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 decisions on the pesticide chemical case amitrole which includes the active ingredient amitrole (3-amino-1,2,4-triazole). The enclosed Reregistration Eligibility Decision (RED) document contains the Agency's evaluation of the data base of these chemicals, 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 also includes requirements for additional data (generic) on the active ingredients 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 are due 90 days from the date of your receipt of this letter. The second set of required responses are due 8 months from the date of your receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in a tolerance is necessary, that tolerance too will be reassessed in the future pursuant to the requirements of FQPA.

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 Nancy Tompkins at (703) 308-8172. Address any questions on required generic data to the Special Review and Reregistration Division representative Mario F. Fiol at (703) 308-8049.

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 703-487-4650).

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

AMITROLE

LIST A

CASE 0095

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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AMITROLE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Assessment

Gabe Patrick	Biological Analysis Branch
Jim Saulmon	Biological Analysis Branch
Arthur Grube	Economic Analysis Branch

Environmental Fate and Effects Assessment

William Effland	Environmental Risk Characterization Branch
Andrew Bryceland	Environmental Risk Characterization Branch
David Wells	Environmental Risk Characterization Branch

Health Effects Assessment

Tom Myers	Risk Characterization and Analysis Branch
Pamela Hurley	Toxicology Branch I
Jeff Evans	Occupational and Residential Exposure Branch
Felicia Fort	Chemistry Branch Reregistration Support

Registration Support

Robert Taylor	Fungicide-Herbicide Branch
Larry Fried	Registration Support Branch

Risk Management

Sherry Sterling	Reregistration Branch
Linda Propst	Reregistration Branch
Mario Fiol	Reregistration Branch
Walter Waldrop	Reregistration Branch
Philip Poli	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
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
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., mg/l, 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
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
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 effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
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 24 (c) 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.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency has completed its reregistration eligibility decision regarding the pesticide amitrole, (3-amino-1,2,4-triazole). This decision includes a comprehensive reassessment of the required target data base supporting the use patterns of currently registered products. Amitrole is a non-food use herbicide used primarily in industrial areas (outdoors), non-agricultural rights-of-way, fencerows, hedgerows, non-agricultural uncultivated areas, soils, ornamental and/or shade trees, and ornamental shrubs and vines.

Amitrole was classified for restricted use (RU) through the Registration Standard issued March 1984. In May 1984, a Special Review of Amitrole was initiated based on carcinogenic risk. In 1992, at the conclusion of the Special Review of Amitrole the Agency reinforced the RU classification of amitrole because of positive carcinogenicity findings.

During the preparation of this Reregistration Eligibility Decision (RED) document, the registrant, CFPI, requested that the Agency rescind the RU classification as part of the reregistration evaluation of amitrole.

After reviewing all the submitted data and comparing other pesticidal chemicals also classified as "restricted use," the Agency has determined that the restricted use classification is no longer appropriate. Amitrole is classified as a B_2-probable human carcinogen. Two thirds of the Agency's calculated cancer risk of 10^{-5} to mixers/loaders (assuming handlers wear long sleeve shirts, long pants, shoes and socks) is from inhalation exposure. The Agency believes that the likelihood of inhalation exposure is almost non-existent since the amitrole is packaged in water soluble bags. Focusing only on cancer risk from dermal exposure, the estimated cancer risk approaches 10^{-6}. Thus, with the low dermal absorption factor (0.5%), continued packaging in water soluble bags, additional protection (although minimal because of the low dermal absorption) afforded by chemical resistant gloves and chemical resistant apron, the Agency concluded that the Restricted Use classification could be rescinded if the registrant agreed to the following conditions: voluntarily cancel their liquid formulation product; retain the cancer warning label; retain the boom sprayer as the only application mode; retain the same use profile as a non-food use pesticide, and provide the Agency with handler exposure studies for mixers/loaders of water soluble packages to confirm the Agency's risk assessment and conclusions. In addition, the registrant understands that any proposed future expansions of their market will require that a separate risk assessment be performed for any new use/application method. Furthermore, amitrole labels must carry a ground water advisory and the registrant must submit additional ecological studies to complete the Agency's risk assessment.

The registrant has requested voluntary cancellation for ornamental plant nursery uses and has agreed to the Agency's conditions cited above. Therefore, the Agency through this document will delete the restricted use classification from the wettable powder formulation (the only remaining product). The Agency has determined that all registered uses for the wettable powder

formulation packaged in water soluble bags are eligible for reregistration if labeled and used as specified in this RED document.

