated 3.44 μg/L annual average) are below the Agency's DWLOCs for EPTC for all populations. Therefore, there are no concerns for short-term aggregate exposure.

Table 15. Drinking Water Levels of Comparison for Short-term Aggregate Exposure

Population	PRZM-EXAMS (μg/L)	SCI-GROW (μg/L)	aPAD (mg/kg/day)	Average Food Exposure (mg/kg/day)	Residential Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	$DWLOC_{short-term}$ (μg/L)
Adult Male	3.44	1.84	0.067	0.000231	0.04	0.026769	937
Adult Female	3.44	1.84	0.067	0.000229	0.04	0.026771	803
Children 1-6	3.44	1.84	0.067	0.000435	0.0003	0.066315	663

Chronic (Non-Cancer) Aggregate Risk

Chronic (non-cancer) aggregate risk estimates do not exceed the Agency's level of concern. The aggregate chronic dietary risk estimates include exposure to EPTC residues in food and water. No chronic residential use scenarios were identified. Exposure (food only) to combined residues of EPTC and its metabolites of toxicological concern, based on a Tier 3 refinement using average residues from field trial and percent of crop treated data, represents 17.4% of the chronic PAD for the most highly exposed population subgroup (children 1-6 years).

Exposure to all other groups represents less than 14.8% of the chronic PAD. Using conservative screening-level models, the estimated maximum mean of annual means of EPTC in

surface water is 3.44 μg/L. This estimated average concentration is less than Agency's drinking water level of comparison for exposure to EPTC in drinking water as a contribution to aggregate chronic dietary risk. Based on the available information, the Agency concludes with reasonable certainty that no harm to any population will result from chronic dietary exposure to EPTC.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

Birds

EPTC is essentially non-toxic to birds on an acute basis. In all acute and subacute tests, little or no mortality occurred at the highest test levels. Therefore, for risk assessment purposes, acute risk will be assessed using either an LD_{50} of >2,510 mg/kg (for granular formulations) or a dietary LC_{50} of >5,280 ppm (for spray formulations).

It is assumed that if exposure does not approach or exceed levels at which little or no mortality occurred, acute lethal effects are unlikely.

No chronic toxicity data are available for birds. However, because EPTC may be applied more than once per season, avian reproductive testing is required.

Mammals

EPTC does cause some acute lethal effects to mammals, with LD_{50} s ranging from 916 mg/kg and up. The LD_{50} of 916 mg/kg is used to assess possible acute lethal risks to mammals from granular uses.

To assess acute risk from sprays, the mammalian acute oral LD_{50} is used to estimate a 1-day LC_{50} in ppm dietary concentration. This estimation takes into account how much a mammal eats in one day which is expressed as a proportion (percent) of body weight. The following formula is used:

$$\text{1-day } LC_{50} \text{ (ppm)} = \frac{LD_{50} \text{ (mg/kg)}}{\text{proportion of body weight consumed per day}}$$

For example, if a small mammal (15 gram or 0.015 kg) is assumed to eat close to its body weight per day (i.e. 0.95 [95% of its body weight), the 1-day dietary LC_{50} would be: 916 (LD_{50} in mg/kg) /0.95 (proportion body weight consumed) = 964 ppm (1-day dietary LC_{50})

This value represents the concentration that would have to be in the diet of a mammal in order to achieve the LD_{50} of 916 mg/kg within one day of eating. This 1-day LC_{50} is then compared to estimated maximum dietary residues in the field. If estimated residues exceed ½ (0.5) the 1-day LC_{50}, the Agency assumes there is a high possibility of acute risk to mammals.

Using a food consumption factor of 0.95 yields a relatively conservative estimate of a 1-day LC_{50}, and larger animals that eat a lower proportion of their body weight per day would have proportionately higher 1-day LC_{50} values. For example, using the same LD_{50}, a mammal that consumes 15% of its body weight per day, would have a calculated 1-day LC_{50} of approximately 6,100 ppm. 916 (LD_{50} in mg/kg) / 0.15 (proportion of body weight) = 6,107 ppm (1-day dietary LC_{50}).

To assess acute risk from granular formulations, the LD_{50} is compared with the mg a.i./square foot. If the mg a.i./square foot exceed ½ the LD_{50} for an individual, the Agency assumes there is a high potential for acute risk. In the calculation shown above, the LD_{50} for a 15 gram mammal was estimated to be about 14 mg/animal (16 mg/kg X 0.015 mg animal = 13.7mg/animal).

To assess sublethal risk to mammal, the rat 2-generation reproduction study is used. The results showed no reproductive effects or lethality at the highest test level of 800 ppm. However, there were sublethal effects to the adult rats at 200 ppm. The effects were reduced body weight and degenerative cardiomyopathy. While these are not reproductive effects, they are effects that could result in adverse impacts to individuals in the field. Therefore, for assessing potential for sublethal risks to mammals, a NOAEL of 50 ppm will be used.

Beneficial Insects

The LD_{50} for bees is >12.09 ug/bee. Since the LD_{50} s are greater than 11 ug/bee, EPTC is relatively non-toxic to bees on an acute contact basis.

b. Toxicity to Aquatic Animals

EPTC is slightly toxic to fish, with LC_{50} s from several tests ranging from 14 ppm to 27 ppm. The LC_{50} of 14 ppm will be used to screen for possible acute risks to fish.

EPTC is moderately toxic to aquatic invertebrates, with EC EC_{50} s ranging from 6.5 ppm to 66 ppm. The EC EC_{50} of 6.5 ppm will be used to screen for possible acute risks to aquatic invertebrates.

While there are adequate data to assess the potential for acute risk to fish and aquatic invertebrates, there are no chronic data for either fish or invertebrates. These tests are required, since EPTC is applied more than once per season and is likely to get into surface water

Furthermore, many EPTC uses are in coastal counties, resulting in potential exposure to marine species. Testing with marine fish, shrimp, and mollusks is required.

c. Toxicity to Terrestrial Plants

Ten species (four monocot and six dicot species) were tested in two kinds of terrestrial plant tests; vegetative vigor studies, and seedling emergence studies. The toxicity test results (EC_{25} and

EC_{05}) from the most sensitive representative are used to assess risk to terrestrial plants. The EC_{25} is used to assess risk to plants in general, and the EC_{05} is used to assess risk to endangered plant species. The EC_{05} is a smaller number than the EC_{25} and represents a more sensitive endpoint; the goal being to be more protective of endangered plants than for plants in general.

Usually, the plant species with the lowest EC_{25} is also the plant species with the lowest EC_{05}. However, in the case of the EPTC vegetative vigor studies, the plant test yielding the lowest EC_{25} (winter wheat, EC_{25}=0.22 lb a.i./acre) did not yield the lowest EC_{05}(EC_{05}=0.087 lb a.i./acre). Therefore, to assess possible effects to endangered species, an EC_{05} from velvet leaf (EC_{05}= 0.023 lb a.i./acre) was used.

Table 16. Showing the test results for terrestrial plants that are used in this risk assessment.

Species	Test Type / effect	EC_{25} lb a.i./acre*	EC_{05} lb a.i./acre
Wild Oats (monocot)	seedling emergence/ phytotoxicity	0.10	0.017
Winter wheat (monocot)	vegetative vigor/ phytotoxicity	0.22	Not used
Velvet leaf (dicot)	vegetative vigor/ phytotoxicity	Not used	0.023

The vegetative vigor study results, in which foliage of actively growing plants were sprayed with EPTC doses, are used for assessing risk to plants from foliar exposure (drift) only. The seedling emergence study results, where seeds are grown in soil which has been treated with EPTC, are used to assess risk from runoff and drift.

Toxicity to Aquatic Plants

To assess the potential for risk to aquatic plants, the green alga EC_{50} of 1.36 ppm, and the duckweed EC_{50} of 5.6 ppm were used.

2. Environmental Fate

a. Environmental Fate Assessment

Soil metabolism and volatilization from soil and water are the most important dissipation pathways for EPTC in the environment. Because the metabolism and volatilization of EPTC can occur simultaneously, it is difficult to evaluate them independently. Abiotic hydrolysis, and direct photolysis and photo degradation are not significant degradation pathways for EPTC on soil. Although it is suspected that EPTC is degraded microbially in water, data have not been submitted to confirm this. Environmental fate properties are summarized in table below. The primary environmental (soil/water) degradates are EPTC-Sulfoxide and dipropylamine.

Possible soil and water degradates(including EPTC sulfoxide (ESO)(3.4% of applied), EPTC sulfone (2%), N,N-dipropylformamide (1.9%) , dipropylamine (35.7%), and ethanesulfonic acid (unlabeled fragment- 5.4% radioactivity) were identified in photolysis study determined to be

unacceptable by the Agency due to using a light type (black light) that did not correspond to sunlight light spectrum. In the terrestrial field dissipation studies, only two degradates were detected in soil samples: EPTC-sulfoxide, and di-n-propylamine (dipropylamine). EPTC-sulfoxide (ESO) (maximum = 6% of total residues, 0.36 ppm) was identified in an aerobic soil metabolism study.

Table 17. Summary of key environmental fate properties.

Fate Property	Value
Terrestrial Field Dissipation Half-life	2 to 18.8 days; mean 8.6 days
Henry's Law Constant	1.1 x 10^{-5} m^3 - atm/g-mol @20°C
Aerobic soil metabolism half-life	10.3 to 36.9 days; mean = 24.17 days (nonlinear) 36.5 to 74.9 days; mean = 58.55 days(ln-transformed) bi-phasic 1st phase: 12.7 to 27.7 days 2nd phase: 73.0 to 127 days
Anaerobic soil metabolism half-lives	31 to 127 days; mean = 73.1 days
Abiotic and Direct Photolysis	Stable
Hydrolysis @ pH 5, 7, 9	Stable
Soil/Water Partition Coefficient:K_d/K_{oc}	0.77 to 2.99/136 to 264

A number of submissions by the registrant in addition to open literature have been used to develop the environmental fate assessment for EPTC. These submissions were reviewed, evaluated and summarized. The environmental fate data base is incomplete, but is sufficient to allow for an environmental fate assessment of parent EPTC that generally fits the pattern suggested by the monitoring data which are available.

Soil metabolism and volatilization from soil are the most important dissipation pathway, for EPTC in the environment. EPTC is highly volatile (vapor pressure 1.60 x 10^{-2} mm Hg @ 20°C, Henry's Law Constant ~1 x 10-5 m^3 - atm/g-mol @ 20°C). EPTC is readily lost from the soil by volatilisation when applied, and is not immediately incorporated into the soil. The rate at which a chemical volatilizes from th3e soil is affected by any factors, such as soil properties, chemical properties, and environmental conditions. Microbes attack sites on thiocarbamates which possibly include the alkyl groups, the amide, and the ester linkages. Results from laboratory tests are inadequate to determine the relative rates of metabolism and volatilization.

Terrestrial field dissipation studies indicate that EPTC is generally not very persistent with dissipation half-lives ranging from 2 to 18.8 days (mean 8.6 days). However, since volatilization was not measured during these field studies, the contribution of volatilization to the dissipation of EPTC could not be determined. Volatilization appears to be an especially significant dissipation pathway the first few days after application. Other studies (field and laboratory) that measured the volatilization of EPTC, with traps, suggested that significant quantities of EPTC were lost through volatilization. The Agency requires that the registrant submit data to assess volatilization under typical field use conditions.

Laboratory tests to measure the aerobic soil degradation (dissipation) rates indicated that half-lives (ln-normal transformed linear regression) of 36 to 75 days, or (DT50s) or half-lives (untransformed non-linear regression) of 10 to 37 days. The rate of EPTC degradation decreases with time. By estimating the degradation rates (or half-lives) for the first or second portions (time) of the lab studies, the half-lives range from 13 to 28 days, and 73-127 days, respectively. Anaerobic soil metabolism studies suggest that EPTC is somewhat more persistent under anaerobic conditions with half-lives of 31 to 127 days.

EPTC has low affinity for binding to soil (K_{OC}s < 264) suggesting a potential to leach. However, because EPTC generally does not persist long in soils, the potential to leach to ground water is greatly reduced. Microbial degradation and volatilization are important dissipation pathways, however, the rate of these processes will decrease with increasing depth below the soil surface. Limited or no leaching of EPTC was noted in the terrestrial field dissipation studies. Few detections of EPTC were noted in ground-water monitoring studies. In unaged leaching columns, 9 percent of applied EPTC was found in leachate of loam and clay loam soils, and 55 and 78 percent were found in leachate for loamy sand and sandy loam soils, respectively. In aged soil columns, an average of 22% of the parent was detected in the leachate. Less than 0.01 percent of applied radio labeled (^{14}C) found in the leachate was attributed to degradates. Considering the information available, the Agency does not believe that significant levels of EPTC will reach ground water.

In a laboratory photolysis study, the identified soil degradates include EPTC sulfoxide (ESO), EPTC sulfone, N,N-dipropylformamide, dipropylamine, and ethanesulfonic acid. In the terrestrial field dissipation studies, two degradates were detected in soil samples: EPTC-sulfoxide, and di-n-propylamine. The fate of the degradates is not considered adequately in this assessment due to inadequate environmental fate data. However, limited data indicates that the EPTC degradates are less persistent than the parent. EPTC-sulfoxide was found in an aerobic soil metabolism study to be no greater than 6% (0.36 ppm) of applied EPTC. In a column leaching study, less than 0.01 percent of applied radio labeled EPTC in the leachate was a degradate. Several of the field dissipation studies provide limited information on the degradates ESO (0.23 ppm max) and di-n-propylamine (0.074 ppm max).

The degradates dropped below the limit of detection (0.01 ppm) by 61 days after application. The only degradate identified in the anaerobic soil metabolism study was ESO sulfoxide (0.01 ppm). Half-lives were estimated by the registrant to be 7 and 13-14 days, respectively , for dipropylamine and ESO. The field dissipation studies, metabolism studies, and the leaching studies suggest that the EPTC degradates are less mobile and generally less persistent than parent EPTC, since the degradates represent less than a percent of the applied EPTC. This conclusion is arrived at more from the weight of evidence rather than any direction measurements. The measurement of soil/water partition (K_d) coefficients for the degradates would provide more certainty.

b. Environmental Fate and Transport Data

The registrant has suggested that the first step in the metabolic breakdown of EPTC in soils appears to be oxidation to the sulfoxide (ESO). Additional sulfur and carbon oxidation

(hydroxylation) leads to the formation of dipropylamine. Oxidation of the N-alkyl carbon side chain is supported by the release of $^{14}CO_2$ from EPTC, ESO, and the amine. The registrant reports that others have proposed that a minor pathway in the metabolism is N-alkyl hydroxylation and the subsequent dealkylation. Sulfoxidation followed by the release of carbamic acid has been proposed as a major metabolic pathway in soil. The dealkylated products (not detected in registrants studies) are metabolized to $^{14}CO_2$ in the soil. In the terrestrial field dissipation studies, two degradates were detected in soil samples: EPTC-sulfoxide and di-N-propylamine. Hydrolysis, photolysis, and sorption are not significant dissipation pathways for EPTC.

Degradation

Based upon a limited number of registrant-sponsored studies, EPTC does not appear to be subject to abiotic hydrolysis, under the conditions of these studies. Therefore, hydrolysis does not appear to be a significant dissipation pathway for EPTC.

The potential for EPTC to degrade through hydrolysis was determined by the registrant. Solutions of EPTC (90 ppm) were prepared with bacteria free water buffered at pH 5.0, 7.0, and 9.0. Aliquots of each solution were transferred to individual tubes, and incubated for 30-days in the dark at 25°C and 40°C ($\pm$ 0.5°C) in water baths . Analytical results at both temperatures and at each pH showed that no hydrolysis of EPTC (no hydrolytic loss of EPTC) occurred at either temperature or either pH. Further there was no loss of EPTC in the Aqueous Photolysis Study.

Based upon a limited number of registrant-sponsored studies, EPTC does not appear to be subject to direct photolysis, under the conditions of these studies. Therefore, direct photolysis does not appear to be a significant dissipation pathway for EPTC. EPTC was determined to photolytically stable ("no appreciable disappearance of ^{14}C-EPTC occurred") to photolysis in water, based upon a study determined to be acceptable and valid by the Agency.

Three studies to ascertain the direct photolysis rate of EPTC in water were submitted to the Agency. One was determined to be acceptable, one was determined to be supplemental, and the third was determined to be invalid. EPTC did not photo degrade in sealed quartz tubes when continuously irradiated with a xenon lamp at 25°C for 13.8 days, in the valid, acceptable study. EPTC accounted for 94 to 103 percent of the radioactivity in the irradiated samples, and 97 to 100 percent in the dark controls. The registrant indicated that the 13.8 days of continuous, irradiation with the xenon arc lamp was equivalent to 33.2 days of natural sunlight. Possible water degradates including EPTC sulfoxide (ESO)/(3.4% of applied), EPTC sulfone (2%), N,N-dipropylformamide (1.9%), dipropylamine (35.7%), and ethanesulfonic acid (unlabeled fragment- 5.4% radioactivity) were identified in a photolysis study determined to be unacceptable by the Agency using a light spectrum (black light) that did not correspond to natural sunlight.

EPTC was shown to be stable to photodegradation on soil in an acceptable study submitted to the Agency. Therefore, photo degradation on soil does not appear to contribute significantly to the disappearance of EPTC.

Radio labeled (^{14}C)EPTC applied to a loamy soil surface did not photo degrade when continuously irradiated with a xenon lamp at 25°C for 31 days. Parent EPTC comprised 90.8 to 102 percent, and 83 to 101 percent of the applied radioactivity in the irradiated and dark control samples, respectively. Most of the radioactivity ($\geq$ 94.5% of the applied) was extracted from the sample with acidified methanol. Approximately 0.2 percent was recovered as unextracted, 1.5 percent was recovered from ethylene glycol and sulfuric acid traps, and 0.34 to 1.3 percent was recovered from the KOH traps. Material balances were 99.2 to 104 percent of the initial material.

Outstanding Issues

Several questions or points needing additional clarification were identified in the Agency review. The registrant is required to respond to these items. Issues include why there was essentially no volatilization radioactivity study, when EPTC is so volatile. A contradiction between the analysis of some soil properties of the Keeton sandy loam also needs to be addressed.

The Agency determined that the photolysis in air data requirement was not met by the submission of a scientific publication (Kwok et al., 1992). The study was not long enough (single sampling); thus, no conclusions about the atmospheric half-life could be made. The study authors concluded that oxidation by OH^- radicals are the dominant atmospheric loss processes, once EPTC enters the atmosphere through volatilization. Study authors report that there was no atmospheric decay of gas-phase concentrations in air in the dark over 4 hours. The data indicated that in light EPTC would have a short atmospheric lifetime of less than 1 day, due to its reaction with OH^- radicals in the atmosphere.

In the atmosphere, EPTC will remain mostly in the vapor phase. Non validated data suggests that the vapor phase of EPTC degrades rapidly by reacting with photochemically produced hydroxyl radicals (half-life estimated to be 14 hrs). Physical removal from the atmosphere also occurs through wet deposition. Thus, EPTC appears to have the potential to be transported offsite via in the vapor phase, because it was one of a number of pesticides found in more than 25 percent of the rain samples collected in three watersheds in Minnesota (Minnesota Dept. of Agriculture, 2/24/99 SFIREG Water Quality and Pesticide Disposal Working Committee). The Agency previously also determined that air photolysis study was not required, at this time, but be placed in reserve, because the study may be determined to be necessary at a future time.

The registrant conducted several studies to address the aerobic soil metabolism data requirement. Aerobic soil metabolism of EPTC does not appear to follow the natural log (ln) transformed first-order reaction rate equation ($\ln C(t) = \ln C_o - kt$) very well over the entire study duration. Instead, it appears to follow a "bi-phasic" pattern. The registrant and the Agency's scientists previously determined two loss rates (or half-lives) of EPTC using linear regression on ln-transformed data. Thus, the steeply sloping portion of the concentration versus time curve (initial times) was analyzed separately from the flatter portion (later times) of the curve. The steeper portion of the curve was defined as the initial phase, and the flatter portion of the curve was defined as the secondary.

For this assessment, half-lives and decay rates of EPTC were determined using data from the entire duration, of each study. The decay rate of EPTC appears to follow pseudo first-order type kinetics throughout the study duration when nonlinear regression is applied to the untransformed form of the equation, ($C=C_oe^{-kt}$) where C_o is the initial concentration, C is concentration, t is time, and k is the decay rate constant. The parameter k was estimated by non-linear regression of C versus time. The decay rate constant (k) was also estimated using linear regression on the log-normal transformed data.

Table 18. Summary of degradation rate constants and estimated half-lives for EPTC in three soils and upper 90th confidence bounds.

Soil	"Ln-normal transformed First-Order" Degradation Rate Constants - k (day^{-1}) (coefficient of determination) and Half-life (days) for EPTC by phase duration[1].	
	Initial[1] [phase duration]	Secondary[1] [phase duration]
Keeton sandy loam[2]	0.0547 (0.96); 12.7 [0-31d]	0.0054 (0.98); 127.4 [31-205d]
Sorrento loam[2]	0.0250 (0.97); 27.7 [7-31d]	0.0095 (0.98); 73.0 [31-205d]
Atterberry silt loam[2]	0.0324 (0.98); 21.4 [7-80d]	na[4]; 60.8
Keeton sandy loam[3]	0.0254 (0.96); 27.3 [0-63d]	0.0048 (0.95); 143 [63-314d]
	Data from entire duration of study included.	
	Pseudo First-order Integrated average ($C(t) = C_oexp(-kt)$ k ($days^{-1}$); Half-life (days)	Ln transformed Pseudo !st-order $\ln C(t) = \ln C_o - kt$ k ($days^{-1}$); Half-life (days)
Keeton sandy loam[2]	0.067292 (0.96); 10.3	0.01170 (0.63); 59.2
Sorrento loam[2]	0.018772 (0.96); 36.9	0.01090 (0.95); 63.6
Atterberry silt loam[2]	0.030297 (0.99); 22.8	0.01900 (0.93); 36.5
Keeton sandy loam[3]	0.026070 (0.93); 26.6	0.00925 (0.79); 74.9
$Rate_\alpha = mean \pm t_\alpha * (std/\sqrt{4})$ $Rate_{0.9} = 24.17 + 2.353*(10.99/\sqrt{4}) = 37.08$ days (0.0187 $days^{-1}$) - Non-linear $Rate_{0.9} = 58.55 + 2.353*(16.12/\sqrt{4}) = 77.49$ days (0.0089 $days^{-1}$)) - Ln-transformed		

1. EPTC initially declined at a faster rate followed by a slower decline rate. The registrant consider the two rate class as phase. Phase duration represents the period of the study considered in each phase.
2. MRID Numbers 42120805 and 42120806.
3. MRID Number 40420402
4. na - Rate constant provided but appears to be the slope of a line between 2 data only.

Due to differences in soils chemical and physical properties, differences in microbial populations, and experimental conditions, the degradation of EPTC doesn't result in a unique degradation (dissipation) rate, but results in a range of values.

The decay rate constants, k, were used to determined the half-lives (rate = ln2/half-life) or DT50. The half-life and DT50 are equivalent when conducting a linear regression on ln-transformed data or non-linear regression on untransformed data, when using the "pseudo" first order kinetics model. Depending upon which method was used, the half-life values ranged 10.3 to 74.9 days. The

calculated coefficients of determination were closer to 1.00 for the non-linear regression (0.93-0.99) compared to the transformed linear regression (0.63-0.95).

The first study was conducted to obtain information on both aerobic and anaerobic soil metabolism. The same soil (Keeton sandy loam from CA) was used for both "redox" conditions. The Agency determined that this aerobic soil metabolism study did not satisfy data requirements. Several recommendations were made as to what information would need to be submitted so that the data requirement could be fulfilled. This study was determined to provide supplemental information concerning the metabolism and volatilization of EPTC

The registrant proposed that EPTC degraded and volatilized in aerobic soil at two rates. The first rate suggested that EPTC degrades rapidly, with a first half-lives of 14 to 21 days (half-life 17 days) (ln-normal transformation). A second, slower rate of degradation also was determined to occurs between 30 and 63 days (half-life 47 days) after 80% of original parent had dissipated was also suggested. The Agency noted that the data indicates that the aerobic soil half-life of EPTC would be longer than 17 days. A half-life of 74.9 days was estimated, using all the data, assuming that the ln-normal first-order degradation rate model was correct.

The decay rate of EPTC appears to fit better a pseudo first-order type ($C=C_oe^{-kt}$) relationship without transforming the data as indicated by the coefficient of determination ($r^2 = 0.93$). The estimated rate of decline is 0.026068 $days^{-1}$ ($T_{1/2}$ = 26.6 days). The half-lives were calculated from the EPTC residues extracted from soil, and about 45% of the applied radioactivity had volatilized as parent by day 30. Volatilization was rapid, much of the volatilization occurred during the first seven days. Although the decline in EPTC soil residues appears to support the reported half-life of 26.6 days, volatilization contributed more to the initial decline than aerobic soil metabolism (as measured by CO_2 and $^{14}CO_2$ production).