The generic data base supporting the reregistration of amitrole has been reviewed and determined to be substantially complete for all eligible uses. However, the following studies to be conducted on the generic active ingredient are required to complete the Agency's risk assessment: Guideline 71-4(a) and (b) Avian Reproduction studies (quail and duck) and Guideline 72-4(b) Aquatic Invertebrate Life Cycle with Daphnia magna. In addition, the following confirmatory studies are also required: Guideline 123-1(a) Seedling Emergence; Guideline 123-2 Aquatic Plant Growth (five species); and Guidelines 231 and 232 handler exposure studies to provide dermal and inhalation data on mixers and loaders during the use of water-soluble packages.

Before reregistering products containing amitrole, the Agency is requiring that product specific data, a revised Confidential Statement of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable and in accordance with section 3(c)(5) of FIFRA, the Agency will reregister the product.

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 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 ingredient 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.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of amitrole. The document consists of six sections. Section I is the introduction. Section II describes amitrole, 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 amitrole. Section V discusses the reregistration requirements for amitrole. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. 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 Decision:

- **Common Name:** Amitrole
- **Chemical Name:** Amitrole (3-amino-1,2,4-triazole)
- **Chemical Family:** Triazole
- **CAS Registry Number:** 61-82-5
- **OPP Chemical Code:** 004401
- **Empirical Formula:** $C_2H_4N_4$
- **Trade and Other Names:** Amizol, Amitrol T, AT Liquid, AT-90, Amino Triazole Weedkiller 90, Azaplant, Azaplant Kombi, Azolan, Azole, etc.
- **Basic Manufacturer:** CFPI of France.

B. Use Profile

The following information is on the currently registered uses of amitrole with an overview of use sites and application methods. A detailed table of amitrole uses can be found in Appendix A.

Type of Chemical: Herbicide

Mechanism of Action: Inhibits carotenoid synthesis, chlorophyll formation, and limited regrowth of buds.

Use Groups and Sites:

TERRESTRIAL NON-FOOD CROP

Industrial areas (outdoor), non-agricultural rights-of-way/fence-rows/hedgerows, non-agricultural uncultivated areas/soils, ornamental and/or shade trees, ornamental shrubs and vines

Pests: Broadleaves: alfalfa, ash, bigleaf maple, blackberry, Canada thistle, chrysanthemum, dewberry, dock, hemp, honeysuckle, kochia, kudzu, locust, marijuana, pigweed, poison ivy, poison oak, salmonberry, sowthistle, sumac, sunflower, western horsenettle, whitetop, wild cherry

Grasses: annual bluegrass, barnyardgrass, bermudagrass, cheat, couchgrass, foxtail, quackgrass, reed canarygrass, ripgut brome, ryegrass, wild barley, witchgrass

Other plants: horsetail, nutgrass

Formulation Types:

Single Active Ingredient (AI) Products

Solid/dust -- 90% (Technical)
Wettable powder -- 90% (Water soluble bags)
Emulsifiable concentrate* -- 21.6% (No-glug container)
(*The registrant has requested cancellation of this product's registration)

Methods and Rates of Application:

Wettable powder: For industrial areas (outdoor), nonagricultural rights-of-way/fence-rows/hedgerows, nonagricultural uncultivated areas/soils, ornamental and/or shade trees, ornamental woody shrubs and vines, spray when needed by fixed-boom sprayers attached to tractors, trucks or railway wagons (ground equipment) at 3.6 lb AI/acre.

Emulsifiable concentrate:* For nonagricultural rights-of-way/fence-rows/hedgerows, nonagricultural uncultivated areas/soils, ornamental and/or shade trees, when needed, spray at foliar or at nurserystock stage, by fixed-boom sprayers attached to tractors, trucks or railway wagons (ground equipment) at 8 lb AI/acre.

Use Limitation: Do not feed or graze animals on treated areas.
Do not apply directly to water or wetlands.

C. Estimated Usage of Pesticide

The Agency estimates that annual usage of amitrole during 1984 was between 500,000 and 800,000 pounds of active ingredient but, by 1989, had decreased to between 50,000 and 100,000 pounds of active ingredient. Total annual usage of amitrole declined even further in 1990 to between 40,000 and 60,000 pounds of the active ingredient. It is probable that amitrole usage since 1990 is at this level or below.

Primary areas of use are in combination with residual herbicides on highway guard rails, bridge abutments, shoulders and median strips to reduce or eliminate mowing and improve

visibility at intersections, of traffic signs under guard rails, and around other structures, and in railroad yards, around signal equipment, loading areas to keep vegetation free for maximum visibility, safety and prevent growth of potentially combustible weeds.
Additionally, public areas around industrial sites such as power substations, electric transmission towers, fence lines, petroleum tank farms, lumber yards and other areas which need to be kept vegetation free are also other major market areas of amitrole for the same reasons; that is, for improved visibility, personal safety, and fire prevention.

D. Regulatory History/Data Requirements

Amitrole was first registered in l948 for use on non-crop sites including rights-of-way, marshes and drainage ditches, ornamentals and around commercial, industrial, agricultural, domestic, and recreational premises. In 1958 amitrole was registered for use on cranberries on a no-residue basis for post-harvest application only. In 1971 all amitrole food uses were canceled by the Agency because experimental animal data demonstrated an oncogenic potential by the dietary route. There are no tolerances for any food crop or water which will be used for irrigation, drinking, or other domestic purposes, and to date no new registrations or establishment of tolerances for amitrole have been requested.

A Registration Standard for amitrole was issued on March 30, 1984 (NTIS Pub. No. PB87-104766). The Registration Standard required the submission of product chemistry, environmental and ecological effects data, and toxicology data. The Registration Standard also informed registrants that even though amitrole was not used on food crops and there was no dietary exposure to the chemical, the Agency had major concerns for dermal exposure, with inhalation furnishing only a minor contribution to the total body burden. Human exposure, in some circumstances, occurred at doses which resulted in antithyroid effects in laboratory animals, and that amitrole's use patterns and application techniques met the oncogenicity risk criterion for Special Review. The Agency determined that it was not going to reregister any current product and it was not going to register any new product containing amitrole until all pivotal data were reviewed and a decision on the continued reregistrability of products containing amitrole was made. All use patterns and applications techniques, except homeowner uses, were to be classified as restricted, with labeling and protective clothing requirements to reduce exposure and minimize risk during the period of data development.

On May 15, 1984, the Agency issued a Notice of Special Review (Position Document-1) of pesticide products containing amitrole. The Agency's Special Review was initiated to address the use of amitrole on non-crop sites (highway rights-of-way primarily) and by homeowners, and examined the carcinogenic risk to mixers, loaders and applicators. The data indicated that amitrole induced thyroid, pituitary and liver tumors in laboratory animals. The registrant voluntarily acted on a number of measures that reduced worker exposure to amitrole. Among these were the deletion of the high exposure application methods such as knapsack sprayers, the adoption of a "no-glug" container design for the liquid formulation to reduce splashing while pouring, the addition of protective clothing requirements to labels, and packaging of the wettable

powder formulation in water soluble packets. Lastly, the registrant voluntarily canceled all homeowner products.

During the Special Review phase, two Data Call-Ins (DCIs) were issued by the Agency. A DCI was issued on February 22, 1990 requesting efficacy, usage and worker exposure monitoring data for both liquid and powder formulations of amitrole. A second DCI was issued on August 16, 1991, requesting product chemistry, ecological and environmental fate studies and toxicology studies.

Based on a risk and benefit assessment, the Agency concluded that the benefits provided from the use of amitrole (taking into considerations the measures previously discussed) outweigh the risks. Thus, the Agency on October 8, 1992, issued a Notice of Final Determination (57 FR 46448) of the Amitrole Special Review. The Agency continued to require: restricted use (RU) classification, a cancer warning statement on the label, application methods remain limited to boom sprayers, and protective clothing requirements remain on the label. The Notice was published in the Federal Register and comments were invited for 30 days. No comments were received.

During the preparation of this Reregistration Eligibility Decision (RED) document, the registrant requested reconsideration of the previous Registration Standard Decision (affirmed by the Special Review decision) that all amitrole products bear a restricted use classification. The Agency, after review of the submitted data and comparing other pesticidal chemicals also classified as "restricted use," determined that the restricted use requirement could be dropped if the registrant were to meet certain conditions. The registrant has agreed to voluntarily request cancellation of the liquid formulation product in a "no-glug" container (a product posing higher risks to handlers); retain the cancer warning label; retain boom sprayer as the application mode; retain the same use profile as a non-food pesticide (non-cropland use only); and provide the Agency with additional studies; specifically, handler exposure studies to mixers and loaders of water soluble packages to confirm or complete the Agency's risk assessment and conclusions. Additionally, any proposed future expansion of their market (i.e., home-owner use), will require a separate risk assessment.