EPTC sulfoxide (ESO) was the only degradate identified by TLC, with the average concentration reaching its highest value at 14 days (5.6% of applied, 0.33 ppm), and then decreased to 0.07 ppm (1.2%) at 63 days. In an associated study, the registrant added two degradates of EPTC (ESO and dipropylamine). The registrant indicated that the apparent half-life values for EPTC, dipropylamine, and ESO were reported as 22-26 days, 7 days, and 13-14 days, respectively, in the Bethany soil (stated to be from IL, no other data reported). These results indicate that ESO and dipropylamine are less persistent than EPTC in the study.

Two additional aerobic soil metabolism studies submitted by the registrant were determined to be scientifically valid and provide additional information. Half-life values were obtained in a manner similar to that discussed for the previous study. These studies indicated that EPTC degraded and volatilized much more rapidly in the first phase (early part of study) in three soils under an aerobic soil environment. Half-lives ranged from between 12.7 and 27.7 days for the first phase. Slower rates of degradation (half-lives 60.8 to 127.4) were determined in the second phase (r^2s = 0.95-0.98). The EPTC sulfoxide degradate, ESO, was the only degradate identified which never accounted for more than 6 percent (0.36 ppm) of the total residues.

Half-lives for the three soils included in this study were recalculated by the Agency, using the pseudo first-order type ($C=C_oe^{-kt}$) relationship without transforming the data. The regression equations obtained using nonlinear regression on all the untransformed data had better coefficients of determination (r^2s = 0.96 to 0.99) than the linear regression using ln-transformed data (0.63 to 0.95). The recalculated half-lives (or DT50s) ranged from about 10 to 37 days, using the non-linear method, and 36.5 to 74.9 day, using ln-transformed data and linear regression.

The Agency previously suggested that the aerobic soil half-life of EPTC (17days) may be longer than reported, because that value combines volatilization and microbial degradation. The Agency also determined the half-life, by excluding the amount collected in the "traps", to account for losses from volatilization. The recalculated half-life was 46 days. Although the decline of EPTC residues in soil was supported by the half-life (rate), volatilization contributed more to the initial decline than aerobic soil metabolism. Aerobic metabolism may be of secondary importance in the decline of EPTC from these soils. In these studies, the decrease in EPTC residues was primarily due to volatilization, since 33 to 81% of applied radio activity was present as volatile parent at end of the studies. The Agency concluded that volatilization may be an important route of dissipation in the environment, even with incorporation.

The recommendations on how to make the studies satisfy data requirements were suggested by the Agency in the data review. The outstanding issues included a contradiction (e.g., %organic matter) of the analysis of soil properties associated with the Keeton sandy loam.

The registrant submitted two studies to address the anaerobic soil metabolism data requirement. These studies were determined to be scientifically valid and therefore able to provide additional information to the Agency. The Agency estimated the half-life as 127 days, and concluded that the anaerobic metabolism could be quite slow. These data suggested that the volatilization of EPTC contributed more to the initial decline of EPTC than did the anaerobic metabolism as measured by CO_2 evolution. The second study was also determined by the Agency to be scientifically valid and adequate to provide supplemental information. The study shows that EPTC degraded and volatilized in three soils with estimated half-lives of between 31.4 days and 83.6 days. EPTC - sulfoxide (ESO) was the only degradate identified and never accounted for more than 0.01 ppm (<0.2%).

No anaerobic or aerobic aquatic metabolism data have been submitted for EPTC. The Agency requires that the registrant conduct one or more aerobic and anaerobic aquatic metabolism studies to support the registered uses of EPTC. This requirement is due to the wide spread use of EPTC, high application rates, its low soil partition coefficient, and detections (wide spread) in surface water bodies. The environmental fata data and use profiles suggests that while there is a potential for EPTC to reach surface water exists, because of degradation and volatilization it is not very persistent in an aquatic environment. The rate of degradation in water will allow for a better understanding of the fate of EPTC in water where volatilization is limited (e.g., still water, deep water). This data would allow for a higher degree of certainty when assessing the fate of EPTC and its degradates on water quality.

The laboratory volatility study submitted by the registrant was acceptable and satisfied the data requirements. EPTC (non-labeled @ 99.8% purity and Radio labeled (N-propyl-1-^{14}C-EPTC @ 99.4% purity and specific activity of 393 dpm/µg) was added to a sandy loam soil. Volatile EPTC was collected in foam plugs in the flow through system. Fifty-five percent of the total amount of EPTC volatilized during the first two hours of the study. The rate of volatilization decreased with time and was essentially complete within four hours, where about 76 percent of the applied radioactivity volatilized during this period. The data also indicated that volatility is a potential major route of dissipation of EPTC in the environment. After 25 hours, the material balance averaged 99.1 percent. Parent EPTC was the only significant residue detected in the foam traps during the study.

The registrant submitted a study conducted by the USDA to address field volatility data requirement. The Agency reviewed the information and determined that the study partially satisfies the data requirement. EPTC can be applied through irrigation water, or chemigation. A study conducted by USDA researchers provides some information about the fate of EPTC when applied via the flood irrigation of alfalfa (Cliath et al., 1980). The following was reported when EPTC was applied in the flood-irrigation water. Of the 2.71 lb/ac applied (average concentration 2170 ppb), 73.6 percent volatilized (2.0 lb/ac) during the observation period of 52 hours. Seven percent (0.19 lb/ac, concentrations ranging between 1970 to 1440 ppb during observation period) of the applied EPTC was removed in the tailwater runoff. This suggests that EPTC concentrations in runoff water at a treated field edge can exceed 1000 ppb. Of the 73.6 percent measured to be lost through volatilization, 28.4 percent volatilized from water and 45.2 percent volatilized from wet soil. They determined that for this experiment, 80.6 percent of the EPTC applied to the alfalfa was lost through runoff and volatilization. It was concluded that losses could be reduced by reducing the amount of irrigation water lost as tailwater. These data indicate that volatility is a potential major route of EPTC dissipation in the environment.

In the atmosphere EPTC will remain mostly in the vapor phase. Non validated data suggests that the vapor phase of EPTC degrades rapidly by reacting with photochemically produced hydroxyl radicals (half-life estimated to be 14 hrs. Physical removal from the atmosphere also occurs through wet deposition. Thus, EPTC appears to have the potential to be transported offsite via in the vapor phase.

The Agency required additional information on the volatilization of EPTC when it is soil incorporated in the field. In this assessment it was determined that field data should be submitted which assesses the volatilization of EPTC under typical use condition.

Mobility

The affinity of EPTC to bind, or sorb, to four soils as reflected by the adsorption (Freundlich K_{ads} ~0.8 to 3.0) and desorption (K_{des} ~2.1 to 4.8) values appears to relatively low.

Table 19. Summary of four soils: selected soil properties.

Soil Series	%sand	%silt	%clay	pH	%OC[1]	CEC	Mean (of 2)		
							n^2	K_d (std)	K_{oc}(std)
Keeton	64.4	26.0	9.8	7.7	0.29	8.5	1.10	0.77 (0.02)	264 (8)
Columbia	80.2	14.0	5.8	7.8	1.1	12.2	1.06	1.61 (0.04)	146 (4)
Sorrento	45.6	34.0	20.8	6.8	1.8	20.7	1.04	2.57 (0.07)	143 (4)
Atterberry	17.8	56.4	25.8	5.6	2.2	24.6	1.10	2.99 (0.07)	136 (3)

[1] %OC is Percent soil organic carbon.
[2] n term in slope of the sorption isotherm (1/n).

Thus, considering the relatively low measured K_{ads} and calculated K_{oc} values obtained, EPTC appears to have a medium to high potential for leaching. The percent EPTC in leachate and the K_ds estimated from the column leaching studies also indicated that EPTC has a high potential to leach. Its susceptibility to volatilization and biodegradation may modify its potential to contaminate ground water. The rates of volatilization and biodegradation will probably decrease with increasing depth below the soil surface. Overall, the binding of EPTC appears to be relatively unimportant in the overall dissipation reactions of herbicide. The Agency One-liner database reports a RF value of 0.56 for the Felton sandy loam.

Leaching/Adsorption/Desorption

The registrant conducted a batch equilibrium study to determine the Freundlich (K_{ads}) and desorption values (K_{des}) for EPTC. The four soils considered in the experiment were the Keeton sandy loam, Columbia loamy sand, Sorrento loam, and the Atterberry silt loam.. The calculated K_{ads}, assuming the Freundlich isotherm, for the four soils ranged from 0.77 to 2.99 mL/g. The calculated K_{des} for the four soils ranged from 2.08 to 4.76. The n value in the slope term (1/n) ranged from 1.05 to 1.15 for adsorption and desorption phases. EPTC adsorption by these four soils increased as soil organic carbon increased. Thus, the K_{oc} model appears valid (also statistically significant). For these, soils the K_{oc} values ranged from 136-266, with a mean of 173. Previously, the Agency determined that this study was acceptable, and partially fulfilled the EPA data requirement

Leaching of Aged and Unaged

The registrant conducted EPTC aged and unaged leaching column experiments by applying Radio labeled ^{14}C-EPTC to the soil which was re-packed in soil columns. The study was determined to be both scientifically valid, and satisfies the data requirements in conjunction with the leaching/adsorption/ desorption study. Four soil textures (loamy sand, sandy loam, loam, and clay loam), sieved to 1-mm, were re-packed in columns to a depth of 30 cm with a vibrator. In the aged leaching study, an average of 22 percent of the applied parent EPTC was recovered in the leachate. In the study, 9 percent of the applied parent was found in the leachates to the loam and clay loam soils, and 55 and 78 percent of the parent were found in the leachates of the loamy sand and sandy loam soils, respectively. In both the aged and unaged leaching columns, less than 0.01 percent of the applied ^{14}C found in the leachate were degradates (including EPTC sulfoxide). The K_d values

estimated for EPTC in the four soils in this study were 0.38, 0.68, 1.82, and 1.28 for the sandy loam, loamy sand, loam, and clay loam, respectively.

It was noted by the study authors that total recoveries (mass balance) were low (68.6 and 85.3% of applied ^{14}C). The authors attributed the low recoveries to the volatility of the test substance. This was determined to be a plausible explanation, since a substantial amount (up to 80%) of the EPTC volatilized in the aerobic and anaerobic metabolism studies. Also, in the laboratory volatility study, up to 77 percent of the applied EPTC volatilized after four hours.

Field Dissipation

Nine terrestrial field dissipation studies have been submitted by the registrant and reviewed by the Agency. These studies were determined to be unacceptable and thus did not meet the 164-1 statutory data requirement. The Agency indicated that some, if not all, the studies could be upgraded. Until such time that the outstanding issues are addressed, these studies provide supplemental data. It is was also noted that although some outstanding issues remain to be addressed by the registrant, the Agency determined that EPTC was not persistent to moderately persistent in soil.

It was also noted that EPTC did not appear to be mobile in soils, even though the Freundlich K_ds were less than 5. However, insufficient water (rain and/or irrigation) may have been applied to the study plots for significant leaching of EPTC residues to have occurred. These studies indicated that EPTC had dissipation half-lives of 2 to 56.8 days, with an average half-life of 12.6 days. However, the two studies were reevaluated. The maximum field dissipation half-life, considering the reevaluation of the two studies, resulted in a range of values from 2 to 18.8 days, with an average half-life of 8.6 days.

Several of the studies provide limited information on the degradates EPTC sulfoxide and di-N-propylamine. The data were not adequate to evaluate the formation and decline of degradates or their mobility. The registrant will be required to submit data to assess volatilization under typical field use conditions (e.g., soil incorporated, watered-in, or applied via-chemigation). This will allow for a quantitative (or semi-quantitative) assessment of the loss of EPTC via volatilization.

ACCUMULATION

Accumulation in Rotational Crops

The Agency database indicates that EPTC in unlikely to accumulate in wheat, sugar beets, and soybean plants, based on a valid study.

Accumulation in Irrigated Crops

Bioaccumulation of EPTC in Fish: The Agency determined that the studies submitted by the registrant pertaining to accumulation of EPTC in fish were scientifically valid and provide supplemental information. Studies showed that [^{14}C]EPTC did not substantially accumulate in

bluegill sunfish exposed to [^{14}C]EPTC at 0.084 ppm in a flow-through system for 28 days. The bioconcentration factor (BCF) in the flow-through accumulation study was 97X for viscera and 34X for fillet.

The bioaccumulation and elimination of [^{14}C]EPTC by bluegill sunfish was investigated in a dynamic flow-through system (Forbis, 1987). The flow system was comprised of two aerated tanks containing 70 liters of water. The treated tank received the [^{14}C]EPTC (specific activity 3.41 x 10^9 dpm, 99% radio purity diluted to 1270 dpm/µg) from a stock solution. The treated and control tanks received 120 fish. The fish were exposed for 28 days to the Radio labeled material at 22 $\pm$ 2 oc, followed by depuration in EPTC free water for 14 days. Fish and water samples were collected after 4-hours, 1, 3, 7, 14, 21, and 28 days after both EPTC-treated water and the EPTC-free water.

Fish were sectioned into edible and nonedible (viscera) portions for analysis. During the exposure period, tissue concentration in the fillet, viscera, and whole fish increased from 0.6 to 3.1 ppm, 1.9 to 9.2 ppm and 1.7 to 5.0 ppm, respectively. Recovery of [^{14}C]EPTC residues in water, nonedible, and edible fish tissue at sampling days 21 and 28 were, respectively, 88.6 % and 92.8%, 885 %. and 84.6% and 91.4 %, and 99.7%. Bioconcentration factors were 37X, 60X, and 110X, respectively, in the edible, whole fish, and non-edible fish tissues. The study did not meet data requirements because no storage stability data were submitted by the registrant. Fish samples were frozen and stored up to 7 months before analysis

c. Water Resources

EPTC is capable of contaminating ground water and surface water, because it has been detected in both media. This section presents a summary of the assessment of the potential of EPTC to contaminate ground water, surface water, and drinking water from labeled uses. The assessment includes Tier II (PRZM/EXAMS) estimates of environmental concentrations (EECs) in surface water, for EPTC applied at the several label rates and numbers of applications to alfalfa, citrus, corn, and potatoes. These crops represent the major uses and generally reflect the highest use rates and amounts. Surface-water monitoring data sources available in the EPA's STORET data base and the USGS National Water Quality Assessment Program (NAWQA) were also considered.

The potential for EPTC residues to contaminate ground water was assessed using the ground-water concentration screening model (SCI-GROW) and monitoring data available in the Agency's Pesticides in Ground Water Data Base (PGWDB), STORET data base, and NAWQA studies. The purpose of this analysis is to provide an estimate of environmental concentrations of EPTC in surface water bodies and ground water, for use in the human health and ecological risk assessment as part of there registration process.

Ground Water

The ground-water monitoring data confirm that EPTC has the potential to contaminate ground water. The majority (more than 90%) of EPTC concentrations in ground water were reported

to be "0" or less than the detection limit (generally ≤ 0.05 µg/L). With the exception of three data values, the maximum EPTC concentration reported in the PGWDB, for the NAWQA program, and the STORET database were 0.33 µg/L, 0.45 µg/L (<2% of the sites had detections), and 0.50 µg/L, respectively. Of the three samples where higher ground water concentrations were noted, the first (2.7 µg/L) is cited by the USGS and represents ground water at a mixer-loader site.

The remaining two concentration value were reported in STORET for a site in Alabama (both 1500 µg/L). There was no statement as to the source of EPTC in the STORET data base, or an explanation as to why the values were so high. Based upon the environmental fate profile of EPTC and the other available monitoring data, it is unlikely, if in fact these concentration data are correct, would be the result of normal agricultural practices. EPTC is mobile in soil as indicated by K_{OC}s ranging from 136 to 266 mL/g. EPTC does not appear to be persistent, under most conditions, but where microbial degradation is inhibited or volatilization is restricted, EPTC could be persistent.

Surface Water

Surface-water monitoring data confirm that EPTC contaminates surface water bodies. The frequencies (4 to 25%) of reported EPTC detection in surface water depended on type of site or water body sampled, and were greater than frequencies of detection (0 to 2%) in ground water sampled in NAWQA or reported in STORET. The states with the highest frequencies of detection in surface water correspond with the regions with greatest EPTC use. Maximum EPTC concentrations in NAWQA depended on site type (stream, lake), and ranged from 0.037 to 40 µg/L (the maximum value, 40 µg/L, was outside the range of the method calibration). In the STORET database, concentrations in surface water ranged from 0.001 to 10.0 µg/L (streams 0.0 to 10.0 µg/L, lakes 0.005 to 0.09µg/L).

EPTC is used in most regions of the United States on a variety of crops with different application rates and methods, application intervals, and total amounts permitted to be applied. Tier II surface water modeling was conducted for EPTC, on several major crops at high exposure sites, using the EPA's PRZM and EXAMS models. The crops modeled were alfalfa, beans, citrus, corn, and potatoes. They were selected from label information, because they generally represent the maximum application rates, number of applications, and the maximum total amount applied. Lower concentrations were predicted for those scenarios having the lowest application rates and the fewest number of applications.

PRZM/EXAMS output consists of an estimated daily concentration in a standard water body. For each scenario, the annual peak value is highest daily concentration in a year, thus, there are 36 peak values. These values are sorted (maximum to minimum) and the 90^{th} percentile value is selected (1-in-10-year). The range of the 90^{th} percentile peak EECs, for a number of scenarios was, 3.67 to 41.69 ppb. The other EECs represent the 90^{th} percentile of the running mean over a specified period of time (i.e., 96-hour, annual). The ranges for ten scenarios of the 1-in-10-year, or 90^{th} percentile, for the non peak EECs were 96-hour (3.43 to 39.33 ppb), 21-day (2.82 to 31.16 ppb), 60-day (1.76 to 20.56 ppb), 90-day (1.33 to 16.72 ppb), and annual means (0.37 to 3.44 ppb).

The range of the 90th percentile upper bound of the means of the annual mean of daily values for the ten scenarios was 0.19 to 3.8 ppb. In general, the lowest EECs were generated for beans and corn, whereas the highest EECs were for citrus.

Drinking Water

The range of peak EPTC EECs (6.35 to 57.35 µg/L) generated by PRZM/EXAMS, for the ten scenarios, corresponds reasonably well with the range of highest surface water concentrations of EPTC observed (without considering data limitations or modeling short comings) in the STORET and NAWQA (10 to 40 µg/L). The 90th percentile upper-bound EPTC value for the means of annual means of the daily EECs ranged from 0.19 to 3.80 µg/L. Monitoring for EPTC has been conducted, in at least thirty states. The range of the means for the ten scenarios was 0.15 to 3.44 µg/L. The monitoring data indicates that EPTC concentrations in surface water are generally very low (generally less than 0.05 µg/L, but rarely greater than 1 µg/L). However, EPTC concentrations in surface water have occasionally been detected at levels up to approximately 40 µg/L. The EPTC EECs are suggested based upon the evaluation of both the monitoring data and modeling results.

For surface water, monitoring data rarely exceeded (or reached) 10 µg/L), and the peak EECs generated from the modeling were similar in magnitude.. The environmental fate data indicates that EPTC would not be persistent under many environmental conditions, an observation supported by relatively short half-lives observed in terrestrial and aquatic environments.

Monitoring data suggests that concentrations of EPTC in ground water will be less than those found in surface water. However, its persistence in ground water would probably be greater than in surface water, since losses due to volatilization would be expected to be much less. SCI-GROW estimates provide a Tier 1 screening level estimate of ground-water concentrations. The value represents an estimate of chronic exposure for ground water (long term average rather than peak) under vulnerable conditions. The predicted values by SCI-GROW (1.84 and 5.89 µg/L) are generally greater than those observed in the monitoring data, but are of similar order of magnitude as the maximum values observed in monitoring (<0.50 µg/L). It is recommended that 2 µg/L and 0.5 µg/L be used as the estimates of acute and chronic drinking water levels for ground water. The acute and chronic values for ground water are selected for essentially the same reason that the surface water values were selected.

3. Exposure and Risk Characterization

The focus of this ecological risk assessment is risk to mammals and terrestrial plants. The risk to other organisms is either negligible, or cannot be assessed with available data. Risk was assessed for uses that represent the full range of application rates. Risk was assessed for use rates ranging from 3 lb a.i./acre (corn, beans and alfalfa) up to 15 lb a.i./acre (ornamentals). The ornamental use was included because it has an exceptionally high application rate, not because it represents a significant usage of EPTC. For birds, fish, and invertebrates, peak rates and exposures were used to show that there was no risk (acute data only; chronic data are lacking). For mammals,

risk quotients for only 3 application rates are presented (3, 6 and 15 lb a.i./acre), since these represented the full range of uses of EPTC. For terrestrial plants, risk quotients are presented for rates ranging from 3 to 6 lbs a.i./acre. Risk to terrestrial plants from the ornamental use, at 15 lb a.i./acre, is discussed, but risk quotients for terrestrial plants are not calculated because of the high uncertainty in estimating runoff from that usage.

There are some risks that cannot be assessed with available data. Since avian reproduction test results are not available, potential sublethal or reproductive effects to birds cannot be assessed. EPTC does cause sublethal effects to mammals at expected exposure levels, so it is important that avian reproduction testing be conducted. EPTC is expected to reach water repeatedly due to multiple applications. However, chronic testing results are not available for fish or invertebrates. These tests would be of value to determine if EPTC causes sublethal or reproductive effects to freshwater organisms which may affect aquatic populations.

EPTC is also used on crops that are grown in coastal counties. However, acute test results with estuarine fish, shrimp and mollusks are not available, so risk to these organisms cannot be assessed. The freshwater organism testing suggests that EPTC is not particularly toxic to aquatic organisms in general. However, estuarine species can be more sensitive than freshwater organisms, so acute tests with these organisms would be valuable. Reproductive testing with shrimp is also required. The chronic estuarine fish study is reserved.

a. Ecological Exposure and Risk Characterization

Exposure to Terrestrial Animals

Since EPTC is applied as a spray, a granular, and by chemigation, three different methods are used to estimate exposure to terrestrial animals.

To assess maximum exposure to terrestrial animals from sprays, the application rate in lb a.i./acre is multiplied by environmental concentrations in the nomograph, as shown below.

Table 20. Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 lb a.i./A

Food Items	EEC (ppm) Predicated Maximum Residue [1]	EEC (ppm) Predicted Mean [1] Residue
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants	135	45
Fruits, pods, seeds[2]	15	7

[1] Predicted maximum and mean residues are for a 1 lb a.i./a application rate, and are based on Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994).

[2] Residues on insects may be similar to that which occurs on forage, small seeds and fruits; however, neither Hoerger and Kenega nor Fletcher obtained residue data on insects.

The maximum residues are shown in the following table. For example, if EPTC is sprayed at 6.1 lbs a.i./acre, the maximum residues likely on any terrestrial food items would be approximately 1,464 ppm.(6.1 (lbs a.i./acre) X 240 (ppm after 1 lb a.i./acre) = 1,464 ppm). For some uses, EPTC may be applied more than one time per season. However, because of its volatility, it is expected to dissipate between treatments, such that subsequent applications will not result in buildup on terrestrial food items over time. So, for a given application rate, the same maximum exposure concentration is assumed to occur whether EPTC is applied once, or several times per year.

Table 21. Estimated maximum residues on terrestrial animal vegetative food items in ppm at the rates shown. Rates shown represent the maximum, or close to maximum, label rates.

Vegetation type	**Application rate of 3 lb a.i./acre: beans, alfalfa**		**6.1 lbs a.i./acre: potatoes, nonbearing citrus, corn**		**15 lbs a.i./acre: ornamentals**	
	maximum	mean	maximum	mean	maximum	mean
short grass	720	255	1,464	518.5	3,600	1,275
tall grass	330	108	671	219	1650	540
broad leaf	405	135	823	274	2025	675
seeds, small fruit	45	21	9	42	225	105

To assess exposure from granular formulations, the Agency calculated the mg of active ingredient in a square foot. This calculation takes into account the fact that EPTC granular formulations must somehow be soil incorporated to be effective. Thus, only a percentage of what is applied is assumed to be available to terrestrial animals. This is done using the following formula:

$$\text{mg a.i./square foot} = \frac{\text{application rate in lbs a.i./acre X number of mg/pound X percent available}}{\text{number of square feet in one acre}}$$

The mg a.i./sq ft are shown in the table 19. For a granular application of 6 lbs a.i./acre, there would be approximately 9.4 mg a.i./square foot.

(6 (lbs a.i./acre) X 453,590 (mg in a pound) X 0.15 (15% available after incorporation) = 408,231 mg /acre 408,231 (mg/acre) / 43,560 (square feet per acre) = 9.37 or 9.4 mg / sq foot).

Table 22. Estimated mg a.i./square foot following granular applications of EPTC at the rates shown*.

Application Rates/Crops	3 lbs a.i./acre: corn	4 lbs a.i./acre: beans, alfalfa, nonbearing citrus	6 lbs a.i./acre: potatoes	15 lbs a.i./acre: ornamentals
Corresponding coverage	4.7 mg/sq ft	6.24 mg/sq ft	9.4 mg/sq ft	23 mg/sq ft

* Rates shown represent the maximum label rates. In each case, soil incorporation is assumed such that only 15% of the applied remains on or near the surface.

To determine exposure to birds and mammals from application through chemigation, the Agency attempted to estimate the likely concentration of EPTC in the chemigation water, as shown in table in the following table.

Table 23. Assessment of concentrations of EPTC in chemigation water

Crop	Application rate (lb a.i./acre)	Concentration	Comment on estimation
Corn	6.1 in 0.5" to 0.75" chemigation	53 ppm to 35 ppm	1 lb a.i./acre in 0.5"= 8.8 ppm 1 lb a.i./acre in 0.75"=5.8 ppm 6.1 x 8.8 = 53.7 ppm 6.1 x 5.8 = 35.8 ppm
Potatoes	3.1 to 6.1	probably similar to corn	uncertain because amount of water was unspecified
Beans	3.1 to 3.9	probably less than corn	uncertain because amount of water was unspecified, but rate per acre is lower than corn
Alflafa	2 to 4	2.17 ppm	measured conc in sprinkler system, Claith et al. (1980)

Initially, the predicted maximum residues are compared to the toxicity thresholds to determine if risks are likely. If risks are likely, they are further discussed in the risk characterization. In the case of EPTC, acute risks to birds are considered unlikely, however, mammals may be at risk as identified in the risk discussion below.

Exposure and Risk to Birds

To assess acute exposure and risk of EPTC to birds, the Agency used two methods; one for spray applications, the other for granular applications. Note that since chronic testing with birds was not available, only acute risk can be assessed.

Spray Formulations

For spray applications, the upper limit concentrations on food items are compared to the dietary LC_{50}. If these upper limit concentrations on food items fail to exceed levels that were not lethal in the laboratory, the Agency concludes acute risk is unlikely.

The maximum residues on avian food items from major EPTC uses is not expected to exceed 1,464 ppm (6.1 lb a.i./acre sprayed on vegetation in treated areas). The maximum residue on food items from any EPTC use is not expected to exceed 3,600 ppm (ornamental use of 15 lb a.i./acre sprayed on vegetation). These residue levels are well below the concentration which, in the laboratory, caused little or no acute effects (5,280 ppm).

Granular Formulations

Possible risk to birds from granular formulations is determined by comparing the acute oral LD_{50} for a wild bird with the number of milligrams active ingredient likely to occur in a square foot. If the milligrams in a square foot exceed the 0.5 of the LD_{50}, there is a high possibility of acute risks. In the case of EPTC, the LD_{50} for birds is determined to be greater than 2,510 mg/kg. This translates to a dose of about 500 mg for a 200 gram bird (2,510 mg/kg X 0.2 kg = 502 mg). Assuming only 15% of the granules that are applied remain on the surface (i.e. to which birds may be exposed), the number of mg per square foot EPTC from the maximum granular application rate for a major usage of EPTC would be approximately

9.4 mg a.i./foot^2 = $\frac{6 \text{ lbs ai/A} \times 453{,}590 \text{ ppm} \times 15\% \text{ exp.}}{43{,}560 \text{ ft}^2/\text{A}}$ = 9.4 mg/ft^2

This is well below the dose level 502 mg at which little or no acute effects are expected.

Therefore, acute risk to birds is not expected from maximum exposure from spray or granular formulations of EPTC.

Exposure and Risk to Mammals

EPTC is a risk to small mammals. Mammals are at risk from both acute effects and subchronic effects. The risk quotients are presented below; please see the following sections for further discussion of acute and sublethal risks to mammals.

Acute Risk to Mammals from Granulars

Table 24. Estimated mg ai/square foot following granular applications of EPTC at the rates shown and the associated risk quotients (LD_{50} s per square foot) based on an LD_{50} of 14 mg/animal (for a 15 g mammal).

3 lbs ai/acre: corn	4 lbs ai/acre: beans, alfalfa, nonbearing citrus	6 lbs ai/acre: potatoes	15 lbs ai/acre: ornamentals
4.7 mg/sq ft	6.24 mg/sq ft	9.4 mg/sq ft	23 mg/sq ft
RQ 0.3	0.4	0.6	1.6

0.5 = LOC for potentially high acute risk
0.2 = LOC for possible restricted use
0.1 = LOC for possible effects to endangered mammals

Rates shown represent the maximum label rates. In each case, soil incorporation is assumed that mammals are only exposed to the 15% that remains on or near the surface.

Granular application rates of around 6 lb ai/acre or higher may represent a risk of acute effects to mammals. Endangered mammal species may be affected at granular application rates of 3 lb ai/acre or higher. Note that this calculation was based on an LD_{50} for a small (15 gram) mammal. Other larger mammals would have larger LD_{50} s, and would be at less risk. For example, a 100 gram (0.1 Kg) mammal would have a LD_{50} of approximately 92 mg/animal (916 X 0.1=91.6). Even at the highest application rate, the high acute risk LOC is not exceeded for this size mammal.

EPTC treated clay particles are very small. Analysis of the number of particles that need to be consumed to exceed ½ the LD_{50} suggest that risks to mammals by this route of exposure are unlikely.

Acute Risk to Mammals from Sprays

All registered spray uses of EPTC represent a risk of acute lethal effects to small mammals and may affect small endangered mammals. Without adequate mitigation measures EPTC could potentially become a candidate for restricted use, based on acute risk to mammals. Larger mammals (for example: a one kg mammal) that eat proportionately less of their body weight per day would be at less risk.

Table 25. Estimated risk quotients to mammals feeding on terrestrial animal vegetation at the rates shown represent the maximum label rates. All LC_{50}s extrapolated‡ from rat LD_{50} of 916 mg/kg

Risk quotient (RQ) = EEC/LC_{50}**	**Application rate of 3 lb ai/acre: beans, alfalfa**		**6.1 lbs ai/acre: potatoes, nonbearing citrus, corn**		**15 lbs ai/acre: ornamentals**	
	maximum	mean*	maximum	mean*	maximum	mean*
EEC range (ppm)	45-720	21-255	91-1,464	42-518	225-3,600	105-1,275
RQs(LC_{50}‡=964ppm)0.015 Kg herbivore	0.04-0.7	0.02-0.2	0.09-1.5	0.04-0.5	0.2-3.7	0.1-1.3
RQs (LC_{50}‡=1390ppm) 0.035 Kg herbivore eats 66% body wt daily	<0.1-0.5	<0.1-0.1	<0.1-1.0	<0.1-0.3	0.1-2.5	<0.1-0.9
RQs (LC_{50}‡=6100ppm) 1.0 Kg herbivore eats 15% body wt daily	<0.1-0.1	<0.1-<0.1	<0.1-0.2	<0.1-<0.1	<0.1-0.5	<0.1-0.2
0.5 = LOC for potentially high acute risk 0.2 = LOC for possible restricted use 0.1 = LOC for possible effects to endangered mammals			‡1-day LC_{50}=LD_{50} (mg/kg) X body wt (Kg) X 100 (%) mg/kg food % body wt eaten daily X body wt (Kg)			

* Mean EECs assuming maximum application rate.
**Compare RQs with LOCs

There are risk to small herbivores (0.015 kg) which ingest 95% of their body daily. The risk to larger herbivores (0.035 kg ingesting 66% of body weight, and 1kg ingesting 15% of body weight are only of concern at the maximum rate for 3 lbs a.i./a, and at mean and maximum for 6.1 and 15 lbs a.i./a.

Acute Risk from Chemigation

The concentration of EPTC in chemigation water is not expected to be high enough to cause acute risk to mammals or birds.

Sublethal Risk to Mammals

Please refer to the previous table showing the range of maximum and mean residues on mammal food items. Essentially all spray uses of EPTC result in residues greater than the NOAEL of 50 ppm, and therefore represent a potential for sublethal risks to mammals. Even mean residue levels from maximum application rates exceed the NOAEL by sizeable margins. The endpoint for the 50 ppm NOAEL is based on reduced body weight of the adult rat, and damage to the heart muscle. There were no reproductive effects evident in the study at the highest test level of 800 ppm. Thus, whatever effects were occurring to the individual adult rats did not seem to affect their reproduction.

The estimated concentration of EPTC in corn chemigation water may reach 54 ppm, assuming 0.5 of an inch of water into which 6.1 lb ai/acre are mixed. This barely exceeds the mammal chronic NOAEL of 50 ppm.

Exposure and Risk to Aquatic Animals and Plants

Refined aquatic exposure modeling resulted in a maximum peak concentration of 0.04 ppm. This is far lower than the lowest fish LC_{50} (14 ppm), the lowest aquatic invertebrate EC_{50} (6.5 ppm),

the EC EC_{50} for alga (1.36 ppm), and the EC EC_{50} for the aquatic vascular plant, duckweed (5.6 ppm). This indicates the EPTC is unlikely to have acute (i.e. lethal) effects on aquatic animals or plants.

Exposure and Risk to Terrestrial Plants

Being a herbicide, EPTC is observed to be a risk to terrestrial plants. Non-target plants are exposed to EPTC moving off the treatment site by spray drift, and surface water runoff. Monitoring studies in Minnesota found that more than 25 percent of rainfall samples contained EPTC.

Exposure to Terrestrial Plants

Exposure is estimated for two kinds of terrestrial plants; plants growing in upland soils (dry habitats), and plants growing in wetland soils (wet habitat). Both kinds of terrestrial plants may be exposed to EPTC from movement offsite in the form of spray drift and/or runoff.

Since EPTC sprays are only applied by ground equipment, movement offsite due to drift is assumed to be relatively low (approximately 1% of the applied). So in the following equations, if the method of application is a spray, the amount of drift added to the exposure is 1% of the application rate.

In addition to considering where plants grow, exposure must be estimated to compare with results from two kinds of plant tests; the vegetative vigor study, and the seedling emergence study. The vegetative vigor study involves exposing only the foliage of actively growing plants. The only route of exposure that is assumed to reach the foliage of plants is that which moves off-site as spray drift. The seedling emergence study involves treating the soil in which seedlings grow. Both spray drift and runoff are assumed to reach off-site soil.

Table 26. Which route(s) of exposure are compared with which test endpoints.

Study	Plants growing in upland (dry) soils	Plants growing in wetland soils
Vegetative vigor: EC_{25} (nonendangered plants) and EC_{05} (for endangered plants)	Spray drift only (in the case of granular formulations, no offsite foliar exposure is expected)	Spray drift only (in the case of granular formulations, no offsite foliar exposure is expected)
Seedling emergence: EC_{25} (nonendangered plants) and EC_{05} (for endangered plants)	Spray drift (except for granular formulations) + sheet Runoff (see equation #1 below)	Spray drift (except for granular formulations) + channelized runoff (see equation #2 below)

Runoff to plants growing in upland soils is assumed to closely resemble 'sheet runoff,' in which unchannelized water moves from a 1-acre treated site to an immediately adjacent 1-acre site. The following equation is used to estimate this exposure:

equation #1: exposure (lb ai/acre) = $\frac{\text{(appl rate (lb ai/acre) X \% runoff)}}{\text{5 cm (depth of soil incorporation)}}$ + drift

Runoff to plants growing in wetland soils is assumed to be channelized runoff, in which water from a treated field (approximately 10 acres) channelizes, and drains into a lowland habitat, thus exposing plants growing there. The following equation is used to estimate this exposure:

equation #2: exposure (lb a/acre) = (appl rate (lb ai/acre) X 10 (acres) X % runoff) + drift
5 cm (depth of soil incorporation)

Table 27. The percent (%) runoff used in the equations is based on the solubility of the chemical, using the following criteria.

Solubility	Percent Runoff
<10 ppm	1%
10 to 100 ppm	2%
>100 ppm	5%

Since the reported water solubility value of EPTC is 370 ppm, 5 percent runoff is assumed for all terrestrial plant exposures.

The following table summarizes the expected off site exposure to terrestrial plants at various application rates.

Table 28. Estimates of exposure to non-target plants offsite. EECs are in lb ai/acre so they can be compared with the results of terrestrial plant toxicity tests, which are either an EC_{25} or an EC_{05} in lb ai/acre.

EECs for Terrestrial Plants in lb ai/acre

Use Pattern (G=granular S=Spray)	Depth of soil Incorp. (cm)	Drift (0.01 [1%]; S) (0%; G),	Upland (dry) soils from sheet runoff (0.05 [5%]) + Drift	Wetland soils from channelized runoff (0.05 [5%]) + Drift
4.5 lb ai/acre (G) beans	5	none	0.045	0.45
Upland EEC= (4.5 lb/a X 0.05 X 1 acre) / 5 (depth inc.) + no drift = 0.045 lb/a Wetland EEC=(4.5 lb/a X 0.05 X 10 acres) / 5 (depth inc.) + no drift = 0.45 lb/a				
3 lb ai/acre (G) corn* 4 lb ai/acre (G) alfalfa*	3.7 5	none	0.04	0.4
Upland EEC= (3 lb/a X 0.05 X 1 acre) / 3.7 (depth inc.) + no drift = 0.04 lb/a Wetland EEC=(3 lb/a X 0.05 X 10 acres) / 3.7 (depth inc.) + no drift = 0.4 lb/a * Applications to corn are incorporated to a depth of 3.7 cm, while applications to alfalfa are incorporated to a depth of 5 cm. Therefore, the amount available for runoff, and subsequent exposure to plants from runoff, is approximately the same, even though the application rates in lbs ai/acre are different.				
3.1 lb ai/acre (S) beans, alfalfa	5	0.031 (3.1 X 0.01)	0.062	0.34
Upland EEC= (3.1 lb/a X 0.05 X 1 acre) / 5 (depth inc.) + 0.031 lb/a (drift) = 0.062 lb/a Wetland EEC=(3.1 lb/a X 0.05 X 10 acres) / 5 (depth inc.) + 0.031 lb/a (drift) = 0.34 lb/a				
6 lb ai/acre (G) potatoes	5	none	0.06	0.6
Upland EEC= (6 lb/a X 0.05 X 1 acre) / 5 (depth inc.) + no drift = 0.06 lb/a Wetland EEC=(6 lb/a X 0.05 X 10 acres) / 5 (depth inc.) + no drift = 0.6 lb/a				
6.1 lb ai/acre (S) corn, potatoes	7.5	0.01	0.10	0.47
Upland EEC= (6.1 lb/a X 0.05 X 1 acre) / 7.5 (depth inc.) + 0.061 lb/a (drift) = 0.09 lb/a Wetland EEC=(6.1 lb/a X 0.05 X 10 acres) / 7.5 (depth inc.) + 0.061 lb/a (drift) = 0.36 lb/a				

With multiple applications, for crops such as potatoes and alfalfa, the exposure to plants from the second treatment may be higher than from a single application. However, the amount of increase

cannot be estimated with any degree of certainty with current models and the difference will not change the risk conclusions significantly.

Risk to Terrestrial Plants

The following table shows the risk quotients for various use patterns.

Table 29. Showing risk quotients for non-target terrestrial plants in areas adjacent to EPTC treated sites

	RQs for Terrestrial Plants					
Use pattern (G=granular S=Spray)	**Drift exposure EECs compared to vegetative vigor test results***		**Upland (dry) soils EEC compared to seedling emergence test results***		**Wetland soils EEC compared to seedling emergence test results***	
	EEC/EC_{25} 0.22 lb ai/a MRID 43217101	EEC/EC_{05} 0.023 lb ai/a MRID 42120802 ending. sp.	EEC/EC_{25} 0.10 lb ai/a MRID 42120802	EEC/EC_{05} 0.017 lb ai/a MRID 42120802 ending. sp.	EEC/EC_{25} 0.10 lb ai/a MRID 42120802	EEC/EC_{05} 0.017 ai/a MRID 42120802 ending. sp.
4.5 lb ai/acre (G) beans*	none	none	0.45	2.6	4.5	26
3 lb ai/acre (G) corn* 4 lb ai/acre (G) alfalfa*	none	none	0.4	2.4	4.0	24
3.1 lb ai/acre (S) beans, alfalfa*	0.14	1.3	0.62	3.4	3.6	20
6 lb ai/acre (G) potatoes*	none	none	0.6	3.5	6.0	35
6.1 lb ai/acre (S) corn, potatoes *	0.28	2.7	1.0	5.9	4.7	28

* Exposure from the various routes (drift and/or runoff) are compared to the terrestrial plant EC25 to determine risk to terrestrial plants in general (nonendangered), and to the EC05 to determine possible effects to endangered plants.

This table shows that most uses of EPTC are a risk to terrestrial plants, except for some drift exposure, which shows applications up to approximately 6 lbs ai/acre. Some usage is at higher application rates (ornamentals). The risk quotients could be higher; possibly over twice as high, for a 15 lbs ai/acre application rate. However, EECs were not calculated, because of the high degree of uncertainty in calculating runoff exposure from this use. Endangered plants may also be affected.

Endangered Species

The level of concern is exceeded for endangered and terrestrial plants species such as monocots and dicots . Non-target terrestrial plants in adjacent fields or habitats are potentially at risk from spray drift from some uses and from runoff for all registered uses. EPTC also appears to have the potential to be transported off site via the vapor phase as it was one of a number of residues found in more than 25 percent of the rain samples collected in three water sheds in Minnesota. In addition, being a herbicide, EPTC may also have an indirect effect on endangered insects by adversely affecting the plants on which they depend.

As member of the Endangered Species Task Force, the registrant will be required to obtain information which identifies endangered and threatened species of concern which may be found in areas adjacent to crops treated with EPTC.

b. Environmental Risk Characterization

EPTC is volatile and must be soil incorporated to a depth of 1.5 to 4 inches within a relatively short time (within 2 to 36 hours following application) in order to be efficacious for control of weed germination. The method of EPTC application and soil incorporation appears to have more effect on the potential for risks expressed as risk quotients than either the use site or the use rate. Based on the available toxicity data, all EPTC uses, except for chemigation, yield risk quotients which exceed the levels of concern for high acute (LOC = 0.5) and sublethal risks (LOC = 1) to small herbivorous and/or insectivorous mammals and for non-target terrestrial plant species (LOC = 1).

None of the application methods or uses appear to pose acute risks to birds, beneficial insects, or freshwater organisms. Risks could not be assessed for acute effects on estuarine fish, oysters, and shrimp, or for reproductive effects on birds, freshwater fish and invertebrates, and estuarine fish and invertebrates, because toxicity studies have not been submitted to support applications on major crops grown in coastal counties or to support multiple applications. No information is available on the toxicity of EPTC degradates or metabolites. The half-life of one degradate, EPTC sulfoxide, appears to be shorter than the half-life for EPTC.

Field conditions and crop growth stage for EPTC applications are dependent on the use site. EPTC may be used at practically all stages of crop growth, including applications at pre-plant, at-plant, pre-emergence, post-emergence, foliar application, lay-by, and a fall application. In all cases, soil incorporation is necessary for efficacy to reduce volatilization of EPTC. The depth of soil incorporation ranges from 1.5 to 4 inches. Since EPTC is more volatile on wet soils, the labels recommend that soils should be dry to a depth of about 0.5 inches prior to application. Fields need to be "cleaned" to uproot any germinated weeds prior to any EPTC application. Vegetation in the fields at treatment may include crop residues and uprooted weeds.

Mechanical incorporation into the soil disrupts the soil surface and exposes insects and soil organisms and leaves some vegetation on the soil surface. The amount of vegetation in the field during spray applications may vary from abundant to sparse in "clean fields." Freshly plowed fields attract many bird species to feed on insects and soil organisms. Mammals, such as opossums, skunks, raccoons, field mice and foxes, may be attracted to feed in plowed fields at dusk and during the night.

The endpoint for the mammalian chronic effects based on adverse effects, and were identified in a two-generation rat reproduction study at 200, and 800 ppm EPTC. The overall NOAEL value for the study was 50 ppm, based on maternal effects (including decreased body weight and degenerative cardiomyopathy) at 200 ppm.. No reproductive effects were identified at 800 ppm, the highest test concentration. At 800 ppm, the pups had reduced body weight.

Degenerative cardiomyopathy is an abnormality in the function of the heart muscle, which seriously reduces physical abilities of the effected animal. The Agency considers maternal effects, such as cardiomyopathy, to be a subchronic effect. Cardiomyopathy is a cumulative effect increasing from one exposure to next (i.e., multiple exposures are additive in their effect on the heart muscle).

Reduced body weight and degenerative cardiomyopathy are ecologically significant because they expected to adversely effect biological competition for food, reproductive dominance, and predator avoidance.

In two cases, sufficient information was available on chemigation uses to assess any risk to non-target organisms, based on EPTC concentrations in the water applied to a crop. EPTC use on corn in the semi-arid areas of the Pacific Northwest is 6.1 lbs a.i./A, in 0.5 to 0.75 inches of water. Based on an application of 0.5 inch, the EPTC concentration is about 54 ppb in the chemigation water. In a standing alfalfa field study in California's Imperial Valley (Claith *et al*. 1980), EPTC was applied at a rate of 3.04 kg/ha (i.e., 2.7 lbs ai/A) at an average concentration of 2.17 ppm in the head ditch water, and the irrigation water flowed across the field and collected on the far side of the field. During the 52 hour monitoring period, 28.4 percent of the total EPTC applied volatilized from water, 45.2 percent volatilized from wet soil, and 7 percent ran off the far side of the field as 1.92, 1.97, 1.76 and 1.44 ppm EPTC.

The EPTC concentrations in water bodies from chemigation for use on these two crops pose no risk to any fish or wildlife group. In the case of alfalfa, there was no risk to non-target terrestrial plants, because the runoff was collected in ditches at the far side of the field. Risks to non-target terrestrial plants from the corn in the Pacific Northwest use were estimated based on spray drift and runoff following a rain event. Risks from spray drift alone exceeded only the endangered and threatened plant species LOC. Risks from rainfall runoff were assumed to be similar to broadcast applications or slightly higher, if the higher soil moisture content increased the amounts of water in the runoff.

Risk quotients from granular applications exceed the levels of concern for high acute toxicity for small herbivorous and/or insectivorous mammals, and for high risks to non-target terrestrial plants. Since the EPTC granules are very fine clay particles, it is unlikely that small mammals would consume a sufficient number of granules to be affected. Granular applications of these small particles are assumed not to be blown into adjacent habitats as is the case for spray drift. Thus, the risks from granular formulations would appear to be limited to runoff into habitats of non-target terrestrial plants, with concern levels slightly less than spray application, because there is no spray drift from granular applications.

Risk quotients from broadcast spray applications exceed the Agency's levels of concern for high acute and sublethal effects for small herbivorous and/or insectivorous mammals, and for high risks to non-target terrestrial plants. If irrigation is used to incorporate EPTC into the soil, risks to small mammals would be limited to the time period between application and some time after irrigation began when the residues of wildlife food items are diluted and/or leach into the soil. Irrigation may possibly increase the risks to non-target plants if higher soil moisture content increases runoff from rain events. If the spray application is soil incorporated using mechanical means, EPTC concentration levels will continue to exist on the exposed vegetation on the soil surface until the EPTC residues volatilize or are washed into the soil by rain.

On a per pound active ingredient per acre basis, broadcast spray applications appear to pose the highest risks to small mammals and non-target terrestrial plants. EPTC spray applications are likely limited to killing a few small mammals and are not expected to produced adverse effects on mammalian reproduction or to significantly effect populations of small mammals. Except for alfalfa, vegetation is sparse in most treated fields compared to the more lush vegetative strips adjacent to treated fields. Also, the duration of exposure to potentially lethal residues are limited due to the high volatility of EPTC on exposed food items and to the predilection of EPTC residues to wash off and leach into the soil with rain. The duration of potential risks to small mammals is uncertain, because persistence of EPTC on food items is mostly a function of local climatic conditions, such as temperature, winds, soil moisture, and rainfall. Fate studies indicate that field dissipation half-lives range from about 2 to 19 days.

Non-target terrestrial plants in adjacent fields or habitats are potentially at risk from spray drift from some uses and from runoff for all registered uses. Chemigation and soil incorporation by wetting increase soil moisture levels which may increase runoff levels. Non-target terrestrial plants are at risk from spray drift at application rates of $\geq$ 2.6 lbs ai/A, runoff into wet habitats at all registered use rates; and runoff into dry habitats at use rates $\geq$ 2 lbs ai/A. The level of concern for endangered terrestrial plant species is exceeded for both monocots and dicots and the concerns need to be addressed by the registrant.

The Agency has identified the following endangered and threatened species groupings as potentially at risk from EPTC uses: small mammalian herbivores, small mammalian insectivores and terrestrial plants. In consultations with the U.S. Fish and Wildlife Service in 1983-84 for the Forestry "cluster" and again in 1989 in a re-initiation on "clusters", jeopardy to some plants were identified in both consultations for EPTC. As member of the Endangered Species Task Force, Zeneca, is involved in obtaining information which identifies endangered and threatened species of concern which may be found in areas adjacent to crops treated with EPTC.

Volatility as a major route of field dissipation raises concerns about the atmospheric fate of EPTC, its aerial transport and whether aerial deposition poses the potential for risks to small mammals and non-target terrestrial plants. The fate of EPTC in the atmosphere and the potential for atmospheric offsite deposition is uncertain. Based on toxicity data, aerial deposition would not appear to be a risk to animals or aquatic habitats. But risks to non-target terrestrial plants are a concern based of the sensitivity of a number of terrestrial plant species to seedling emergent effects on wild oats (EC_{25} 0.10 lbs ai/A), vegetative effects (EC_{25}) at 0.22 lbs ai/A, significant reduction in dry weight (EC_{25}) at 0.23 lbs ai/A for winter wheat, and EC_{05} values as low as 0.017 lbs ai/A for wild oats.

Whether these levels of EPTC are likely to be atmospherically deposited into soils or on vegetation is uncertain. The absence of reported atmospheric deposition incidences does not preclude the occurrence of such events. Zeneca reported one 6(a)2 incident in Pennsylvania in which there was a reduction in the stand and stunted plants in alfalfa and stunted and killed tomato plants. No additional details were provided, but EPTC was identified as the possible cause of the symptoms.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing EPTC as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing EPTC. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of EPTC**.**

These data were sufficient to allow the Agency to determine that EPTC can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing EPTC as the active ingredients are eligible for reregistration. Actions needed to reregister particular products are addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the data required for reregistration, current guidelines for conducting acceptable studies to generate such data and published scientific literature. Although the Agency has found that all uses of EPTC are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing EPTC, if new information comes to the Agency's attention or if data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on reviews of the generic data for the active ingredient EPTC, the Agency has sufficient information on the health effects of EPTC and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that EPTC products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, the Agency concludes that products containing EPTC for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of EPTC are eligible for reregistration under the conditions specified in this RED.

B. Regulatory Position

The following is a summary of the Agency's regulatory position and rationale for managing risks associated with the use of EPTC. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

In order to be eligible for registration the registrant the following changes are required:

Risk to occupational handlers

- The exposure assessments indicate that occupational handlers are at risk to dermal and inhalation exposure, and that additional protective measures are necessary to reduce these risks. Therefore, various forms of additional personal protective equipment (PPE) (e.g., double layer clothing and respirators) and engineering controls (e.g., enclosed cockpits) are necessary for certain handler scenarios to reduce the risks to below the Agency's level of concern.

- In order to mitigate risks to homeowners, the registrant will be required to add label language which prohibit the use of the belly grinder, which contributes to the highest level of exposure, for home owner products. The registrant will also be required to delete all residential emulsifiable concentrate formulation uses from the EPTAM 7E label. In addition the registrant will be required to change the maximum rate of 15 lbs per acre for the Eptam 2.3 granular products to the typical rate of 5 lbs per acre for residential products.

- Risk quotients for granular and spray applications suggest that EPTC poses adverse effects to small herbivorous and insectivorous mammals for most uses and adverse effects on non-target terrestrial plants for all uses. EPTC use could also cause adverse effect on endangered species. As member of the Endangered Species Task Force, the registrant will be required to obtain information which identifies endangered and threatened species of concern which may be found in areas adjacent to crops treated with EPTC.

The registrant will also be required to provide additional data as following:

Guideline:	**Study:**
870.6300	Developmental neurotoxicity study in the rat
860.1340	Residue Analytical methods-Plant
860.1360	Multiresidue Method
860.1380	Storage Stability Data
860.1520	Processed Food/ Feed
860.1500	Crop field Trials

Guideline:	**Study:**
850.2100	Acute Avian Oral (quail/duck)
850.2300	Avian Reproduction (quail/duck)
850.1010	Invertebrate toxicity
850.1025	Estu/mari tox mollusk
850.1035	Estu/mari tox shrimp
850.1045	Estu/mari tox fish
850.1300	Life cycle invertebrate
835.4300	Aerobic Aquatic Metabolism
835.8100	Field Volatility
835.1240	Leach/adsorption/deportation

1. Food Quality Protection Act Findings

With EPTC, there was an increased incidence and severity of neuronal necrosis/degeneration in both the central and peripheral nervous systems of both rats and dogs. Because of the neurotoxic effects (neuronal necrosis/degeneration) and the potential for residential exposure to infants and children from use of EPTC, the Agency's FQPA Safety Factor Committee recommended that the 10x FQPA safety factor be retained for all populations which includes infants and children. The uncertainty regarding the effects on the developing fetal nervous system after such exposure is being addressed by the requirement of a developmental neurotoxicity study in rats.

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for EPTC, with the amendments and changes specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered available information on the aggregate exposures (both acute and chronic) from non-occupational sources, and food and drinking water, as well as the possibility of cumulative effects from EPTC and other compounds that may have a similar mechanism of toxicity.

In assessing aggregate risk, the agency considered potential dietary exposure of the general population to EPTC residues from food and drinking water, and potential dermal and inhalation exposure from use in residential settings. The aggregate assessment for the general population and specific subgroups addressed food, water, and residential exposures. Short-term aggregate risk estimates do not exceed the Agency's's level of concern.

Acute and chronic risk from food do not exceed the Agency's level of concern. Acute and chronic dietary (food) exposure analyses were conducted using the Dietary Exposure Evaluation Model (DEEM). In both assessments, exposure (consumption) was compared to a population adjusted dose (PAD) reflecting retention of the FQPA 10x factor. The PAD is equal to the acute or chronic RfD divided by the FQPA Safety Factor. The Agency considers dietary residue contributions greater than 100% of the PAD of concern. Acute dietary exposure at the 95^{th} percentile comprised 40.5% of the aPAD for the general population and 87.5% of the aPAD for the most highly exposed subgroup, children (1-6 years). Chronic dietary exposure comprised 9.6% of the cPAD for the general population and 17.4% of the cPAD for the most highly exposed subgroup, children (1-6 years). The acute analysis at the 95^{th} percentile is a conservative, deterministic upper-bound estimate which utilized tolerance-level input residues and assumed 100% crop treated. The chronic analysis (Tier 3) is a refined estimate which used average field trial residues and percent of crop treated data.

Chronic (non-cancer) aggregate risk estimates do not exceed the Agency's level of concern. The aggregate chronic dietary risk estimates include exposure to EPTC residues in food and water. No chronic residential use scenarios were identified. Exposure (food only) to combined residues of

EPTC and its metabolites of toxicological concern, based on a Tier 3 refinement, using average residues from field trial and percent of crop treated data, represents 17.4% of the chronic PAD for the most highly exposed population subgroup (children 1-6 years). Exposure to all other groups represents less than 14.8% of the chronic PAD. Using conservative screening-level models, the estimated maximum 1-in-10 year annual average of EPTC in surface water is 3.44 μg/L. This estimated average concentration is less than the drinking water level of comparison for exposure to EPTC in drinking water as a contribution to aggregate chronic dietary risk. Based on available information, the Agency concludes with reasonable certainty that no harm to any population will result from chronic dietary exposure to EPTC.

b. Determination of Safety for Infants and Children

EPA has determined that established tolerances for EPTC, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of EPTC residues in this population subgroup.

During the early stages of the FQPA implementation process, EPA recognizes that it will be necessary to make some decisions before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents regarding the application of FQPA to its regulatory determinations. These early decisions will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

If, as a result of this later implementation process, EPA determines that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

2. Tolerance Reassessment Summary

At this time, the Agency does not believe it has sufficient reliable information concerning common mechanism issues to determine whether EPTC, a thiocarbamate, shares a common mechanism of toxicity with other cholinesterase-inhibiting chemicals. Therefore, for the purposes of this tolerance reassessment, the Agency has assumed that EPTC does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals.

Established tolerances for residues of EPTC in/on plant commodities are currently expressed in terms of residues of EPTC *per se* [40 CFR §180.117]. Based on results of acceptable plant metabolism studies, the Agency's Metabolism Committee has determined that the tolerance expression for EPTC should be revised to regulate residues of EPTC, EPTC sulfoxide, EPTC sulfone, and glutathione conjugate of the sulfone metabolite, and all subsequent conjugates thereof.

The hydroxylated metabolites of EPTC (i.e., N-2-hydroxy propyl EPTC, N-3-hydroxy propyl EPTC, and 2-hydroxymethyl EPTC) were determined not to be of toxicological concern because of the low levels (10% of TRR) at which they are formed in plants. However, to facilitate development by the registrant of an analytical method for enforcement purposes, the Metabolism Committee concluded that the hydroxylated metabolites could be used as marker compounds of EPTC metabolites mentioned in the preceding paragraph. The tolerance expression, therefore, will now consist of residues of EPTC *per se* and the EPTC hydroxylated metabolites mentioned above. Hence, all EPTC tolerances have been reassessed, based on residue data for the combined residues of EPTC and its hydroxylated metabolites.

The Agency considers residues of EPTC in animal commodities to be a Category 3 situation under 40 CFR §180.6(a), in which it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues in animal commodities. No tolerances on animal commodities are warranted.

The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops. As a result of this update, EPTC tolerances for certain raw agricultural commodities which have been removed from the livestock feeds table need to be revoked. Also, some commodity definitions must be corrected.

Tolerances were reassessed based on residue data depicting combined residues of EPTC and its three hydroxylated metabolites (i.e., N-(2-hydroxy)propyl; N-(3-hydroxy)propyl; S-(2-hydroxy)ethyl metabolites). In the tolerance reassessment, a level of quantification (LOQ) of 0.05 ppm was chosen for EPTC because the LOQ is < 0.05 ppm (see section entitled GLN 860.1500: Crop Field Trials), and the level of detection (LOD) of the enforcement analytical method is 0.02-0.04 ppm. For each of the three hydroxylated metabolites, the LOQ of the 0.01 ppm of the proposed enforcement method (see section entitled GLN 860.1340: Residue Analytical Methods) was used. Hence, the minimal tolerance is 0.08 (0.05 for EPTC, plus 0.03 for the combined hydroxylated metabolites) since this represents the minimal quantifiable amount. A summary of EPTC tolerance reassessments is presented in Table 27. Pending independent laboratory validation of the enforcement analytical method for the hydroxylated metabolites, the reassessed tolerances represent revised EPTC tolerances.

Tolerances Listed Under 40 CFR §180.117

Pending submission of supporting storage stability data, sufficient field trial data have been submitted to reassess the established tolerances for the following commodities: almond, hulls, cottonseed, safflower seed, and sunflower seed.

Sufficient field trial data are not available to adequately reassess the established tolerances for the following commodities: flaxseed, fruits, citrus, and strawberries.

The majority of the established group tolerances for residues of EPTC *per se* are based on obsolete crop groupings and, for many, the minimum requirements for the establishment of crop group tolerances have not been satisfied. Therefore, the Agency is recommending the revocation of the group tolerances listed below, concomitant with the establishment of individual tolerances for the affected commodities. The recommendations listed below should be considered tentative in the absence of complete supporting storage stability data for EPTC residues for which storage stability data remain outstanding, including the hydroxylated metabolites that will be used as marker compounds.

- Sufficient data have been submitted for sugar beet roots and potatoes, which are presently covered by the tolerance established for "vegetables, root crop." Available data for sugar beet roots can be translated to garden beet roots, and available data for potatoes can be translated to sweet potato. The tolerance for this obsolete group should be deleted and individual tolerances should be established for: beet, garden, roots, beet, sugar, roots, potato, and sweet potato.

- Sufficient data have been submitted for sugar beet tops, which are presently covered by the tolerance established for "vegetables, leafy." Available data for sugar beet tops can be translated to garden beet tops. The tolerance for this obsolete group should be deleted and individual tolerances should be proposed for: beet, garden, tops (leaves), and beet, sugar, tops (leaves).

- Sufficient data have been submitted for beans (succulent and dry) which are presently covered by the tolerance established for "vegetables, seed and pod." The available data for succulent beans can be translated to succulent peas. The tolerance for this obsolete group should be deleted and individual tolerances should be established for: bean, seed (dry), bean, succulent, and pea, succulent.

- Sufficient data have been submitted for tomatoes which are presently covered by the tolerance established for "vegetables, fruiting." The tolerance for this group should be deleted and an individual tolerance should be established for tomato.

- Sufficient data have been submitted for almonds and walnuts which are presently covered by the tolerance established for "nuts." The tolerance for this obsolete group should be deleted and individual tolerances should be established for: almond, nutmeat, and walnut, nutmeat.

- Sufficient data have been submitted for field corn grain and sweet corn (K + CWHR), which are presently covered by the tolerance established for "grain crops." The tolerance for this group should be deleted and individual tolerances should be established for: corn, field, grain, corn, pop, grain, and corn, sweet (K + CWHR).

- Sufficient data have been submitted for field corn forage and fodder (stover) and sweet corn forage and fodder (stover), which are presently covered by the tolerance established for "forage grasses." The tolerance for this group should be deleted and individual tolerances should be established for: corn, field, forage; corn, field, stover; corn, pop, stover; corn, sweet, forage, and corn, sweet, stover.

- Sufficient data have been submitted for alfalfa forage, clover forage, and hay which are presently covered by the tolerance established for "legumes, forage." Available data for clover forage and hay can be translated to the forage and hay of Birdsfoot trefoil and lespedeza. The tolerance for this obsolete group should be deleted and individual tolerances should be established for: alfalfa, forage, alfalfa, hay, Birdsfoot trefoil, forage, Birdsfoot trefoil, hay; clover, forage; clover, hay, lespedeza, forage, and lespedeza, hay. (Because product labels prohibit use of EPTC on cowpeas and restrict use on peas to succulent peas, no tolerances for cowpea forage and hay or field pea vines and hay are required.)

The established tolerance for castor beans should be revoked since the registered use of EPTC on castor beans is more appropriately classified as a non-food use. Castor beans and oil products are not consumed by humans or livestock; thus, a tolerance for EPTC residues of concern in/on castor beans is not necessary.

The established tolerance for cotton, forage should be revoked since cotton forage is no longer considered a significant livestock feed item.

The established tolerances for asparagus, small fruits, and pineapples should be revoked since there are no registered uses of EPTC on these crops.

Tolerances to be Proposed Under 40 CFR §180.117

A tolerance for EPTC residues of concern in/on cotton gin byproducts must be established once adequate field residue data, reflecting the maximum registered use pattern, have been submitted and evaluated.

The available processing data for potatoes indicate that residues of EPTC and its hydroxylated metabolites concentrate minimally (1.4-fold) in granules processed from treated potatoes. This low degree of concentration of EPTC residues in granules does not warrant a tolerance for this processed commodity.

The available processing data for sugar beets indicate that residues of EPTC and its hydroxylated metabolites concentrate appreciably (4-fold) in molasses processed from treated sugar beets. Therefore, a tolerance of 0.4 ppm for the combined residues of EPTC and its hydroxylated metabolites in molasses must be established.

Table 30. Tolerance Reassessment Summary for EPTC.

Commodity	Current Tolerance, ppm [1]	Reassessed Tolerance, ppm [2]	Comment *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.117			
Almonds, hulls	0.1(N)	0.08	[*Almond, hulls*] Pending submission of supporting storage stability data, sufficient field trial data have been submitted to reassess the established tolerance.
Asparagus	0.1(N)	Revoke	There are currently no registered uses of EPTC on asparagus.
Beans, castor	0.1(N)	Revoke	EPTC use on castor beans is classified as a non-food use.
Cotton, forage	0.1(N)	Revoke	This item is no longer considered a significant livestock feed item (Table 1, OPPTS 860.1000).
Cottonseed	0.1(N)	0.08	[*Cotton, undelinted seed*] Pending submission of supporting storage stability data, sufficient field trial data have been submitted to reassess the established tolerance.
Flaxseed	0.1(N)	TBD [3]	[*Flax, seed*] Sufficient field trial data are not available to adequately reassess the established tolerance.
Fruits, citrus	0.1(N)	TBD [3]	[*Citrus fruits (Citrus spp., Fortunella spp.) group*] Sufficient field trial data are not available to adequately reassess the established tolerance.
Fruits, small	0.1(N)	Revoke	There are currently no registered uses of EPTC on small fruits.
Grain crops	0.1(N)	Revoke	The established tolerance should be revoked and individual tolerances should be proposed for: corn, field, grain; corn, pop, grain; and corn, sweet (K + CWHR).
Grasses, forage	0.1(N)	Revoke	The established tolerance should be revoked and individual tolerances should be proposed for: corn, field, forage; corn, field, stover; corn, pop, stover; corn, sweet, forage; and corn, sweet, stover.
Legumes, forage	0.1(N)	Revoke	The established tolerance should be revoked and individual tolerances should be proposed for: alfalfa, forage; alfalfa, hay; Birdsfoot trefoil, forage; Birdsfoot trefoil, hay; clover, forage; clover, hay; lespedeza, forage; and lespedeza, hay.
Nuts	0.1(N)	Revoke	The established tolerance should be revoked and individual tolerances should be proposed for: almond, nutmeat; and walnut, nutmeat.
Pineapples	0.1(N)	Revoke	There are currently no registered uses of EPTC on pineapple.
Safflower, seed	0.1(N)	0.08	Pending submission of supporting storage stability data, sufficient field trial data have been submitted to reassess the established tolerance.
Strawberries	0.1(N)	TBD [3]	[*Strawberry*] Sufficient field trial data are not available to adequately reassess the established tolerance.
Sunflower, seed	0.1(N)	0.08	Pending submission of supporting storage stability data, sufficient field trial data have been submitted to reassess the established tolerance.
Vegetables, fruiting	0.1(N)	Revoke	The established tolerance should be revoked and an individual tolerance should be proposed for tomato.

Tolerances Listed Under 40 CFR §180.117

Commodity	Current Tolerance, ppm [1]	Reassessed Tolerance, ppm [2]	Comment *[Correct Commodity Definition*
Vegetables, leafy	0.1(N)	Revoke	The established tolerance should be revoked and individual tolerances should be proposed for: beet, garden, tops (leaves); and beet, sugar, tops (leaves).
Vegetables, root crop	0.1(N)	Revoke	The established tolerance should be revoked and individual tolerances should be proposed for: beet, garden, roots; beet, sugar, roots; potato; and sweet potato.
Vegetables, seed and pod	0.1(N)	Revoke	The established tolerance should be revoked and individual tolerances should be proposed for: bean, seed (dry); bean, succulent; and pea, succulent.
Tolerance To Be Established Under 40 CFR §117 (a)			
Alfalfa, forage	--	0.2	
Alfalfa, hay	--	0.6	
Almond, nutmeat	--	0.08	
Bean, seed (dry)	--	0.08	
Bean, succulent	--	0.08	
Beet, garden, roots	--	0.1	The recommended tolerances are based on translation of data from sugar beet roots and tops.
Beet, garden, tops (leaves)	--	0.5	
Beet, sugar, molasses	--	0.4	
Beet, sugar, roots	--	0.1	
Beet, sugar, tops (leaves)	--	0.5	
Birdsfoot trefoil, forage	--	0.1	The recommended tolerances are based on translation of data from clover forage and hay.
Birdsfoot, hay	--	0.1	
Clover, forage	--	0.1	
Clover, hay	--	0.1	
Corn, field, forage	--	0.08	
Corn, field, grain	--	0.08	
Corn, field, stover	--	0.08	
Corn, pop, grain	—	0.08	
Corn, pop, stover	—	0.08	
Corn, sweet (K + CWHR)	--	0.08	
Corn, sweet, forage	--	0.08	
Corn, sweet, stover	--	0.08	

Cotton gin byproducts	--	TBD [3]	
Lespedeza, forage	--	0.1	The recommended tolerances are based on translation of data from clover forage and hay.
Lespedeza, hay	--	0.1	
Pea, succulent	--	0.08	The recommended tolerance is based on translation of data from succulent beans.
Potato	--	0.1	
Sweet potato	--	0.1	The recommended tolerance is based on translation of data from potatoes.
Tomato	--	0.08	
Walnut, nutmeat	--	0.08	

[1] The current tolerance expression is in terms of residues of EPTC *per se*.

[2] Tolerances were reassessed based on residue data depicting combined residues of EPTC and its three hydroxy metabolites (i.e., its N-(2-hydroxy)propyl; N-(3-hydroxy)propyl; and S-(2-hydroxy)ethyl metabolites). In the tolerance reassessment a level of quantification (LOQ) of 0.05 ppm was chosen for EPTC because the LOQ is < 0.05 ppm (see section entitled GLN 860.1500: Crop Field Trials), and the level of detection (LOD) of the enforcement analytical method is 0.02-0.04 ppm. For each of the three hydroxylated metabolites, the LOQ of the 0.01 ppm of the proposed enforcement method (see section entitled GLN 860.1340: Residue Analytical Methods) was used. Hence, the minimal tolerance is 0.08 (0.05 for EPTC, plus 0.03 for the combined hydroxylated metabolites) since this represents the minimal quantifiable amount.

[3] TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required.

3. Codex Harmonization

There are no proposed or established Codex maximum residue limits (MRLs) for residues of EPTC in/on various plant and animal commodities. Therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

4. Risk Mitigation

a. Risk Mitigation for Occupational Handler Exposure

Based on occupational handler exposure scenarios, handlers are at risk to exposure from EPTC. There are both short and intermediate term endpoints, but the intermediate endpoints, which are the endpoint the Agency is using to regulate EPTC, results in risks of concern. The exposure assessments indicate that handlers are at risk to dermal and inhalation exposure, and that additional protective measures are necessary to reduce their exposure risks. To address this concern, various forms of additional personal protective equipment (PPE) (e.g., double layer clothing and respirators) and engineering controls (e.g., enclosed cockpits) are necessary for certain handler scenarios to reduce the risks below the Agency's level of concern (see the table below for specific handler protection requirements).

To lessen the risks to occupational handlers posed by EPTC, in addition to baseline (long pants, long sleeve shirt, socks, and shoes), the Agency is requiring the following mitigation for EPTC products:

- Mixers/Loaders of the emulsifiable concentrate (EC) must wear and use chemical resistant (CR) gloves, CR apron, and CR footwear. In addition, to support chemigation M/L must wear an organic vapor (OV) respirator.
- Mixing/Loading EC for Impregnation on Dry Bulk Fertilize must wear CR gloves, CR apron, must also use Closed System.
- Loaders of granules for aerial equipment must wear an OV respirator.
- Applicators of dry bulk fertilizer using a specialized truck* must wear an OV resp.
- Mixers/Loaders/Applicators of the EC using hand-held equipment must wear CR gloves.
- Aerial applicators must be in an enclosed cockpit.
- Loaders/Applicators of the granular using hand-held equipment must wear CR gloves.
- Loader/Applicators using the Belly Grinder (hand-held broadcast spreader, must wear double layers, CR footwear.

Occupational Handler Dermal and Inhalation Mitigation

Handler dermal exposure to EPTC is below the Agency's level of concern for some exposure scenarios. The target MOE=100 is achieved for exposure scenarios 1a, 1b, 1d, 5, 8, 10, and 11, when additional PPE such as chemical resistant gloves, footwear, apron and respirator were applied. Where baseline PPE did not result in acceptable MOE, the Agency assessed risk using double layers of body protection. However, since maximum PPE resulted in MOE above 1000s for some scenarios the Agency reassessed these scenarios using CR gloves in addition to baseline PPE for all applicators except the belly grinder. As a result, MOEs were acceptable with gloves only. The belly grinder did not achieve an MOE greater then 100 with baseline PPE and gloves until a double layers were added.

Although there is no data to specifically assess the exposure reduction to mixers/loaders afforded by a chemical-resistant apron (CRA), the Agency is substituting the double layer body protection for the CRA and believes that the resulting reduction is significant. Available data indicate that the preponderance of non-hand exposure to mixers/loaders is to the front torso. Therefore, for mixers/loaders the use of a chemical-resistant apron is probably approximately equivalent to double-layer body protection.

Handler inhalation exposure to EPTC for all scenarios except three were below the Agency's level of concern. Handler inhalation mitigation is achieved for these three scenarios when an organic vapor respirator is applied. Due to lack of data at baseline additional PPE levels, closed cockpits, will be required for aerial applicators.

For dry bulk fertilizer applications using a specialized truck, despite the fact that the intermediate dermal and short-term and inhalation MOE's are still unacceptable even with engineering controls, the Agency has determined that this use pattern will remain. It would be relatively unusual for the handler to mix the highest amount (800,000 lbs fertilizer/day) at the maximum rate everyday. Also, the estimates are based on surrogate data which the Agency believes overestimates the risk.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc).

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

For each end-use product, PPE requirements for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE is established using the process described in PR Notice 93-7 or more recent EPA guidelines determined by comparing the PPE requirements based on the toxicity of the active ingredient, as listed earlier, with the PPE required based on the acute toxicity of the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) would apply to the end-use product. As discussed in the risk mitigation section above, the additional PPE is needed due to EPTC's high acute toxicity or other adverse effects, such as increased incidence and severity of neuronal necrosis/degeneration in both the central and peripheral nervous systems of both rats and dogs, the potential for residential exposure to infants and children.

The following table provides a detail summary of handler protective equipment that will be required on various labels.

Table 31. Summary of Handler Personal Protective Equipment.

Exposure Scenario	Additional PP Required	Engineering Controls
Mixing/Loading Emulsifiable Concentrate for Chemigation (1a)	Single layer clothing, Chemical resistant (CR) apron, CR footwear, CR gloves, Organic Vapor respirator (OV).	None
Mixing/Loading Emulsifiable Concentrate for Ground Application (1b)	Single layer clothing CR footwear , CR gloves, CR apron.	None
Mixing/Loading Emulsifiable Concentrate for Impregnation on Dry Bulk Fertilizer (1c)	Single layer clothing,, CR gloves, CR apron.	Closed System
Mixing/Loading Emulsifiable Concentrate or Handgun (Hydraulic Sprayer) Application(1d)	Single layer clothing, CR footwear, CR gloves, CR apron.	None
Loading Granular with Aerial Equipment (2b)	Single layer clothing, OV respirator	None
Applying Dry Bulk Fertilizer with Specialized Truck (4b)	Single layer clothing, OV respirator	None
Applying Spray to the Soil with Handgun Application (5)	Single layer clothing, CR gloves	None
Applying granulars with Aerial Equipment (7	Single layer clothing	Enclosed Airplane Cockpit

Exposure Scenario	Additional PP Required	Engineering Controls
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil with a Low Pressure Hand Wand (8)	Single layer clothing, CR gloves	None
Mixing/Loading/Applying Emulsifiable Concentrate to the Soil a with Backpack Sprayer (9)	Single layer clothing,, CR gloves	None
Loading/Applying Granular with a Push-Type Spreader (10)	Single layer clothing,, CR gloves	None
Loading/Applying Granular with a Belly grinder Spreader (11)	Double layer clothing, CR footwear, CR gloves	None

Risk from Occupational Post-Application Exposures

The current restricted entry interval (REI) for EPTC is 12 hours, with the exception that if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

EPTC is applied is a soil-directed herbicide that must be thoroughly incorporated immediately following application through mechanical means or watering-in. It is applied as a pre-plant application and as a post-emergent application to established plants. Post-emergent applications include crops such as tomatoes and beans, where hand labor activities involving contact with the soil subsurface such as staking are common. For post-emergent applications to ornamentals in nurseries, there are no restrictions on the timing of transplanting/harvesting the ornamentals following application. For all crops, labeling instructions direct users to use shallow cultivation (i.e., mechanical or hand raking/hoeing) after application to control weeds that escape control.

No product-specific postapplication exposure data were available for EPTC, therefore a surrogate range-finder postapplication assessment was conducted. The surrogate assessment assumed that 20 percent of the EPTC applied was available for transfer (i.e., dislodgeable) at 12 hours following application/incorporation. A transfer coefficient of 1000 cm^2/hr would be appropriate for tasks that would involve contact with the soil subsurface, such as hoeing, raking, staking, thinning, irrigating, and transplanting (ornamentals). An eight hour work day and the maximum EPTC application rate of 15 pounds active ingredient per acre was used. Using the high end assumptions in this surrogate assessment, the margin of exposure at 12 hours after application/incorporation was over a thousand.

Therefore, the EPA is establishing a 12-hour restricted-entry interval for all uses of EPTC. The labeling should state that the REI does not begin until EPTC has been appropriately incorporated as directed. The WPS exception allowing unrestricted entry to treated areas following application and appropriate incorporation provided the soil subsurface will not be contacted should be cited on the labeling using the standard language for soil incorporation.

Occupational (both Worker Protection Standard and non-WPS) Labeling Rationale

During the reregistration process, EPA considers all relevant generic and product-specific information to decide what protections and risk mitigation is needed for all products. Products may contain various types of occupational uses, which may or may not be covered by the Worker Protection Standard (WPS).

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses covered by the WPS. Uses covered by the WPS include all commercial and research uses on farms, forests, nurseries, and in greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). The WPS covers not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes.

Post-Application/Entry Restrictions

Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REIs) for all uses covered by the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

b. Risk Mitigation for Residential Handler Exposure

Residential Handlers

Residential exposure risk from EPTC result from application by home owner and commercial handlers when applying at residential sites. Since PPE is not a viable option for residential mitigation, and application with a belly grinder spreader results in an MOE which exceeds the Agency's level of concern, the registrant is required to add label language that prohibits the use of the belly grinder for home owner application.

The low pressure hand wand application is also above the Agency's level of concern therefore, the registrant will be required to drop the Eptam 7E home owner garden and residential emulsifiable concentrate formulation use from the 7E label. This product must be labeled for professional use only.

To lessen EPTC dermal and inhalation exposure risk the registrant will be required to change the residential maximum rate of 15 lbs per acre for the Eptam 2.3 granular to the typical rate of 5 lbs per acre.

Accordingly, in order to be eligible for registration of homeowner products, registrants will be required to:

- Prohibit the use of the belly grinder for home owner application.

- Drop all residential emulsifiable concentrate formulation use from the 7E label. Only granular products my be registered for use by residential consumers. Any EC products registered for such use must be canceled by the registrant.

- Change the residential maximum rate of 15 lbs per acre for the Eptam 2.3 granular to the typical rate of 5 lbs per acre.

These use patterns will still be permitted at residential sites when applied by licensed occupational handlers.

Residential Post-Application

The primary unacceptable scenario to residential post-application to EPTC is toddlers or children potentially ingesting EPTC-treated soil. While it is the Agency's policy to routinely conduct screening level assessments for incidental ingestion of granules from treated areas, the Agency believes a toddler's exposure to EPTC granules may be outside the scope of concern because of small formulation particle size. Since the particle size is relatively small and if used according to label directions and soil incorporated, it is unlikely that EPTC granules would be accessible to a child. Nonetheless, the Agency estimates that fewer than 50 EPTC granules, if eaten, would result in adverse effects. Therefore, the agency is requiring that the potential for children's exposure to EPTC granulars be further minimized by additional labeling which states, " Keep off sidewalks, driveways, patios, or similar surfaces .

Risk from Non-Occupational Post Application Exposure

Human exposure to EPTC applied in parks, around buildings, golf course sandpit would be minimum as long as EPTC is to soil incorporation or is watered in. Therefore, the Agency has decided to require the standard labeling requirement of, "Do not enter or allow others to enter until sprays have dried and incorporation is complete." No changes to the registration are needed.

c. Ecological Risk Mitigation

Residue levels of EPTC on vegetation exceed levels of concern for high acute risks and effect on endangered species for small mammals. Soil incorporation reduces the amount of vegetation exposed, but the vegetation remaining at the surface poses a potential risk to small mammals. Since soil incorporation is necessary within the 24 hours specified on the label for good weed control, exposed vegetation on the field surface after soil incorporation will be sparse. The scarcity of the treated vegetation and the rapid volatilization of EPTC from the exposed vegetation in the couple days, reduces the magnitude and possibility of risks to a short time period. The scarcity of the vegetation in the field is less inviting for hungry mammals than vegetative areas surrounding the field, which also lowers the probability that many small mammals will feed in the field and will be affected by EPTC. Given the low probability of EPTC dietary exposure to small mammals, any mortality is unlikely to have any serious effect on the local populations of small mammals, with the exception of an endangered species.

(1) Mammalian Mitigation

To assess the risk associated with mammals consuming EPTC treated areas, an LD_{50} of 916 mg/kg is used to assess possible acute lethal dietary risks. Therefore, the concentration that would have to be in the diet of a mammal in order to achieve the LD_{50} would be 916 mg/kg within one day of eating. Since EPTC is incorporated into the soil two to four inches after application, and is highly volatile in liquid or granular formulation, it is unlikely that a mammal will be able to consume enough EPTC in one day to achieve the lethal does. Also, limited mortality is unlikely to have any serious effect on the local populations of small mammals Therefore, no additional action is necessary action at this time.

(2) Terrestrial Plant Mitigation

The level of concern is exceeded for endangered and terrestrial plants species such as monocots and dicots . Non-target terrestrial plants in adjacent fields or habitats are potentially at risk from spray drift from some uses and from runoff for all registered uses. EPTC also appears to have the potential to be transported off site via the vapor phase as it was one of a number of residues found in more than 25 percent of the rain samples collected in three water sheds in Minnesota. In addition, being a herbicide, EPTC may also have an indirect effect on endangered insects by adversely affecting the plants on which they depend.

As member of the Endangered Species Task Force, the registrant will be required to obtain information which identifies endangered and threatened species of concern which may be found in areas adjacent to crops treated with EPTC.

Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift

management practices. The Agency is now requiring interim measures for aerial applications that must be placed on product labels/labeling as specified in Section V . The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to apply the data and the Ag DRIFT computer model to its risk assessments. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim the following spray drift related language is required on product labels that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method: "Do not allow this product to drift".

V. Actions Required of Registrant

A. Data Requirements

The registrant will also be required to provide additional confirmatory data as following:

Guideline:	**Study:**
870.6300	Developmental neurotoxicity study in the rat
860.1340	Residue Analytical methods-Plant
860.1360	Multiresidue Method
860.1380	Storage Stability Data
860.1520	Processed Food/ Feed
860.1500	Crop field Trials

Guideline:	**Study:**
850.2100	Acute Avian Oral (quail/duck)
850.2300	Avian Reproduction (quail/duck)
850.1010	Invertebrate toxicity
850.1025	Estu/mari tox mollusk
850.1035	Estu/mari tox shrimp
850.1045	Estu/mari tox fish
850.1300	Life cycle invertebrate
835.4300	Aerobic Aquatic Metabolism
835.8100	Field Volatility
835.1240	Leach/adsorption/deportation

B. Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing EPTC. For the specific labeling statements, refer to the table below.

A summary of EPTC labeling requirements which mitigate occupational handler risk are stated in the following table.

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
Manufacturing Use Products		
Required on all MAPS	"Only for formulation into herbicide products intended for the following use(s):" [*registrants inserts uses that are being supported by MP registrant*]. " This product may not be formulated into liquid products intended for residential consumer use."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This chemical is toxic to mammals. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	
End Use Products Intended for Occupational Use (Label Contains WPS Uses)		
RED PPE Requirements[1] for Emulsifiable Concentrate Products:	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category" [registrant *inserts A,B,C,D,E,F,G,or H*] "on an EPA chemical-resistance category selection chart." Mixers, Loaders and Handlers exposed to the concentrate must wear: -- Long-sleeved shirt and long pants -- Chemical resistant gloves such as" (*registrants inserts correct gloves*) "-- Chemical resistant apron -- Chemical resistant footwear and socks In addition to the above PPE, persons mixing and loading into chemigation systems, must wear a NIOSH approved respirator with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an (OV) cartridge, or - a canister with any N^2,R,P or HE prefilter	

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
RED PPE Requirements[1] for Emulsifiable Concentrate Products: (continued)	Applicators and other handlers exposed to the dilute must wear: -- Long-sleeved shirt & long pants -- Shoes plus socks In addition to the above PPE, applicators using back-pack or hand-held equipment must wear chemical resistant gloves such as" (*registrant inserts correct gloves*). "In addition to the above PPE, applicators applying dry-bulk fertilizer with a specialized truck designed to treat more that 80 acres, must wear a NIOSH approved respirator with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an (OV) cartridge, or - a canister with any N[2],R,P or HE prefilter" * If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped. "Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category" [*registrant inserts A,B,C,D,E,F,G,or H*] "on an EPA chemical-resistance category selection chart." Loaders, applicators (except when using a belly grinder) flaggers and other handlers must wear: -- Long-sleeved shirt and long pants -- Shoes plus socks In addition to the above PPE, applicators using a push-type spreader chemical resistant gloves such as" (*registrant inserts correct gloves*) "In addition to the above PPE, loaders supporting aerial applications must wear a NIOSH approved Respirator with: - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an (OV) cartridge, or - a canister with any N[2],R,P or HE prefilter	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
RED PPE Requirements[1] for Granular Products (continued)	Applicators using a belly grinder (hand-held broadcast spreader) must wear: -- Coveralls over long-sleeved shirt and long pants -- Chemical resistant gloves such as (Registrant inserts correct gloves) -- Chemical resistant footwear and socks"	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." *For granular products also add:* "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE requirements)
Engineering Controls for Granular Products	"Engineering Controls Aerial applicators must be in an enclosed cockpit. When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-5), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following PPE and User Safety Requirements.)
Engineering Controls for EC Products	"Engineering Controls Commercial (for-hire) handlers engaged in impregnating this product into dry bulk fertilizer must: -- use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4), and -- wear the personal protective equipment required for mixers/loaders, except shoes may be substituted for chemical-resistant footwear, and -- have immediately available for use in case of an accident a NIOSH-approved respirator with: -- an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or -- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an (OV) cartridge, or -- a canister with any N^2,R,P or HE prefilter. When other handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-5), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following PPE and User Safety Requirements.)

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"Environmental Hazards This chemical is toxic to mammals. Do not apply directly to water, or to area where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of: 12 Hours."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: -- coveralls -- chemical resistant gloves -- socks and shoes"	
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.
Spray drift language that must be placed on each product that can be applied aerially:	"Aerial Spray Drift Management Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
General Application Restriction for products applied as liquid sprays (regardless of type of application equipment)	"Do not allow this product to drift"	Place in the Direction for use
The following language must be placed on each product that can be applied aerially:	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use
The following language must be placed on each product that can be applied aerially	Aerial Drift Reduction Advisory This section is advisory in nature and does not supersede the mandatory label requirements. **INFORMATION ON DROPLET SIZE** The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
The following language must be placed on each product that can be applied aerially:	**"CONTROLLING DROPLET SIZE** Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"BOOM LENGTH** For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"APPLICATION HEIGHT** Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"SWATH ADJUSTMENT** When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
The following language must be placed on each product that can be applied aerially:	**"WIND** Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE INVERSIONS** Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"SENSITIVE AREAS** The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use
	End Use Products Intended for Occupational Use (Label Contains Non-WPS Uses Only)	
RED PPE Requirements[1] for Emulsifiable Concentrate Products:	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category" [*registrant inserts A,B,C,D,E,F,G,or H*] "on an EPA chemical-resistance category selection chart." Mixers, Loaders and Handlers exposed to the concentrate must wear: -- Long-sleeved shirt and long pants -- Chemical resistant gloves such as (*registrant inserts correct gloves*) -- Chemical resistant apron -- Chemical resistant footwear and socks	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
RED PPE Requirements[1] for Emulsifiable Concentrate Products: (continued)	Applicators and other handlers exposed to the dilute must wear: -- Long-sleeved shirt & long pants -- Shoes plus socks -- Chemical resistant gloves when using back-back or hand-held equipment"	Precautionary Statements: Hazards to Humans and Domestic Animals
RED PPE Requirements[1] for Granular Products	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category" [*registrant inserts A,B,C,D,E,F,G,or H*] "on an EPA chemical-resistance category selection chart." Loaders, applicators (except when using a belly grinder) and other handlers must wear: -- Long-sleeved shirt and long pants -- Shoes plus socks -- Chemical resistant gloves such as" (*registrant inserts correct gloves*) "when using a push-type spreader Applicators using a belly grinder (hand-held broadcast spreader) must wear: -- Coveralls over long-sleeved shirt and long pants -- Chemical resistant gloves such as" (*Registrant inserts correct gloves*) " -- Chemical resistant footwear and socks"	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE requirements)
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
Environmental Hazards	"Environmental Hazards This chemical is toxic to mammals. Do not apply directly to water, or to area where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."	Precautionary Statements under Environmental Hazards
Entry Restrictions for EC Products	"Do not enter or allow others to enter until sprays have dried and incorporation (if required) is complete."	Directions for Use Under General Precautions and Restrictions
Restricted Interval for Granular Products	"Do not enter or allow other to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete following application. If the incorporation is accomplished by watering-in, do not enter or allow others to enter the treated area until the surface is dry following the watering-in."	
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Directions for Use under General Precautions and Restrictions
Site Specific Application Restrictions	"For professional use only. Not for use by residential consumers."	Place on the Front Panel and in the Direction for Use under General Precautions and Restrictions
	End-Use Products Intended for Residential/Consumer Users Only	
Entry Restrictions	"Do not allow people or pets to enter treated area (except those persons involved in the incorporation) until incorporation is complete following application. If the incorporation is accomplished by watering-in, do not enter or allow others to enter the treated area until the surface is dry following the watering-in."	Directions for Use Under General Precautions and Restrictions
General Application Restrictions	"Do not apply this product in a way that will contact people or pets."	
General Use Restrictions	"Not for professional use. For use by residential consumers only. "	Place on the Front Panel and in the Direction for Use under General Precautions and Restrictions

Table 32. Summary of RED Labeling Requirements for EPTC

Description	Required Labeling	Placement on Label
Specific Application Restrictions	"Do not use a belly grinder (hand-held broadcast equipment) when applying this product"	Directions for Use Under General Precautions and Restrictions
Specific Application Restrictions	Labels must be amended to reflect that the maximum application rate of 5 lbs a.i/acre per application for any granular product for residential consumer ornamental garden.	
Other use Application Restrictions	For "Peas" remove limitation on peas intended for processing only. For cotton, the maximum use seasonal use rate is 2 lbs per AI/A.	
General Labeling Restriction	"Keep off sidewalks, driveways, patios, or similar surfaces".	Directions for Use Under General Precautions and Restrictions
Specific Use Restrictions	Only granular products may be registered for use by residential consumers. Any EC products registered for such use will be voluntarily canceled by the registrant.	

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.
[2] If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.
Instructions in the Labeling Required section appearing in quotations represent the exact language that must appear on the label.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this RED. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrant may distribute and sell EPTC products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrant remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

Appendix A. TABLE OF USE PATTERNS ELIGIBLE FOR REREGISTRATION

EPTC Maximum Use Table

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Alfalfa					
Preplant Soil incorporated Ground	5% G 10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate By Region[2] National=3.0-4.0; N/PNW/W=4.0 EC Rate By Region N/PNW/W=2.0-4.0; SE=1.5 in SC; 3.0 in other areas within SE; SW=3.0; AZ/CA=2.0-4.0	1	14	Application of spray formulation may be made in 10-50 gallons of water per acre (GPA). Do not apply if a grass or a grain crop is to be planted with the legume crop.
Postplant/postemergence Irrigation	6 lb/gal EC 7 lb/gal EC	EC Rate By Region N/SW=2.0-3.0; W/PNW=2.0-3.0; AZ/CA=2.0-3.0	1 per cutting for W Region	14	Application may be made to established alfalfa plants by metering the recommended dosage into the irrigation water.
Postemergence Ground/Aerial	10% G 20% G	G Rate By Region W (except NV)=2.0-3.0	1 per cutting or per 30-day interval	14	Application should be followed by irrigation (flood or sprinkler) .
Almonds					
Postemergence Irrigation	6 lb/gal EC 7 lb/gal EC	EC Rate By Region W=2.2-3.0; AZ/CA=3.0	2	14 16	Application may be made after the last cultivation for the season by metering the recommended dosage into the irrigation water.
Beans (Succulent or Dry)					
Fall treatment Soil incorporated Ground	10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate=4.0-4.5 EC Rate=4.0-4.5	1	45	Use limited to dry beans grown in MN and ND. Application of spray formulation may be made in 10-50 GPA. Do not apply to the following types of beans: adzuki, cowpeas (blackeyed peas and blackeyed beans), soybeans, lima, mung, Garbanzo, or other flat-podded beans except Romano.

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Preplant (including bed treatment) or at-planting Soil incorporated (including subsurface) Ground	5% G 10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate By Region National=3.0 N/PNW=4.0 EC Rate By Region N/PNW=3.0-4.0; SE=1.5-3.0; W/SW=3.0; AZ/CA=3.0	1 for small white beans or green beans grown on coarse textured soils	45	Application of spray formulation may be made in 10-50 GPA. Do not apply to the following types of beans: adzuki, cowpeas (blackeyed peas and blackeyed beans), soybeans, lima, mung, Garbanzo, or other flat-podded beans except Romano. Some liquid formulations may be tanked mix with alachlor, ethalfluralin, metolachlor, pendimethalin, and trifluralin. Plant beans 7 days following band and broadcast treatments to beds.
Beans (continued)					
Postemergence Layby - soil incorporated or subsurface injection Ground	5% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate 2.0-6.0 EC Rate By Region N/W/PNW=3.0-4.0; SE/SW=3.0; AZ/CA=3.0	1 for small white beans or green beans grown on coarse textured soils	45	Directed spray application (using 10-50 GPA) to soil should be made at the base of the plants before bean pods start to form. Do not apply to the following types of beans: adzuki, cowpeas (blackeyed peas and blackeyed beans), soybeans, lima, mung, Garbanzo, or other flat-podded beans except Romano. Some liquid formulations may be tanked mix with alachlor, ethalfluralin, metolachlor, pendimethalin, and trifluralin.
Postemergence Irrigation	7 lb/gal EC	EC Rate by Region N/SE/W/SW/PNW= 3.0-4.0	1	45	Use limited to dry beans. Application of spray formulation is metered into irrigation water after clean cultivation. Do not apply to the following types of beans: adzuki, cowpeas (blackeyed peas and blackeyed beans), soybeans, lima, mung, Garbanzo, or other flat-podded beans except Romano. Some liquid formulations may be tanked mix with alachlor, ethalfluralin, metolachlor, pendimethalin, and trifluralin.
Beet, Garden					
Preplant Soil incorporated Ground	6 lb/gal EC 7 lb/gal EC	EC Rate By Region PNW=2.0	1	14	

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Beet, Sugar					
Fall treatment Soil incorporated Ground	10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate=4.0-4.5 EC Rate=4.0-4.6	1	49	Application of spray formulation may be made in 10-50 GPA. Some liquid formulations may be tank mixed with cycloate.
Preplant Soil incorporated Ground	6 lb/gal EC 7 lb/gal EC	EC Rate By Region IA/MN/MI/NE/ND/SD =1.5-3.0	1	49	Application of spray formulation may be made in 10-50 GPA. Some liquid formulations may be tank mixed with cycloate.
Postemergence/post-thinning Irrigation	6 lb/gal EC 7 lb/gal EC	EC Rate By Region N/SW/PNW/W= 2.0-3.0; AZ/CA=2.0-3.0	2 for W/PNW Regions	49 for PNW	Application should be made into the first irrigation after the last cultivation of the season. Some liquid formulations may be tank mixed with cycloate.
Postemergence/post-thinning Soil incorporated or subsurface injection Ground	10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate By Region National=3.0 EC Rate By Region N/PNW=1.5-3.0; SW=2.0-3.0; W=3.0 AZ/CA=1.5-3.0	1	49 for PNW	Application should be made after first true leaves have formed. Some liquid formulations may be tank mixed with cycloate.
Birdsfoot Trefoil					
Preplant Soil incorporated Ground	5% G 10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate By Region National=3.0-4.0; N/PNW/W=4.0 EC Rate By Region N=3.0-4.0; SE=3.0; SW=3.0; W/PNW=2.0-4.0; AZ/CA=2.0-4.0	1 [4]	16	Application of spray formulation may be made in 10-50 GPA. Application is prohibited if a grass or a grain crop is to be planted with the legume crop.
Castor Beans					
Postplant Soil incorporated Ground	6 lb/gal EC 7 lb/gal EC	EC Rate By Region N=2.0	1	16	Application of spray formulation may be made in 10-50 GPA.

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Citrus Fruits (Including Grapefruit, Oranges, and Tangerines)					
Postemergence Irrigation	6 lb/gal EC 7 lb/gal EC	<u>EC Rate By Region</u> SE/SW/W=2.6-3.0; AZ/CA=3.0	1	14 for W Region 15 for all Regions on all other labels	Application of spray formulation may be made by metering in flood or furrow irrigation.
Citrus Fruits (Nursery Stock in Nonbearing Groves)					
Postemergence Directed spray Ground	10% G 20% G 6 lb/gal EC 7 lb/gal EC	<u>G Rate By Region</u> National=3.0-6.0 <u>EC Rate By Region</u> SE/SW/W=3.0-6.0; AZ/CA=3.0-6.0	1	15	Application of spray formulation may be made after "lining out" in 10-50 GPA.
Clover (including Ladino Clover)					
Preplant Soil incorporated Ground	5% G 10% G 20% G 6 lb/gal EC 7 lb/gal EC	<u>G Rate By Region</u> National=3.0-4.0; N/PNW/W=4.0 <u>EC Rate By Region</u> N=3.0-4.0; SE=3.0; SW=3.0; PNW/W=2.0-4.0; AZ/CA=2.0-4.0	1 [4]	15	Application of spray formulation may be made in 10-50 GPA. Do not apply if a grass or a grain crop is to be planted with the legume crop.
Postemergence Irrigation	6 lb/gal EC 7 lb/gal EC	<u>EC Rate By Region</u> N/SW/PNW/W= 2.0-3.0; AZ/CA=2.0-3.0	1	45	Application should be made to established ladino clover plants by metering the recommended dosage into the irrigation water.

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Corn (Field and Sweet)					
Preplant Soil incorporated Ground, irrigation, or subsurface injection	10% G 25% G 5 lb/gal EC 6 lb/gal EC 6 lb/gal EC	<u>G Rate By Region</u> PNW=2.0 NE/MidW/S/W=4.0-6.0 <u>EC Rate By Region</u> N=3.0-4.0; PNW=2.0-3.0; E/Central/ W (except AZ/CA)/AZ/CA = 3.0-6.0; All regions except AZ/CA/FL=3.2-5.6	1 [4]	45	Application of spray formulation may be made in 10-60 GPA. Some liquid formulations may be tank mixed with atrazine, cyanazine, or simazine. Delay planting of corn for 7-10 days following treatment.
Postplant Broadcast soil incorporated Ground	5% G	MidW/NE/SE=2.0-3.0	1	45	
Preemergence Soil incorporated Ground	10% G 6 lb/gal EC	<u>G Rate By Region</u> N/SE=2.0-3.0 <u>EC Rate By Region</u> N/SE=2.0-3.0	1	45	Application of spray formulation may be made in 10-50 GPA.
Corn (Pop)					
Preplant Soil Incorporated Ground, irrigation, or subsurface injection	25% G 5 lb/gal EC 6 lb/gal EC 6 lb/gal EC	<u>G Rate By Region</u> NE/MidW/S/W=4.0-6.0 <u>EC Rate By Region</u> E/Central/ W (except AZ/CA)/AZ/CA= 3.0-6.0; All regions except AZ/CA/FL=3.2-5.6	1 [4]	45	Application of spray formulation may be made in 10-60 GPA. Some liquid formulations may be tanked mixed with atrazine, cyanazine, or simazine
Postplant Soil incorporated Ground	5% G	MidW/NE/SE=2.0-3.0	1	45	

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Cotton					
At-planting Ground (subsurface injection or sweep)	6 lb/gal EC	EC Rate By Region SE=1.5	1	30	Use limited to non-irrigated cotton plants. Application of spray formulation may be made in 10-50 GPA.
Postemergence Soil incorporated Ground (subsurface injection or sweep)	10% G [20% G [6 lb/gal EC 7 lb/gal EC	G Rate By Region AZ/CA=2.0 EC Rate By Region SE/SW=2.0	1	30	Use limited to non-irrigated cotton plants. Application of spray formulation should be made when cotton plants have 2 to 4 leaves using 10-50 GPA.
Flax					
Fall treatment Soil incorporated Ground	6 lb/gal EC	EC Rate By Region N=4.0-4.6	1	45	Use limited to flax grown in MN and ND. Application of spray formulation may be made in 10-50 GPA.
Preplant Soil incorporated Ground	7 lb/gal EC	EC Rate By Region PNW=3.0	1 [4]	45	Application of spray formulation may be made in 10-50 GPA.
Lespedeza					
Preplant Soil incorporated Ground	5% G 10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate By Region National=3.0-4.0; N/PNW/W=4.0 EC Rate By Region N=3.0-4.0; SE=3.0; SW=3.0; W/PNW=2.0-4.0; AZ/CA=2.0-4.0	1 [4]	45	Application of spray formulation may be made in 10-50 GPA. Do not apply if a grass or a grain crop is to be planted with the legume crop.
Peas (Succulent)					
Preplant Soil incorporated Ground	6 lb/gal EC 7 lb/gal EC	2.0	1 [4]	45	Use limited to green peas grown in Western WA for processing. Application of spray formulation may be made in 10-50 GPA.

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Potatoes (Irish)					
Fall treatment Soil incorporated Ground	10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate= 4.0-4.5 EC Rate= 4.5-6.0	1	45	Use limited to potatoes grown in MN and ND. Application of spray formulation may be made in 10-50 GPA.
Preplant/at-planting/drag-off, (before or after bed formation) Soil incorporated Ground	5% G 10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate National=3.0-6.0; SE/SW/W=3.0; N/PNW=3.0-6.0 EC Rate By Region SE/W=1.5-3.0 PNW=3.0-4.0 N/SW=3.0-6.0 AZ/CA=3.0	1 [4]	45	Application of spray formulation may be made in 10-50 GPA. Some liquid formulations may be tank mixed with metribuzin and rimsulfuron.
Potatoes (continued)					
Postemergence Layby - soil incorporated Ground	5% G 10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate National=4.0 SE/SW/W=3.0 N/PNW=3.0-4.0 EC Rate By Region N/W=3.0-4.0; SE=3.0; SW/PNW=3.0-6.0; W=3.0-4.0; AZ/CA/ID/OR/WA= 3.0-4.0	1	45	Directed spray application to soil may be made in 10-50 GPA. Some liquid formulations may be tank mixed with metribuzin and rimsulfuron.
Postemergence Layby - irrigation	6 lb/gal EC 7 lb/gal EC	EC Rate By Region N/SW/SE/PNW/W=3.0 AZ/CA=3.0 ID/OR/WA=3.0-6.0	1	30 for W Region 45 for other regions	Application of spray formulation may be made into the irrigation water after clean cultivation. Some liquid formulations may be tank mixed with metribuzin and rimsulfuron.

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Safflower					
Preplant Soil incorporated Ground	5% G 10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate National=3.0 EC Rate By Region N/PNW/W=3.0; AZ/CA=3.0	1 [4]	not stated [3]	Application of spray formulation may be made in 10-50 GPA.
Postemergence Irrigation	7 lb/gal EC	EC Rate By Region AZ/CA=3.0	2	60	Use limited to AZ and CA. Application may be made using flood, furrow, or sprinkler irrigation systems.
Strawberries					
Postplant Soil incorporated Ground	5% G	4.0	1	not stated [3]	Use limited to strawberries grown in KY, NY, OH, PA, and WV. Application should be made after plants have developed new roots and leaves (a minimum of 4 weeks after planting).
Postemergence Soil incorporated Ground	5% G	4.0	1	1	Use limited to strawberries grown in TN. Application should be made on well-established plants. For new beds, application should be made 3 to 4 weeks after planting. For old beds, application may be made after harvest when beds are clean. Do not apply later than the first bloom, or to plants that will be tarped or mulched.
Sunflower					
Fall treatment Soil incorporated Ground	10% G 20% G 6 lb/gal EC 7 lb/gal EC	G Rate=4.0-4.5 EC Rate=4.0-4.6	1	1	Use limited to sunflowers grown in MN and ND. Application of spray formulation may be made in 10-50 GPA.
Preplant (spring) Soil incorporated Ground	20% G 6 lb/gal EC 7 lb/gal EC	G Rate By Region: CO/KS/MN/NE/ND/SD=2.0-3.0 EC Rate By Region CO/KS/MN/MS/ND/SD=2.2-3.0	1 [4]	not stated [3]	Application of spray formulation may be made in 10-50 GPA. Some liquid formulations may be tank mixed with trifluralin.

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Sweet Potato					
Preplant-bed over/up Soil incorporated Ground	6 lb/gal EC 7 lb/gal EC	EC Rate By Region SE/SW=1.5-3.0	1 [4]	not stated [3]	Application of spray formulation may be made in 10-50 GPA
Postplant Broadcast spray Ground	6 lb/gal EC 7 lb/gal EC	EC Rate By Region SE/SW=7.0-7.5	1	1	Application should be made immediately after planting (or within 2 days after planting slips or vine cuttings) using 10-50 GPA.
Tomatoes					
Postemergence layby Soil incorporated Ground	6 lb/gal EC 7 lb/gal EC	EC Rate By Region W/PNW=3.0	1	21	Use limited to Northern CA counties (Butte, Colusa, Contra Costa, Glen, Merced, Sacramento, San Joaquin, Solano, Stanislaus, Sutter, Yolo, and Yuba). Application of spray formulation may be made in 10-50 GPA. Do not use where grain will be planted within 90 days. Do not irrigate for at least 5 days after application.
Walnut					
Postemergence Irrigation	6 lb/gal EC 7 lb/gal EC	EC Rate By Region PNW/W=3.0; AZ/CA=3.0	1		Application of spray formulation may be made into the irrigation water during the entire irrigation period.
Fallow Land					
Preplant Soil incorporated Ground	10% G 20% G 7 lb/gal EC	3.0-6.0	1 [4]	not stated [3]	AZ SLNs: For use on idle season fallow land from June to September. Crop areas must be irrigated at least 30 days prior to planting. Do not plant cotton or crops not listed on the parent label within 90 days after application. CA SLN: Use limited to Imperial, Riverside, and San Bernardino counties of CA for use on fallow land from June to September prior to planting of carrots, cotton, and lettuce. Crop areas must be irrigated at least 30 days prior to planting. Do not plant carrots, cotton, or lettuce within 90 days after application.

Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest Interval, Days	Use Directions and Limitations [1]
Site Application Timing Application Type Application Equipment	Formulation	Single Application Rate (lb ai/A)	Maximum Number of Applications Per Season	Preharvest/ Programing Interval, Days	Use Directions and Limitations [1]
Ornamental (Commercial)					
Preplant Postplant Soil incorporated	2.3% G	5.lb ai/A	1 [4]	not stated [3]	Preplant broadcast. Preplant band application. Postplant application: nursery cultivator or rototiller.
Ornamental(Residential)					
Preplant Postplant Soil incorporated	2.3% G	5.lb ai/A	1 [4]	not stated [3]	Preplant application- Rototiller. Postplant application-For annual weed use, hand rake or hoe or water in immediately after application to a dept of 2 to 3 inches. Belly Grinder use for residential application is prohibited.

[1] The restricted entry interval is 12 hours. The label for the 5.6 lb/gal EC formulation (EPA Reg. No. 10182-388) specifies the following rotational crop restrictions: corn, soybeans, sorghum or tobacco may be planted the spring following Preplant application; wheat may be planted 4 months after Preplant application. No other rotational crop restrictions have been established for any other product.

[2] Regions: E=East; N=North; SE=Southeast; SW=Southwest; W=West; MidW=Midwest; PNW=Pacific Northwest.

[3] For single application per season labeled PHI's are not required for Preplant.

[4] Where there was formally no maximum seasonal application rate specified, it is assumed that 1 Preplant application is sufficient. This must be specified on label in the future.

.

Appendix B. TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within the case EPTC covered by this RED. It contains generic data requirements that apply EPTC in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial non-food
   D. Aquatic food
   E. Aquatic non-food outdoor
   F. Aquatic non-food industrial
   G. Aquatic non-food residential
   H. Greenhouse food
   I. Greenhouse non-food
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor non-food
   N. Indoor medical
   O. Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

REQUIREMENTS		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1 (830.1550)	Chemical Identity	All	42860201
61-2A (830.1600)	Start. Mat. & Mnfg. Process	All	00152450,42860202
61-2B (830.1670)	Formation of Impurities	All	00152450,42860201
62-1 (830.1700)	Preliminary Analysis	All	42860201,00152450
62-2 (830.1750)	Certification of limits	All	42860201
62-3 (830.1800)	Analytical Method	All	42120801
63-2 (830.6302)	Color	All	42120801
63-3 (830.6303)	Physical State	All	42120801
63-4 (830.6304)	Odor	All	42120801
63-6 (830.7200)	Boiling Point	All	42120801
63-7 (830.7300)	Density	All	42120801
63-8 (830.7840)	Solubility	All	42120801
63-9 (830.7950)	Vapor Pressure	All	42120801
63-10 (838.7370)	Dissociation Constant	All	42120801
63-11 (830.7550)	Octanol/Water Partition	All	42120801
63-12 (830.7000)	pH	All	42120801
63-13 (830.6313)	Stability	All	42120801
63-14 (830.6314)	Oxidizing/Reducing Action	All	42120801
63-15 (830.6315)	Flammability	All	42120801
63-16 (830.6316)	Explodability	All	42120801
63-17 (830.6317)	Storage stability	All	42120801
63-18 (830.7100)	Viscosity	All	42120801
63-19 (830.6319)	Miscibility	All	42120801
63-20 (830.6320)	Corrosion characteristics	All	42120801
ECOLOGICAL EFFECTS			
71-1A (850.2100)	Acute Avian Oral - Quail/Duck	A,B,C,G,K	00144280 (Data Gap)
71-2A (850.2300)	Avian Dietary - Quail	A,B,C,G,K	01311275
71-2B (850.2200)	Avian Dietary - Duck	A,B,C,G,K	00144207
71-4A (850.2100)	Avian Reproduction - Quail	A,B,C,K	Data Gap
71-4B (850.2300)	Avian Reproduction - Duck	A,B,C,K	Data Gap
72-1A (850.1075)	Fish Toxicity Bluegill	A,B,C,D,F,E	00131271

72-1B (850.1075)	Fish Toxicity Bluegill - TEP	A,B,C,D	00021834
72-2A (850.1010)	Invertebrate Toxicity	A,B,C,G,K	001312273, 00144209,42945601 (Data Gap)
72-3A (850.1025)	Estu/mari tox mollusk	A,B,C,K	Data Gap
72-3B (850.1035)	Estu/mari tox shrimp	A,B,C,K	Data Gap
72-CA (850.10$5)	Estu/mari tox fish	A,B,C,K	Data Gap
72-4 (850-1350)	Life cycle invertebrate	A,B,C,K	Data Gap
123-1A(850.4225)	Seed Germination/Seedling Emergence	A,B,C,D	42120802, 43217101
123-1B(850.4250)	Vegetative Vigor	A,B,C,D	43217101
123-2 (850.4250)	Aquatic Plant Growth	A,B,C,D	42899801,42921201 42921201,42940901,43096001
141-1 (850.3020)	Honey Bee Acute Contact	A,B,C,D	000365935
TOXICOLOGY			
81-1 (870.1100)	Acute Oral Toxicity - Rat	A,B,C,D	00157868
81-2 (870.1200)	Acute Dermal Toxicity - Rabbit/Rat	A,B,C,D	00157869
81-3 (870.1300)	Acute Inhalation Toxicity - Rat	A,B,C,D	00157870
81-4 (870.2400)	Primary Eye Irritation - Rabbit	A,B,C,D	00157871
81-5 (870.2500)	Primary Dermal Irritation - Rabbit	A,B,C,D	00157872
81-6 (870.2600)	Dermal Sensitization - Guinea Pig	A,B,C,D	00157873
81-7 (870.6100)	Acute Delayed Neurotoxicity - Hen	A,B,C,D	00150325
82-1A (870.3100)	90-Day Feeding - Rodent	A,B,C,D	00144651
82-1B (870.3150)	90-Day Feeding - Non-rodent	A,B,C,D	00161595
82-2 (8703200)	21-Day Dermal - Rabbit/Rat	A,B,C,D	4372502
82-3(870.3250)	90-Day Dermal - Rodent	A,B,C,D	41831202
82-4 (870.3465)	90-Day Inhalation - Rat	A,B,C,D	00157870, 00154784, 41992001
82-5A	90-Day Neurotoxicity - Hen	A,B,C,D	00150325
82-5B (870.6201)	90-Day Neurotoxicity - Mammal	A,B,C,D	42921901,43039701, 43230901
83-1A (870.4100)	Chronic Feeding Toxicity - Rodent	A,B,C,D	00145004,00145311
83-1B	Chronic Feeding Toxicity -Non-Rodent	A,B,C,D	00161595,40442301
83-2A (870.4200)	Oncogenicity - Rat	A,B,C,D	40215001
83-2B	Oncogenicity - Mouse	A,B,C,D	4237001
83-3A (870.3700)	Developmental Toxicity - Rat	A,B,C,D	00138919
83-3B	Developmental Toxicity - Rabbit	A,B,C,D	40442302
83-4 (870.3800)	2-Generation Reproduction - Rat	A,B,C,D	0012128,00161597, 40420408
83-6 (870.6300)	Developmental Neurotoxicity Study	A,B,C,G,K	Data Gap
84-2A	Gene Mutation (Ames Test)	A,B,C,D	00152451,00152452

84-2B	Structural Chromosomal Aberration	A,B,C,D	00152455
85-1 (870.7485)	General Metabolism	A,B,C,D	00085400,40614424

OCCUPATIONAL/RESIDENTIAL EXPOSURE

132-1A (875.2100)	Foliar Residue Dissipation	A,B,C,D,H,I, J, K	reserved
132-1B (875.2200)	Soil Residue Dissipation	A,B,C,D,H,I, J, K	reserved
133-3 (875.2400)	Dermal Passive Dosimetry Exposure	A,B,C,D	reserved
133-4 (875.2500)	Inhalation Passive Dosimetry Exposure	A,B,C,D	reserved

ENVIRONMENTAL FATE

161-1 (835.2120)	Hydrolysis	A,B,C,D,E,F	00141373, 42120803
161-2 (835.2240)	Photodegradation - Water	A,B,C,D,E,F	4040401, 42120803
161-3 (835.2410)	Photodegradation - Soil	A,B,C,J	42120804
161-4 (835.2370)	Photodegradation - Air	A,B,C	42541001
162-1 (835.4100)	Aerobic Soil Metabolism	A,B,C,K	42120805 (Data Gap, upgradable)
162-2 (835.4200)	Anaerobic Soil Metabolism	A,B,C	42120807,40430402 (Data Gap, upgradable)
162-4 (835.4300)	Aerobic Aquatic Metabolism	G	Data Gap
163-1 (835.1240)	Leaching/Adsorption/Desorption	A,B,C,G,K	404420403, 42120808 (Data Gap)
163-2 (835.1410)	Volatility - Lab	A,B,H,I	42120809
163-3 (835.8100)	Field Volatility	A.B.	Data Gap
164-1 (860.6100)	Terrestrial Field Dissipation	A,B,C,K	98250,146934, 146935,404205
164-5 (835.6500)	Long Term Soil Dissipation	A,B,C,D	42120810,42120811
165-1 (860.1850)	Confined Rotational Crop	A,B,C,D	00152457
165-2 (860.1900	Field Accumulation in Rotational Crops		Data Gap
165-4 (850.1730)	Bioaccumulation in Fish	A,B,C,D	40575101 (Data Gap, upgradable)
166-1 (835.7100)	Ground Water - Small Prospective	A,B,C	
201-1 (840.1100)	Droplet Size Spectrum	n/a	Satisfied by Spray Drift Task Force
202-1 (840.1200)	Drift Field Evaluation	n/a	Satisfied by Spray Drift Task Force

RESIDUE CHEMISTRY

171-4C (860.1340)	Residue Analytical Method - Plants	A,B,K	0022281,00022318 (Data Gap)
171-4E (860.1380)	Storage Stability	A,B,K	41977401,41977402 (Data Gap)
171-4F (860.1400)	Magnitude of Residues - Potable H2O	D,E	43849911
171-4K(860.1500)	Crop Field Trials		Data Gap

Fallow fields	A,B	Data Gap
Root and Tuber Vegetables Group		
- Beet, garden, roots	A,B,K	00025035
- Beet, sugar, roots	A,B,K	00022249, 00022275,00022394, 00022398, 00025033,00025037, 00037693, 00037694, 00037705 00057546, 00067275, 43849906
- Potato	A,B,K	00022150, 00022274,00022315, 00025036, 00037691,00090891, 00105790, 00106797, 43849910
- Sweet potato	A,B,K	00025038
Leaves of Root and Tuber Vegetables Group		
- Beet, garden, tops (leaves)	A,B,K	00025035
- Beet, sugar, tops (leaves)	A,B,K	00022249, 00022275,00022394, 00022398, 00025033,00037693, 00037694, 00037705,00057546, 43849906
Legume Vegetables Group		
- Bean (succulent and dry)	A,B,K	00022278, 00022312,00022369, 00022376, 00025025,00025292, 43849912-43849915
- Pea (succulent)	A,B,K	00022146, 00039198
Foliage of Legume Vegetables Group		
- Bean forage and hay	A,B,K	00022272, 00022312,00022369, 00022376, 00025292,00037695, 00057547, 00057548, 00064182
- Pea vines and hay	A,B,K	00022146
Fruiting Vegetables (Except Cucurbits) Group		
- Tomato	A,B,K	00025031, 43849919
Citrus Group	A,B,K	00025021, 0003769 (Data Gap)
Tree Nuts Group		
- Almonds	A,B,K	00022385, 00022399,00025034, 00078437, 43849904
- Walnuts	A,B,K	00022385, 00022399,00025034, 43849905
Cereal Grains Group		
- Corn, field, grain and aspirated grain fractions	A,B,K	00025032, 00098255, 41486002,41831206, 43849922

- Corn, sweet (K+CWHR)	A,B,K	00023047, 00025032, 41486002 43849920
Forage, Fodder, and Straw of Cereal Grains Group		
- Corn, field, forage and stover	A,B,K	00025032, 00098255, 41486002 41831206, 43849922
- Corn, sweet, forage and stover	A,B,K	00025032, 41486002, 43849920
Non-grass Animal Feeds Group		
- Alfalfa, forage and hay	A,B,K	00022145, 00022311,00022386, 00025024, 41724301,41724304, 43849903
- Birdsfoot trefoil, forage and hay	A,B,K	00025029
- Clover, forage and hay	A,B,K	00025027, 43849901
Miscellaneous Commodities		
- Castor beans	A,B,K	00022147, 00039200
- Cotton, seed and gin byproducts	A,B,K	00022397, 00039200,00039201, 00037698, 43849917 (Data Gap)
- Flax, seed	A,B,K	00022273, 00022314, 00067371 (Data Gap)
- Safflower, seed	A,B,K	00022140, 00039200, 43849902
- Strawberry	A,B,K	00022118, 00025279, 00039203 (Data Gap)
- Sunflower, seed	A,B,K	00022276, 00022316,00039200, 00057545, 00057549, 43849908
- Citrus group	A,B	Data Gap
860.1520: Processed Food/Feed		
- Beet, sugar	A,B	43849907
- Corn, field	A,B	43849921
- Cotton, seed	A,B	43849916
- Potato	A,B	43849911
- Sunflower seed	A,B	43849909
- Tomato	A,B	43849918
171-4M (860.1360) Multiresidue Method		Data Gap

Appendix C. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE REREGISTRATION DECISION (BIBLIOGRAPHY)

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence

contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID CITATION

00021834 Knott, W.; Beliles, R.P. (1967) Eptam Safety Evaluation on Fish and Wildlife: Bobwhite Quail, Rainbow Trout, and Bluegill Sunfish. (Unpublished study received Mar 27, 1972 under unknown admin. no.; prepared by Woodard Research Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:120329-S)

00022361 Knott, W.; Beliles, R.P. (1967) Knoxweed 42 Safety Evaluation on Fish and Wildlife: Bobwhite Quail, Rainbow Trout, and Bluegill Sunfish. (Unpublished study received Oct 12, 1967 under unknown admin. no.; prepared by Woodard Research Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:110074-A)

00025286 McCann, J.A. (1972) [Eptam: Toxicity to Rainbow Trout]: Test No. 461. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, unpublished report.)

00025287 McCann, J.A. (1970) [Eptam: Toxicity to Goldfish]: Test No. 286. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, unpublished report.)

00034683 McCann, J.A. (1970) [Eptam 6 E: Toxicity to Goldfish]: Test No. 294. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, unpublished report.)

00034684 McCann, J.A. (1970) [Eptam 6 E: Toxicity to Bluegill]: Test No. 277. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory, unpublished report.)

00084743 Bullock, C. (1968) Thiocarbamate Herbicides--Mosquito Fish Bioassay: Toxicologival Summary T-1272. (Unpublished study received Oct 8, 1981 under 476-2107; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:246020-G)

00131271 Burgess, D.; Forbis, A. (1983) Acute Toxicity of EPTC to Bluegill Sunfish (Lepomis macrochirus): Static Bioassay Report 30651. (Unpublished study received Oct 3, 1983 under 748-235; prepared by Analytical Bio-Chemistry Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:251432-A)

00131272 Forbis, A. (1983) Acute Toxicity of EPTC to Rainbow Trout (Salmo gairdneri): Static Bioassay Report 30652. (Unpublished study received Oct 3, 1983 under 748-235; prepared by Analytical Biochemistry Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:251432-B)

BIBLIOGRAPHY

MRID CITATION

00131273 Boudreau, P.; Forbis, A. (1983) Acute Toxicity of EPTC to Daphnia magna: Static Acute Bioassay Report 30653. (Unpublished study received Oct 3, 1983 under 748-235; prepared by Analytical biochemistry Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, OH; CDL:251432-C)

00131276 Beavers, J.; Jaber, M.; Joiner, G.; et al. (1983) A Dietary LC50 in the Mallard with EPTC: Project No. 145-114. Final rept. (Unpublished study received Oct 3, 1983 under 748-235; prepared by Wildlife International Ltd., submitted by PPG Industries, Inc., Barberton, OH; CDL:251432-F)

00141373 Myers, H.; Bartell, L. (1983) Hydrolysis Studies of EPTC: Report No. WRC 83-59. Unpublished study prepared by Stauffer Chemical Co. 11 p.

00142894 Atkins, E. (1985) Letter sent to J. Slate dated Mar 7, 1985: (Acute contact toxicity of Eradicane 6.7E on honey bees). Includes lab data summary sheet 657. Prepared by Univ. of California, Riverside, Dept. of Entomology. 11 p.

00142895 Majeska, J. (1984) Mutagenicity Evaluation in Bone Marrow Micronucleus: Report NO. T-11906. Unpublished study prepared by Stauffer Chemical Co., Environmental Health Center. 16 p.

00142896 Vispetto, A.; Miaullis, J. (1979) Eptam Rat Metabolism: Project 148170. Unpublished study prepared by Stauffer Chemical Co., Environmental Health Center. 27 p.

00144208 McAllister, W.; Cohle, P. (1984) Acute Toxicity of Eptam Technical to Bluegill Sunfish (Lepomis macrochirus): Static Acute Toxicity Report #31562. Unpublished study T-11450 prepared by Analytical Bio-Chemistry Laboratories, Inc. 51 p.

00144209 Forbis, A.; Burgess, D. (1984) Acute Toxicity of Eptam Technical to Daphnia magna: Static Acute Toxicity Report #31563. Unpublished study T-11449 prepared by Analytical Bio-chemistry Laboratories, Inc. 35 p.

00152457 Thomas, V.; Dennison, J. (1984) Rotational Crop Uptake of ?Radiolabeled Carbonσ-Eptam Residues in Soil: MRC-84-04. Unpublished study prepared by Stauffer Chemical Co. 19 p.

00157868 Naas, D. (1985) Acute Oral Toxicity (LD50) Study in Albino Rats with EPTC Technical: Project No. WIL-13035: Final Report. Unpublished study prepared by WIL Research Laboratories, Inc. 132 p.

BIBLIOGRAPHY

MRID CITATION

00157870 Dudek, B. (1985) Four Hour Acute Aerosol Inhalation Toxicity Study in Rats of EPTC Technical: Report No. 420-1853. Unpublished study prepared by American Biogenics Corp. 44 p.

00161597 Mackenzie, K. (1986) Two-generation Reproduction Study with EPTC in Rats: Report: Study No. 6100-108. Unpublished study prepared by Hazleton Laboratories America, Inc. 1192 p.

40215002 Ross, J. (1987) Interpretation, Exposure Assessment and Risk Assessment Based on Monitoring Data for Agricultural Use of EPTC by the Mixer/Applicator: Lab No.: BR-24060. Unpublished study prepared by PPG Industries, Inc. 23 p.

40222401 Knarr, R.; Iwata, Y. (1986) Application Exposure to EPTC During Ground-spray Application of Eptam 7-E Selective Herbicide to Potato Fields. Unpublished study prepared by Stauffer Chemical Co. 108 p.

40326302 Wiedmann, J. (1987) Genep 7E Mixer Applicator Exposure Study, Nichols Ranch, Chico, California, 1986: Lab No.: BR 24056. Unpublished study prepared by PPG Industries, Inc. 201 p.

40420401 Lee, K. (1987) EPTC--Photodegradation Studies in Water: Laboratory Project ID: RRC 87-54. Unpublished study prepared by Stauffer Chemical Co. 71 p.

40420403 McBain, J. (1987) Eptam Soil Leaching Study: Document Nos. PMS-248 and MRC-87-25. Unpublished study prepared by ICI Americas Inc. 36 p.

40420404 Cliath, M.; Spencer, W.; Farmer, W.; et al. (1980) Volatilization of S-ethyl N,N-dipropylthiocarbamate from water and wet soil during and after flood irrigation of an alfalfa field. Journal of Agricultural & Food Chemistry 28(3):610-613.

40420405 Curry, K. (1987) EPTAM (EPTC) 10-G Field Dissipation Study for Terrestrial Food Crop Uses: Mississippi, 1986: Laboratory Project ID: RRC 87-81. Unpublished study prepared by Stauffer Chemical Co. 74 p.

40420406 Curry, K. (1987) EPTAM (EPTC) 10-G Field Dissipation Study for Terrestrial Food Crop Uses, California, 1986: Laboratory Project ID: RRC 87-82. Unpublished study prepared by Stauffer Chemical Co. 55 p.

BIBLIOGRAPHY

MRID CITATION

40420407 Curry, K. (1987) Eradicane (EPTC) 6.7-E Field Dissipation Study for Terrestrial Food Crop Uses, California, 1986: Laboratory Project ID: RRC 87-88. Unpublished study prepared by Stauffer Chemical Co.66 p.

40420408 Zwicker, G.; Minor, J. (1987) A Two-generation Rat Reproduction Study with EPTAM Technical: T-10123: Addendum to Final Report-Histopathology. Unpublished study prepared by Stauffer Chemical Co. 102 p.

40442302 Gilles, P. (1987) A Teratology Study in Rabbits with Eptam Technical: T-12982: Final Report. Unpublished study prepared by Stauffer Chemical Co. 219 p.

40575100 ICI Americas Inc. (1988) Submission of Metabolism and Accumulation Studies to Support the Registration for Eptam. Transmittal of 2 studies.

40575101 Forbis, A. (1987) Uptake, Depuration and Bioconcentration of [Carbon 14]-Eptam to Bluegill Sunfish (Lepomis macrochirus): Final Report #35816. Unpublished study prepared by Analytical Biochemistry Laboratories, Inc. 45 p.

40575102 Halls, T.; Heitkamp, J. (1988) The Metabolism of [Carbon 14]-Eptam in Bluegill Sunfish (Lepomis macrochirus): ABC Final Report #36366. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 34 p.

41724305 Curry, K. (1990) EPTAM 10-G Field Dissipation Study for Terrestrial Uses (EPTAM 10-G on Alfalfa in California and Arizona): Lab Project Number: EPTC-89-SD-01: US02-89-202. Unpublished study prepared by ICI Americas Inc. 182 p.

41831200 ICI Americas Inc. (1991) Submission of Toxicology & Residue Data to Support the Application for Registration of EPTC. Transmittal of 6 Studies.

41831201 Lees, D.; Leah, A. (1990) EPTC: Acute Oral Toxicity to the Rat of A 250g/kg G Formulation: Lab Project Number: CTL/P/3206: AR5141. Unpublished study prepared by ICI Central Toxicology Laboratory. 23 p.

41831202 Lees, D.; Leah, A. (1990) EPTC: Acute Dermal Toxicity to the Rat of A 250g/kg G Formulation: Lab Project Number: CTL/P/3203: CR2823. Unpublished study prepared by ICI Central Toxicology Laboratory. 27 p.

42120801 Ericson, J. (1991) EPTC: Physical Properties: Lab Project Number: ENV-030: RR 90-422B. Unpublished study prepared by ICI Americas Inc. 50 p.

BIBLIOGRAPHY

MRID CITATION

42120802 Farmer, D.; Canning, L. (1991) EPTC: A Glasshouse Study of Pre and Post-emergence Effects of an 839 g/litre Emulsifiable Liquid Formulation on Terrestrial Non-target Plants: Lab Project Number : 90JH294. Unpublished study prepared by ICI Agrochemicals. 73 p.

42120803 Spurgeon, C. (1989) EPTC: Aqueous Photolysis at 25 C: Lab Project Number: RR 89-048B: ENV-015. Unpublished study prepared by ICI Americas Inc. 27 p.

42120804 Carpenter, M. (1989) Photodegradation Study of Carbon 14-EPTC on Soil Surface: Lab Project Number: 36612: ENV-009. Unpublished study prepared by ICI Americas Inc. 36 p.

42120805 Miaullis, J.; Parker, D. (1989) Metabolism of Carbon 14-EPTC in Aerobic Soil: Lab Project Number: PMS-302: RR 89-002B. Unpublished study prepared by ICI Americas Inc. 68 p.

42120806 Miaullis, J.; Parker, D. (1989) Metabolism of Carbon 14-EPTC in Aerobic Soil: Lab Project Number: PMS-302: WRC-89-146. Unpublished study prepared by ICI Americas Inc. 12 p.

42120807 Miaullis, J.; Parker, D. (1989) Carbon 14-EPTC Metabolism in Anaerobic Soil: Lab Project Number: PMS-303: WRC-89-147. Unpublished study prepared by ICI Americas Inc. 68 p.

42120808 Spillner, C. (1988) Adsorption and Desorption of EPTC in Four Soils : Lab Project Number: PMS-271: RRC 88-06. Unpublished study prepared by ICI Americas Inc. 48 p.

42120809 McGahan, L. (1991) Volatility of Carbon 14-EPTC Applied to Soil: Lab Project Number: PMS-344: RR-91-007B. Unpublished study prepared by ICI Americas Inc. 43 p.

42120810 Curry, K. (1989) Eptam 7-E Field Dissipation Study for Terrestrial Food Crop Uses: EPTC, California, 1988: Lab Project Number: 94CA -88-101: RR 89-015B. Unpublished study prepared by ICI Americas Inc. 183 p.

42120811 Wyatt, N. (1989) Eptam 10-G Field Dissipation Study for Terrestrial Food Crop Uses: EPTC California 1988: Lab Project Number: US02 88-102: RR 89-016B. Unpublished study prepared by ICI Americas Inc. 189 p.

BIBLIOGRAPHY

MRID CITATION

42541001 Kwok, E.; Atkinson, R.; Arey, J. (1992) Gas-phase atmospheric chemistry of selected Thiocarbamates. Environ. Sci. Technol 26(9):1798-1807.

42883501 Smyth, D.; Sankey, S.; Kent, S.; et al. (1993) EPTC: Toxicity to the Blue-Green Alga Anabaena flos-aquae: Lab Project Number: W991/G: FT53/92: BL4806/B. Unpublished study prepared by Brixham Environmental Lab. 25 p.

42899801 Smyth, D.; Sankey, S.; Kent, S.; et al. (1993) EPTC: Toxicity to the Green Alga Selenastrum capricornutum: Lab Project Number: BL4788/B: W9911/E (FT49/92). Unpublished study prepared by Zeneca Limited, Brixham Envirommental Lab. 24 p.

42921201 Smyth, D.; Sankey, S.; Kent, S.; et al. (1993) EPTC: Toxicity to the Freshwater Diatom, Navicula pelliculosa: Lab Project Number: W991/D (FT50/92): BL4787/B: FT50/92. Unpublished study prepared by Brixham Environmental Lab, Zeneca Ltd. 25 p.

42921202 Smyth, D.; Sankey, S.; Kent, S.; et al. (1993) EPTC: Toxicity to the Green Alga, Selenastrum capricornutum: Lab Project Number: W991/E: FT49/92: BL4788/B. Unpublished study prepared by Brixham Environmental Lab, Zeneca Ltd. 24 p.

42940901 Smyth, D.; Kent, S.; Craig, N.; et al. (1993) EPTC: Toxicity to the Marine Alga Skeletonema costatum: Lab Project Number: W991/F (FT52/92): BL4799/B. Unpublished study prepared by Brixham Environmental Lab, Zeneca Limited. 24 p.

42945601 Kent, S.; Sankey, S.; Johnson, P. (1993) EPTC: Acute Toxicity to Daphnia magna: Lab Project Number: BL4730/B: W991/A: FT41/92. Unpublished study prepared by Zeneca Ltd, Brixham Environmental Lab. 20 p.

42921901 Hillebrecht, W. (1993) Letter Sent to Walt Waldrop dated Sep. 9, 1993 concerning an acute neurotoxicity screening study on EPTC. Prepared by Zeneca Ag Products. 1 p.

43039701 Brammer, A. (1993) EPTC: Acute Neurotoxicity Study in Rats: Lab Project Number: AR5527: CTL/P/4092: PAC910-04/01. Unpublished study prepared by Zeneca Central Toxicology Lab. 348 p.

43096001 Smyth, D.; Kent, S.; Sankey, S. et al. (1993) EPTC: Toxicity to the Duckweed Lemna gibba: Lab Project Number: BL4774/B: W991/C (FT51/92). Unpublished study prepared by Brixham Environmental Lab., ZENECA Limited. 25 p.

BIBLIOGRAPHY

MRID CITATION

43217101 Yearsdon, H.; Canning, L.; Russell, C. et al. (1994) EPTC: A Tier II Glasshouse Study to Evaluate the Effects on Seedling Emergence on Terrestrial Non-target Plants: Lab Project Number: 92JH173: RJ1584B. Unpublished study prepared by Zeneca Agrochemicals.
40 p.

43609800 Zeneca Ag Products (1995) Submission of Metabolism Data in Support of EPTC Registration Standard. Tranmsmittal of 2 Studies

00020556 Fang, S.C.; Yu, T.C. (1959) Absorption of EPTC-S-35 by seeds and its metabolic fate during early stages of germination. Pages 91-92, In Western Weed Control Conference; 1959. N.P. (Research progress report; also In unpublished submission received Mar 27, 1972 under unknown admin. no.; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:120329-D)

00021824 Fang, S.C.; Theisen, P. (1960) Uptake of radioactive Ethyl-N,N-di-n-propylthio carbamate (EPTC-S-35) and translocation of sulfur-35 in various crops. Journal of Agricultural and Food Chemistry 8(4):295-298. (Also in unpublished submission received Mar 27, 1972 under unknown admin. no.; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:120329-E)

00021825 Yamaguchi, S. (1961) Absorption and distribution of EPTC-S-35. Weeds 9(3):374-380. (Also in unpublished submission received Mar 27, 1972 under unknown admin. no.; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:120329-F)

00021826 Nalewaja, J.D.; Behrens, R.; Schmid, A.R. (1964) Uptake, translocation and fate of EPTC-C14 in alfalfa. Weeds 12(4):269-272. (Also in unpublished submission received Mar 27, 1972 under unknown admin. no.; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:120329-H)

00022118 Stauffer Chemical Company (1958) Eptam Residue, Strawberry. (Unpublished study received Jan 23, 1961 under 476-1198; CDL: 119603-E)

00022140 Stauffer Chemical Company (1959) Eptam Residues: Safflower--Seed. (Unpublished study received Jan 11, 1965 under 476-1168; CDL: 119601-E)

00022145 Braga, G.; Briano, P.; Jones, E. (1971) Crop Residue Report: FSDS No. B-1765. (Unpublished study including FSDS Nos. B-1769, B-1766, B-1859..., received on unknown date under 476-1198; prepared in cooperation with Sherman Land Co. and

BIBLIOGRAPHY

MRID CITATION

Fresno State College, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:101414-A)

00022146 Williams, W.; Martin, M. (1964) Crop Residue Report: FSDS No. 3257. (Unpublished study including FSDS nos. 3264, 3265, 3266..., received Nov 16, 1964 under 476-1198; prepared in cooperation with T.C. Foods, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:101414-B)

00022147 Stauffer Chemical Company (1962) Crop Residue Report: FSDS No. 3396. (Unpublished study including FSDS nos. 3399, 3823, 3824..., received Nov 16, 1964 under 476-1198; CDL:101414-C)

00022150 Davis, B.; Van Buren, W.H.; Koenig, H.; et al. (1971) Crop Residue Report: FSDS No. B-0010. (Unpublished study including FSDS nos. B-0836, A-15, B-0829..., received Nov 16, 1964 under 476-1198; prepared in cooperation with Russett Chemical Co. and Univ. of Maine, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:101414-F)

00022249 Winterlin, W.; Sheets, D.; Ashton, F.M.; et al. (1972) [Crop Residue Reports and Agricultural Toxicology Reports]: FSDS No. B-0363. (Unpublished study including FSDS No. B-1722, FSDS B-1721, Ag. Toxicology Report No. 1294..., received Jun 27, 1972 under 476-1198; prepared in cooperation with Univ. of California--Davis, Dept. of Botany, submitted by Stauffer Chemical Co.,Richmond, Calif.; CDL:003743-B)

00022272 Martin, R.; Timmer, T. (1976) Fall Application of Eptam 10-G on Beans: Summary of Crop Residue Data. (Unpublished study received Feb 20, 1976 under 476-1620; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225117-A)

00022273 Timmer, G.; Haugrud, H.; Timmer, T. (1976) Fall Application of Eptam 10-G on Flax: Summary of Crop Residue Data. (Unpublished study received Feb 20, 1976 under 476-1620; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225117-B)

00022274 Plissey, E. (1976) Fall Application of Eptam 10-G on Potatoes: Summary of Crop Residue Data. (Unpublished study received Feb 20, 1976 under 476-1620; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225117-C)

BIBLIOGRAPHY

MRID CITATION

00022275 Martin, R.; Plissey, E. (1976) Fall Application of Eptam 10-G on Sugar Beets: Summary of Crop Residue Data. (Unpublished study received Feb 20, 1976 under 476-1620; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225117-D)

00022276 Plissey, E.; Timmer, T.; Timmer, G. (1975) Fall Application of Eptam 10-G on Sunflowers: Summary of Crop Residue Data. (Unpublished study received Feb 20, 1976 under 476-1620; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225117-E)

00022278 Mitchell, E.M. (1975) Cobex (Dinitramine) plus Eptam (EPTC) Residues in Dry Beans--Field Plots 1973, 1974. (Unpublished study received Jun 25, 1975 under 1624-104; submitted by United States Borax & Chemical Corp., Los Angeles, Calif.; CDL: 220073-B)

00022281 Patchett, G.G.; O'Sullivan, R.P. (1973) Residue Method for Eptam. Method no. WRC 73-42 dated Jun 18, 1973. (Unpublished study received Jun 25, 1975 under 1624-104; prepared by Stauffer Chemical Co., submitted by United States Borax & Chemical Corp., Los Angeles, Calif.; CDL:220073-G)

00022311 Weber, J.; Hamilton, K.C.; Howe, J.; et al. (1976) Eptam 7-E (12 Lbs.A.I./Acre/Season) on Alfalfa: Summary of Crop Residue Data. (Unpublished study received Feb 1, 1976 under 476-2154; prepared in cooperation with Univ. of Arizona, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:223274-A)

00022312 Martin, R.; Timmer, T.; Smith, L.; et al. (1976) Fall Application of Eptam 7-E on Beans: Summary of Crop Residue Data. (Unpublished study received Feb 1, 1976 under 476-2154; prepared in cooperation with Univ. of Minnesota, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:223274-R)

00022314 Timmer, G.; Haugrud, H.; Smith, L. (1976) Fall Application of Eptam 7-E on Flax: Summary of Crop Residue Data. (Unpublished study received Feb 1, 1976 under 476-2154; prepared in cooperation with Univ. of Minnesota, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:223274-D)

00022315 Smith, L.; Nyland, R.E. (1976) Fall Application of Eptam 7-E on Potatoes: Summary of Crop Residue Data. (Unpublished study received Feb 1, 1976 under 476-2154; prepared in cooperation with Univ. of Minnesota, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:223274-E)

BIBLIOGRAPHY

MRID CITATION

00022316 Smith, L.; Haugrud, H.; Timmer, T.; et al. (1975) Fall Application of Eptam 7-E on Sunflowers: Summary of Crop Residue Data. (Unpublished study received Feb 1, 1976 under 476-2154; prepared in cooperation with Univ. of Minnesota, Northwest Experiment Station, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL: 223274-F)

00022318 Batchelder, G.H.; Patchett, G.G. (1960) A colorimetric method for the determination of EPTC residues in crops and soils. Journal of Agricultural and Food Chemistry 8(3):214-216. (Also in unpublished submission received Jul 11, 1960 under unknown admin.no.; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:124555-A)

00022369 Houseworth, L.D.; Rolla, H.; Ross, R.H.; et al. (1976) Residues of Profluralin and EPTC in or on Dry Bean Forage, Pods, Green Beans and Shelled Dry Beans from Tank Mix Applications: Report No. ABR-76068. (Unpublished study received Sep 13, 1977 under100-523; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:231588-A)

00022376 Shaw, A.; Thaemert, E.; Binning, L.K.; et al. (1975) Eptam 7-E + Treflan 4-E Tank Mix on Beans. (Unpublished study received Jul 20, 1976 under 476-2154; prepared in cooperation with Morse Laboratories, Inc. and Univ. of Wisconsin, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:224906-A)

00022385 Beard, F.; Aldrich, E.; Senior, L.J. (1969) Crop Residue Report: FSDS No. A-202. (Unpublished study including FSDS nos. A-0203, B-0641, A-0212..., received May 12, 1969 under 476-1198; prepared in cooperation with Western Walnut Association and Jess Co., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL: 003741-D)

00022386 Hamburg, S.; Jost, E.; Glasgow, M.; et al. (1969) Eptam 6E Applied to Alfalfa with a 14 Day Application Restriction. (Unpublished study including FSDS nos. A 617, B-1076, B-1078..., received May 12, 1969 under 476-1198; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:003741-E)

00022389 O'Connor, M.S.; Patchett, G.G.; McKay, J.C. (1967) Eptam Residue Method by Gas Chromatography: Richmond Report No. RR-50. Method dated Sep 6, 1967. (Unpublished study received Mar 25, 1968 under 476-1198; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:003739-C)

BIBLIOGRAPHY

MRID CITATION

00022394 Winterlin, W.; Ashton, F.M. (1968) Report of Analysis: Agricultural Toxicology Report No. 1295. (Unpublished study including ag. toxicology report nos. 1296 and 1297, received Nov. 8, 1972 under 476-1198; prepared by Univ. of California--Davis, Botany Dept., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:101416-A)

00022397 Stauffer Chemical Company (1963) Crop Residue Report: FSDS No. 40-4090. (Unpublished study including FSDS nos. 4091, 4092, 4093..., received Feb 14, 1964 under 476-1198; CDL:101415-C)

00022398 Stauffer Chemical Company (1965) Crop Residue Report: FSDS No. A 1740. (Unpublished study including FSDS nos. A1741-A1743, 3070 ..., received Dec 2, 1965 under 476-1198; prepared in cooperation with Amalgamated Sugar Co. and American Crystal Sugar, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:101413-A)

00022399 Taylor, F.B.; Teel, K.; Taylor, D. (1965) Crop Residue Report: FSDS no. 4379. (Unpublished study including FSDS nos. 4380, 4381, 5048..., received Dec 2, 1965 under 476-1198; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:101413-B)

00023047 Condray, J.; Torell, P.J.; Sweet, R.; et al. (1974) Eradicane. (Unpublished study received Jun 12, 1974 under 476-2131; prepared in cooperation with Oregon State Univ. and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:018045-C)

00025021 Metz, R.W.; Davis, J.; Ashley, B.; et al. (1967) Crop Residue Report: FSDS No. A 2449. (Unpublished study including FSDS nos. A 2448, 4387, 4646..., received Oct 2, 1967 under 8F0643; prepared in cooperation with Kent Fish Co. and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-B)

00025024 Rice, M.L.; Peters, E.J.; Sallee, B.; et al. (1964) Crop Residue Report: FSDS No. 3974. (Unpublished study including FSDS nos. 1464, 3975, 5386..., received Oct 2, 1967 under 8F0643; prepared in cooperation with Oregon State College and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-E)

BIBLIOGRAPHY

MRID CITATION

00025025 Vogel, M.A.; Schulz, H.; Blain, J.; et al. (1967) Crop Residue Report: FSDS No. A 2545. (Unpublished study including FSDS nos. 0423, 2107, 2108..., received Oct 2, 1967 under 8F0643; prepared in cooperation with Univ. of Wyoming, Experiment Station, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-F)

00025027 Lee, W.O.; Rudberg, V.; Gibson, O. (1963) Crop Residue Report: FSDS No. 1789. (Unpublished study including FSDS nos. 2112, 2333, 5076..., received Oct 2, 1967 under 8F0643; prepared in cooperation with Oregon State College and Univ. of California, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-H)

00025029 Lee, W.O. (1958) Crop Residue Report: FSDS No. 1790. (Unpublished study received Oct 2, 1967 under 8F0643; prepared in cooperation with Oregon State College, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-J)

00025031 Yoshida, N.; Navaro, P.; Lider, B.; et al. (1967) Crop Residue Report: FSDS No. A 817. (Unpublished Study including FSDS nos. A 819, 816, 818..., received Oct 2, 1967 under 8F0643; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-L)

00025032 Sife, F.W.; Fertig, S.N.; Freeman, J.F.; et al. (1967) Crop Residue Report: FSDS No. 1458. (Unpublished study including FSDS nos. 5141, 2343, 1866..., received Oct 2, 1967 under 8F0643; prepared in cooperation with Univ. of Illinois and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-M)

00025033 Foy, ?; Buck, C.; Fabricius, J.; et al. (1967) Crop Residue Report: FSDS No. 2317. (Unpublished study including FSDS nos. 3606, 3607, 3612..., received Oct 2, 1967 under 8F0643; prepared in cooperation with Univ. of California and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-N)

00025034 Taylor, F.B.; Jucksch, M.; Van Sponsen, A.; et al. (1965) Crop Residue Report: FSDS No. 5048. (Unpublished study including FSDS nos. 5049, 4379, 5089..., received Oct 2, 1967 under 8F0643; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL: 091115-O)

00025035 Holm, L.; Mack, H.J. (1964) Crop Residue Report: FSDS No. 1471. (Unpublished study including FSDS nos. 0395, 2317, 4112, received Oct 2, 1967 under 8F0643; prepared in cooperation with Univ. of Wisconsin and Oregon State College, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-P)

BIBLIOGRAPHY

MRID CITATION

00025036 Jorgenson, E.; Borda, P., Jr.; Carnesi, T.; et al. (1967) Crop Residue Report: FSDS No. A 1556. (Unpublished study including FSDS no. 1978, FSDS no. A 966, FSDS no. 5201..., received Oct 2, 1967 under 8F0643; prepared in cooperation with Oregon State Univ., Klamath Experiment Station and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-Q)

00025037 Williams, F.; Cormany, C.E.; McCarth, ? (1967) Crop Residue Report: FSDS No. A 44. (Unpublished study including FSDS nos. 4220, 1377, 2447..., received Oct 2, 1967 under 8F0643; prepared in cooperation with American Crystal Sugar Co., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-R)

00025038 Hernandez, T.; Klingman, G.C.; MacHado, J.; et al. (1967) Crop Residue Report: FSDS No. A-2203. (Unpublished study including FSDS nos. 1975, 2005, 1846..., received Oct 2, 1967 under 8F0643; prepared in cooperation with North Carolina State College and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091115-S)

00025279 Stauffer Chemical Company (1958) Eptam Residue Studies--Strawberries. (Unpublished study received Dec 10, 1958 under 476-1198; CDL:102559-K)

00025292 Dyke, L.; Cantrell, D. (1971) Crop Residue Report: FSDS No. B-0005. (Unpublished study including FSDS nos. B-0683, B-0004, B-0012..., received Oct 24, 1972 under 476-1198; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:003744-C)

00037691 O'Sullivan, R.; Norian, G.; Reed, G.; et al. (1979) Eptam 7-E on Potatoes: Summary of Crop Residue Data. (Unpublished study received Aug 14, 1979 under 476-2154; prepared in cooperation with G. Warorian Co. and Porter Land Co., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:238942-A)

00037692 Buxton, R.; McCain, D.; Howe, J. (1979) Eptam Water Run on Citrus: Summary of Crop Residue Data. (Unpublished study received Aug 14, 1979 under 476-2154; prepared in cooperation with Univ. of Arizona, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:238942-B)

00037693 O'Sullivan, R.; Lindgren, H.; Henderson, H.; et al. (1979) Layby Application of Eptam 7-E following Fall Application of Eptam at Labelled Rates: Summary of Crop Residue Data on Sugar Beets. (Unpublished study received Aug 14, 1979 under 476-2154; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:238942-C)

BIBLIOGRAPHY

MRID CITATION

00037694 O'Sullivan, R.; Hammond, M.; Hintz, H.H.; et al. (1979) Multiple Application of Eptam 7-E in Irrigation Water: Summary of Crop Residue Data on Sugar Beets. (Unpublished study received Aug 14, 1979; prepared in cooperation with Spreckles Sugar Co., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:238942-D)

00037695 O'Sullivan, R.; Valincourt, L.X.; Arnst, G.X.; et al. (1979) Eptam 7-E + Tolban 4-E Tank Mix on Beans: Summary of Crop Residue Data. (Unpublished study received Aug 14, 1979 under 476-2154; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL: 238942-E)

00037698 Weimorts, L. (1967) Crop Residue Report: Cotton: Eptam 6E + Karmex DL: FSDS No. A 2469. (Unpublished study received Nov 18, 1967 under 8F0643; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091119-B)

00037705 Stauffer Chemical Company (1967) Crop Residue Report: Sugar Beets: Eptam 6E: FSDS No. B-0014. (Unpublished study received Nov 18, 1967 under 8F0643; prepared in cooperation with Great Western; CDL:091119-I)

00039198 Talbert, R.; Warren, F.; Hemphill, D.D.; et al. (1967) Eptam: Seed and Pod Vegetables Residue Data. (Unpublished study received Oct 2, 1967 under 8F0643; prepared in cooperation with Univ. of Arkansas and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091118-A)

00039200 Weimorts, L.; Newsom, B.; Phillips, R.M.; et al. (1967) Eptam: Stored Commodities Residue Data (Other Than Fruits, Grain, and Vegetables). (Unpublished study received Oct 2, 1967 under 8F0643; prepared in cooperation with U.S. Dept. of Agriculture, Stoneville Station and others, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091118-C)

00039201 Newsom, B.; Phillips, R.M.; Klause, W.; et al. (1967) Eptam: Cotton Forage Residue Data. (Unpublished study received Oct 2, 1967 under 8F0643; prepared in cooperation with U.S. Dept. of Agriculture, Stoneville Station, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:091118-D)

00039203 Stauffer Chemical Company (1966) Eptam: Strawberry Residue Data. (Unpublished study received Oct 2, 1967 under 8F0643; prepared in cooperation with Driscol Associates and Calcagno; CDL: 091118-F)

BIBLIOGRAPHY

MRID CITATION

00057545 Stauffer Chemical Company (1981) Eptam 7-E + Treflan 4-EC Tank Mix Applied Preplant Incorporated to Sunflowers. (Compilation; unpublished study received Feb 13, 1981 under 476-2154; CDL: 244420-A)

00057546 Stauffer Chemical Company (1981) Eptam 7-E + Treflan 4-EC Tank Mix Applied Postemergence Incorporated in Sugarbeets. (Compilation; unpublished study received Feb 13, 1981 under 476-2154; CDL: 244420-B)

00057547 Stauffer Chemical Company (1979) Eptam 7-E + Treflan 4-EC Tank Mix Applied Preplant Incorporated to Snap Beans. (Compilation; unpublished study received Feb 13, 1981 under 476-2154; CDL: 244420-C)

00057548 Stauffer Chemical Company (1980) Multiple Applications of Eptam 7-E on Snap and Dry Beans. (Compilation; unpublished study received Feb 13, 1981 under 476-2154; CDL:244420-D)

00057549 Stauffer Chemical Company (1980) Eptam 7-E + Amiben 2-E Tank Mix Applied Preplant Incorporated in the Spring to Sunflowers. (Compilation; unpublished study received Feb 13, 1981 under 476-2154; CDL:244420-E)

00064182 Ciba-Geigy Corporation (1980) [Residue of Dual 8E and Eptam 6E on Kidney Beans and Various Other Beans]. (Compilation; unpublished study received Mar 31, 1981 under 100-597; CDL:099988-B)

00067275 Stauffer Chemical Company (1976) [Residues of Ro-neet in Sugar Beets]. (Compilation; unpublished study received Jun 22, 1977 under 476-1979; CDL:230772-B)

00067371 Danhaus, R.G.; Mestdagh, P.; Schreurs, R.; et al. (1980) Residues of Triallate, Trifluralin and EPTC in Oilseeds following Preemergent Applications of Far-go, Far-go +Treflan, and Far-go + Eptam Tank Mixes: Report No. MSL-1323. Final rept. Includes undated methods entitled: Analytical residue method for triallate and trifluralin in oilseed crops and Analytical residue method for EPTC in flax seed. (Unpublished

00074451 Lesh, M.R. (1979) Determination of Residues of R-33865, EPTC, Butylate and R-25788 in Corn. Method no. RRC 79-33 dated Nov 2, 1979. (Unpublished study received May 27, 1981 under 1F2456; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL: 070113-C)

BIBLIOGRAPHY

MRID CITATION

00078437 Stauffer Chemical Company (1981) Eptam Split Application of Almonds: Summary of Crop Residue Data. (Compilation; unpublished study received Jul 27, 1981 under 476-2154; CDL:245620-A)

00090891 Stauffer Chemical Company (1979) [Potato Residue Data: Fonofos]. (Compilation; unpublished study received Oct 10, 1979 under 476-2056; CDL:241112-J)

00098255 PPG Industries, Incorporated (1982) Residue Studies with PPG-1292 in Corn to Description of the Analytical Method. Includes method dated Mar 29, 1982. (Compilation; unpublished study received Apr 5, 1982 under 2F2666; CDL:070756-B)

00105790 Stauffer Chemical Co. (1979) Vernam 7E: Residue Data. (Compilation; unpublished study received Mar 16, 1979 under 476-2155; CDL:237823-A)

00106797 American Cyanamid Co. (1978) Amounts of Residues of Prowl, Its Metabolite (CL 202,347) Metribuzin (Sencor or Lexone) and Eptam in or on Potatoes. (Compilation; unpublished study received Oct 5, 1978 under 241-243; CDL:097433-A; 097434)

00152457 Thomas, V.; Dennison, J. (1984) Rotational Crop Uptake of Radio-labeled Carbon -Eptam Residues in Soil: MRC-84-04. Unpublished study prepared by Stauffer Chemical Co. 19 p.

40614424 Lamoureux, G.; Rusness, D. (1987) EPTC metabolism in corn, cotton, and soybean: Identification of a novel metabolite derived from the metabolism of a glutathione conjugate. J. of Agricultural and Food Chemistry 35(1):1-7.

41486002 Hillebrecht, W. (1990) Residue Data Supporting the Use of Granular Formulations of Eradicane on Corn: Report No.: R & RA #1. Unpublished study prepared by ICI Americas, Inc. in cooperation with Stauffer Chemical Co. 114 p.

41724301 Curry, K. (1990) Eptam 10-G Magnitude of the Residue on Alfalfa Seed Following Broadcast Application to Established Alfalfa in California: Lab Project Number: EPTA-89-MR-03. Unpublished study prepared by ICI Americas Inc. 73 p.

41724302 Curry, K. (1990) EPTAM 10-G Magnitude of the Residue Following Ground Application to Established Alfalfa in California and Arizona: Lab Project Number: EPTA-89-MR-01: RR 90-380B. Unpublished study prepared by ICI Americas Inc. 152 p.

BIBLIOGRAPHY

MRID CITATION

41724303 Curry, K. (1990) EPTAM 10-G Magnitude of the Residue on Alfalfa Seed Following Broadcast Applications to Established Alfalfa in Arizona: Lab Project Number: EPTA-89-MR-04: RR 90-397B. Unpublished study prepared by ICI Americas Inc. 75 p.

41724304 Curry, K. (1990) EPTAM 10-G Magnitude of the Residue Following Aerial Applications to Established Alfalfa in California and Arizona: Lab Project Number: EPTA-89-MR-02: RR 90-395B. Unpublished study prepared by ICI Americas Inc. 146 p.

41831206 Curry, K.; Grant, C. (1991) Eradicane 25-G: Magnitude-of-the-Residue Study on Field Corn: Lab Project Number: RR 90-438B. Unpublished study prepared by ICI Americas Inc. 222 p.

41977401 Herman, R. (1991) Interim Report: Storage Stability Validation for EPTC in Field Corn Grain: Lab Project Number: EPTA-90-SS-01. Unpublished study prepared by ICI Americas Inc. 36 p.

41977402 Mckay, J. (1991) Storage Stability Validation for EPTC in Raw Agricultural Commodities and Soil: Lab Project Number: RRC 88-82: 005801. Unpublished study prepared by ICI Americas Inc. 70 p.

42735901 Akhavan, M.; Gao, M. (1993) EPTC: Nature of the Residue in Corn Study: Lab Project Number: RR 93-005B: PMS 348. Unpublished study prepared by Zeneca, Inc. 104 p.

42735902 Ortiz, D. (1993) EPTC: Nature of the Residue in Potatoes: Lab Project Number: PMS351: RR 92-083B. Unpublished study prepared by Zeneca, Inc. 118 p.

42735903 Akhavan, M. (1993) EPTC: Nature of the Residue in Pinto Bean Study: Lab Project Number: PMS 350: RR 93-042B. Unpublished study prepared by Zeneca, Inc. 121 p.

42964101 Ortiz, D. (1993) Addendum to EPTC: Nature of the Residue in Potatoes: Lab Project Number: PMS 351: RR 92-083B RES: WIN0882. Unpublished study prepared by ZENECA Inc. 27 p.

42964102 Akhavan, M.; Gao, M. (1993) Addendum to EPTC: Nature of the Residue in Corn Study: Lab Project Number: PMS 348: RR 93-005B RES: WIN0880. Unpublished study prepared by ZENECA Inc. 24 p.

BIBLIOGRAPHY

MRID CITATION

42964103 Akhavan, M.; Gao, M. (1993) Addendum to EPTC: Nature of the Residue in Pinto Beans: Lab Project Number: PMS 350: RR 93-042B RES: WIN0881. Unpublished study prepared by ZENECA Inc. 19 p.

43609801 Ortiz, D.; Akhavan, M.; Moriarty, J. (1995) EPTC: The Nature of the Residues of Orally Administered (N-propyl-1-(carbon 14))- EPTC in Tissues and Milk of Lactating Goat: Lab Project Number: RR-94-075B: PMS 381: WIN 2698. Unpublished study prepared by Zeneca Ag Products; Analytical Development Corp.; and Colorado State University. 185 p.

43609802 Akhavan, M.; Moriarty, J.; Ortiz, D. (1995) EPTC: The Nature of the Residues of Orally Administered (N-propyl-1-(carbon 14))- EPTC in Tissues and Eggs of Laying Hens: Lab Project Number: RR-94-074B: PMS 380: WIN 2699. Unpublished study prepared by Zeneca Ag Products; Analytical Development Corp.; and Colorado State University. 179 p.

43849901 Francis, P.; Grant, C. (1995) EPTC: Magnitude of the Residue Study on Clover after Treatment with EPTAM 7-E: Lab Project Number: RR 95-044B: EPTC-93-MR-03: 02-CA-93-121. Unpublished study prepared by Zeneca Ag Products. 65 p.

43849902 Storoni, H. (1995) EPTC: Magnitude of the Residue Study on Safflower Seed after Treatment with EPTAM 7-E: Lab Project Number: RR 95-053B: EPTC-93-MR-09: EPTC-94-MR-01. Unpublished study prepared by Zeneca Ag Products. 50 p.

43849903 Francis, P.; Grant, C. (1995) EPTC: Magnitude of the Residue Study on Alfalfa after Treatment with EPTAM 7-E: Lab Project Number: RR 95-052B: EPTC-92-MR-01: EPTC-93-MR-01. Unpublished study prepared by Zeneca Ag Products. 77 p.

43849904 Francis, P.; Grant, C. (1995) EPTC: Magnitude of the Residue Study on Almonds after Treatment with EPTAM 7-E: Lab Project Number: RR 95-055B: EPTC-93-MR-02: 02-CA-93-111. Unpublished study prepared by Zeneca Ag Products. 69 p.

43849905 Francis, P.; Grant, C. (1995) EPTC: Magnitude of the Residue Study on Walnuts after Treatment with EPTAM 7-E: Lab Project Number: RR 95-056B: EPTC-93-MR-12: 18-CA-93-211. Unpublished study prepared by Zeneca Ag Products. 54 p.

43849906 Roper, E. (1995) EPTC: Magnitude of the Residue Study on Sugar Beets after Treatment with EPTAM 7-E: Lab Project Number: RR 95-074B: EPTC-92-MR-04: EPTC-93-MR-10. Unpublished study prepared by Zeneca Ag Products. 60 p.

BIBLIOGRAPHY

MRID CITATION

43849907 Robbins, J. (1995) EPTC: Processing Study on Sugar Beets from a Trial Conducted in Idaho During 1992: Lab Project Number: RR 95-079B: EPTC-92-PR-04: 16-ID-92-227. Unpublished study prepared by Zeneca Ag Products. 79 p.

43849908 Francis, P.; Grant, C. (1995) EPTC: Magnitude of the Residue Study on Sunflowers after Treatment with EPTAM 7-E: Lab Project Number: RR 95-041B: EPTC-93-MR-11: 78-MN-93-201. Unpublished study prepared by Zeneca Ag Products. 52 p.

43849909 Robbins, J. (1995) EPTC: Processing Study on Sunflower Seed from a Trial Conducted in South Dakota During 1992: Lab Project Number: RR 95-067B: EPTC-92-PR-05: 31-SD-92-262. Unpublished study prepared by Zeneca Ag Products. 85 p.

43849910 Roper, E. (1995) EPTC: Magnitude of the Residue Study on Potatoes after Treatment with EPTAM 7-E: Lab Project Number: RR 95-066B: EPTC-92-MR-03: EPTC-93-MR-08. Unpublished study prepared by Zeneca Ag Products. 60 p.

43849911 Storoni, H. (1995) EPTC: Processing Study on Potatoes from a Trial Conducted in Washington During 1992: Lab Project Number: RR 95-073B: EPTC-92-PR-03: 15-WA-92-216. Unpublished study prepared by Zeneca Ag Products. 91 p.

43849912 Francis, P.; Grant, C. (1995) EPTC: Magnitude of the Residue Study on Snap Beans after Treatment with EPTAM 7-E: Lab Project Number: RR 95-014B: EPTC-92-MR-05: 56-NY-92-231. Unpublished study prepared by Zeneca Ag Products. 61 p.

43849913 Storoni, H. (1995) EPTC: Magnitude of the Residue Study on Green Beans after Treatment with EPTAM 7-E: Lab Project Number: RR 95-049B: EPTC-93-MR-07: 02-CA-93-161. Unpublished study prepared by Zeneca Ag Products. 65 p.

43849914 Storoni, H. (1995) EPTC: Magnitude of the Residue Study on Dry Beans after Treatment with EPTAM 7-E: Lab Project Number: RR 95-028B: EPTC-93-MR-05: 02-CA-93-141. Unpublished study prepared by Zeneca Ag Products. 57 p.

43849915 Storoni, H. (1995) EPTC: Magnitude of the Residue Study on Dry Beans after Treatment with EPTAM 7-E Using Chemigation: Lab Project Number: RR 95-043B: EPTC-93-MR-06: 02-CA-93-151. Unpublished study prepared by Zeneca Ag Products. 54 p.

BIBLIOGRAPHY

MRID CITATION

43849916 Robbins, J. (1995) EPTC: Processing Study on Cotton from a Trial Conducted in Arizona During 1992: Lab Project Number: RR95-072B: EPTC-92-PR-01: 14-AZ-92-251. Unpublished study prepared by Zeneca Ag Products. 89 p.

43849917 Francis, P.; Grant, C. (1995) EPTC: Magnitude of the Residue Study on Cotton after Treatment with EPTAM 7-E: Lab Project Number: RR 95-045B: EPTC-93-MR-04: 02-CA-93-131. Unpublished study prepared by Zeneca Ag Products. 67 p.

43849918 Roper, E. (1995) EPTC: Processing Study on Tomatoes from a Field Trial Conducted in California During 1993: Lab Project Number: RR 95-075B: EPTC-93-PR-02: 02-CA-93-226. Unpublished study prepared by Zeneca Ag Products. 76 p.

43849919 Roper, E. (1995) EPTC: Magnitude of the Residue Study on Tomatoes after Treatment with EPTAM 7-E: Lab Project Number: RR 95-071B: EPTC-92-MR-06: EPTC-93-MR-14. Unpublished study prepared by Zeneca Ag Products. 49 p.

43849920 Grant, C. (1995) Eradicane 6.7-E: Magnitude of the Residue Study on Sweet Corn: Lab Project Number: RR 95-078B: EPTC-93-MR-13: 14-CA-93-221. Unpublished study prepared by Zeneca Ag Products. 82 p.

43849921 Barnes, J.; Meier, D.; Grant, C. (1995) Eradicane 6.7E: Residue Processing Study on Field Corn: (Final Report): Lab Project Number: RR 95-068B FIN: EPTC-92-PR-02: 04-IL-92-311. Unpublished study prepared by Zeneca Ag Products. 174 p.

43849922 Barnes, J.; Curry, K.; Francis, P.; et al. (1995) EPTC: Magnitude of the Residue Study for Field Corn Forage, Fodder, and Grain after Treatment with Eradicane 6.7-E: (Final Report): Lab Project Number: RR 93-096B FIN: EPTC-92-MR-02: 40-IA-92-301. Unpublished study prepared by Zeneca Ag Products and Zeneca Agrochemical. 145 p.

44135301 Francis, P.; Robbins, J.; Storoni, H. (1996) EPTC: Determination of the EPTC Hydroxy Metabolites and Their Conjugates in Crops by Gas Chromatography: Lab Project Number: RR 96-089B: 96-089B. Unpublished study prepared by Zeneca Ag Products. 45 p.

44299601 Bussey, R.; Fomenko, J. (1997) Evaluation of EPTC Through the FDA Multiresidue Methods: (Final Report): Lab Project Number: A030.015: RR 97-030B. Unpublished study prepared by Zeneca Ag Products and Maxim Technologies, Inc. 66 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,

3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products

subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You Are Receiving This Notice
Section II	-	Data Required By This Notice
Section III	-	Compliance With Requirements Of This Notice
Section IV	-	Consequences Of Failure To Comply With This Notice
Section V	-	Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries And Responses To This Notice

The Attachments to this Notice are:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form
Attachment 3	-	Requirements Status And Registrant's Response Form
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Attachment 2) and the Requirements Status and Registrant's Response Form (Attachment 3). The Data Call-In Response Form must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

   If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, at (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's

Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and ungradable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data --

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies

require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data --

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development –

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the

specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the

Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and ungradable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but ungradable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are ungradable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active

ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the

parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form; or,

   b. fulfill the commitment to develop and submit the data as required by this Notice; or,

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and Gene Tox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

C. EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Federal Insecticide, Fungicide, and Rodenticide Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Attachment 2) and a completed Requirements Status and Registrant's Response Form (Attachment 3) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

1. EPTC Data Call-In Chemical Status Sheet

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing EPTC.

This Generic Data Call-In Chemical Status Sheet, contain an overview of data required by this notice, and point of contact for inquires pertaining to the reregistration of EPTC. This attachment is to be used in conjunction with (1) the Generic data Call-In Notice, (2) the Generic Data Call-In Response From (Attachment 2), (3) the Requirement Status and Registration's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this EPTC Generic Data Call In (Attachment F). Instruction and guidance accompany each form.

DATA REQUIREMENT BY THIS NOTICE

The additional data requirement needed to complete the generic database for EPTC are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on EPTC are needed. These data are needed to fully complete the registration of all eligible EPTC products.

INQUIRIES AND RESPONSE TO THIS NOTICE

If you have any question regarding the generic data requirements and procedures established by this Notice, please contact Jamil Mixon at (703) 308-8032.

All response to this Notice for the generic data requirements should be submitted to:

Jamil Mixon, Chemical Review Manager
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: EPTC

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3.This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

A.	Terrestrial food
B.	Terrestrial feed
C.	Terrestrial non-food
D.	Aquatic food
E.	Aquatic non-food outdoor
F.	Aquatic non-food industrial
G.	Aquatic non-food residential
H.	Greenhouse food
I.	Greenhouse non-food crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP_*	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled

TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

*See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for Submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for Submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially ungradable. By indicating that I have

chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

Requirements Status And Registrants Response(Insert Requirements Status and registrants response here 1 of 2

Requirements Status And Registrants Response(Insert Requirements Status and

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your

product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to

Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and ungradable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains.

Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, an offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to

develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency

for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and ungradable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but ungradable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are ungradable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will

have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and Gene Tox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution

of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (oc) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

EPTC DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing EPTC.

This Product Specific Data Call-In Chemical Status Sheet, contain an overview of data required by this notice, and point of contact for inquires pertaining to the reregistration of EPTC. This attachment is to be used in conjunction with (1) the Products Data Call-In Notice, (2) the Products Specific Data Call-In Response From (Attachment 2), (3) the Requirement Status and Registration's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this EPTC Product Specific Data Call-In (Attachment 7) Instructions and guidance accompany each form.

DATA REQUIREMENT BY THIS NOTICE

The additional data requirement needed to complete the generic database for EPTC are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on EPTC are needed for specific product. These data are needed to fully complete the registration of all eligible EPTC products.

INQUIRIES AND RESPONSE TO THIS NOTICE

If you have any question regarding the generic data requirements and procedures established by this Notice, please contact Venus Eagle-Kunst at (703) 308-8045.

All response to this Notice for the generic data requirements should be submitted to:

Chemical Review Manager
Product Registration Branch
Special Review and Registration Branch (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: EPTC

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to voluntarily cancel your product, answer "yes." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the EPA registration numbers of your source(s); you would not complete the "Requirements Status and Registrant's Response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

Item 7a. For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with Option 7 (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM FOR PRODUCT SPECIFIC DATA

Item 1-3 Completed by EPA. Note the unique identifier number assigned by EPA in Item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on 8 months after issuance of the Reregistration Eligibility Document unless EPA determines that a longer time period is necessary.

Item 9. Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for Submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the Confidential Statement of Formula (EPA Form 8570-4).

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may

be subject to suspension. By the specified due date, I will also submit: (1) a completed "Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the Confidential Statement of Formula (EPA Form 8570-4).

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "Certification of Offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the Confidential Statement of Formula (EPA Form 8570-4).

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study). I certify that this study will meet all the requirements for Submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29) to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the Confidential Statement of Formula (EPA Form 8570-4).

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and ungradable (Upgrading a Study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the Confidential Statement of Formula (EPA Form 8570-4).

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number(s) for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the Confidential Statement of Formula (EPA Form 8570-4).

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the Confidential Statement of Formula (EPA Form 8570-4).

Items 10-13. Self-explanatory.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

4. EPA'S Batching of EPTC Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing EPTC as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Not with-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Thirteen products were found which contain EPTC as the active ingredient. These products have been placed into two batches and a "no batch" category in accordance with the active and inert ingredients and type of formulation.
NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	10182-220	EPTC...87.8%	liquid
	10182-223*	EPTC...82.6%	liquid
	10182-226	EPTC...87.8%	liquid
	19713-101	EPTC...87.27%	liquid
	34704-701	EPTC...87.8%	liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	4-156	EPTC...2.3%	solid
	192-187	EPTC...2.3%	solid
	769-872	EPTC...2.3%	solid
	829-225	EPTC...2.3%	solid
	10182-172	EPTC...2.3%	solid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	10182-199	EPTC...20%	solid
	10182-217	EPTC...98.5%	liquid
	10182-388	EPTC...67.8%	liquid

*A product specific eye irritation study for 10182-223 is required.
Products in Batch 2 may cite 10182-199.

5. List of All registrants sent this Data call-In

Appendix F. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardtop in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

   If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.

8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List
   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   c. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

Precautionary Statements: Hazards to Humans and Domestic Animals

The following documents are part of the Administrative Record for this RED document and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

a. Health and Environmental Effects Science Chapters.
b. Detailed Label Usage Information System (LUIS) Report.