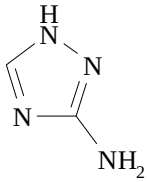
III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

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

Common Name: Amitrole

Chemical Name: Amitrole (3-amino-1,2,4-triazole)



Empirical Formula: $C_2H_4N_4$
Molecular Weight: 84.08
CAS Registry No.: 61-82-5
OPP Chemical Code: 004401

Amitrole technical is a transparent to off-white crystalline powder with a melting point of 159°C. Amitrole is soluble in water (28 g/100 ml at 20°C) and ethanol (26 g/100 ml at 75°C); only slightly soluble in chloroform, acetonitrile, and ethyl acetate; and insoluble in acetone, ether, and hydrocarbons. Amitrole has a vapor pressure 4.4 x 10E-7 mmHg, and the Octanol/Water Partition Coefficient of log K_{ow} = -0.15. Amitrole is stable under typical storage conditions.

B. Human Health Assessment

1. Hazard Assessment

The toxicology data base for amitrole is adequate and will support a reregistration eligibility determination for the currently registered non-food uses of amitrole.

a. Acute Toxicity

Results of the acute toxicity studies conducted with technical amitrole are summarized below:

Table 1. Acute Toxicity Values of Technical Amitrole.

Route	Species	Results	Toxicity Category
Oral	Rat	LD_{50}: Males 24.6 g/kg	IV
Oral	Rat	LD_{50}: 4.08 g/kg	III
Dermal	Rabbit	LD_{50}: >10 g/kg	IV
Dermal	Rat	LD_{50}: >2.5 g/kg	III
Inhalation	Rat	Waived	N/A
Eye Irritation[a]	Rabbit	Mild Irritant	III
Skin Irritation[a]	Rabbit	No Irritation	IV
Dermal Sensitization[a]	Guinea Pig	Non sensitizer	N/A

[a] Not required for TGAI, however, presented here for informational purposes.

The first acute oral study was tested only in the male rat and demonstrated an LD_{50} of 24.6 g/kg (MRID 00063601). In a second acute oral study both males and females were dosed and demonstrated a LD_{50} of 4.08 g/kg (Gaines et al. 1973; no MRID). Although, the second study is based on a literature review and does not provide all the details required in the guidelines, the results are consistent with the first study. It is unlikely that a new study will indicate that amitrole is more acutely toxic via the oral route than a Toxicity Category III. The two studies together are acceptable for regulatory purposes.

The first acute dermal study was tested in rabbits and demonstrated a LD_{50} of greater than 10 g/kg (MRID 00063599). In a second acute dermal study in the rat there were no clinical signs noted at the highest dose tested of 2.5 g/kg (Gaines et al. 1973; no MRID). Both dermal studies had incompletely reported data with little or no details on the conduct of the study. Although neither of the studies are totally acceptable, a new study will not be required due to the consistency of the results of these two studies and due to the low dermal absorption value for this chemical.

The requirement for an acute inhalation study was waived because a 2-year rat inhalation study is available. This study indicates that the acute LC_{50} for inhalation is probably at least greater than 0.5 mg/l. However, the 2-year study was not useful for carcinogenicity risk assessment because of problems associated with the accuracy of the concentrations generated throughout the study. It appears that the target concentrations were grossly exceeded due to technical problems. The highest target concentration that was to be tested was 0.5 mg/l. The animals probably received much more, including possible oral ingestion. Survival was a problem, but not immediately. Therefore, it is likely that the acute inhalation toxicity of the chemical is at least Toxicity Category III (MRID 00127930).

Amitrole is a Toxicity Category III primary eye irritant in rabbits. The study resulted in cornea damage which cleared within 72 hours and conjunctival redness which cleared within 7 days (MRID 00127930).

Amitrole is a Toxicity Category IV primary dermal irritant in rabbits (MRID 00160450) and amitrole is not a skin sensitizer in guinea pigs (MRID 00160449).

Human Data

Oral Exposure

IARC Monographs, 1974: 39-yr old woman showed no signs of intoxication following the ingestion of a commercial preparation containing 30% amitrole and 56% diuron. It was reported that 50% of the estimated dose was eliminated in urine within a "few hours" of exposure. Unchanged amitrole was found in the urine; no metabolites were identified.

Dermal Exposure

Dynamac, 1982: Five male "spraymen" were exposed to amitrole for 10 working days (5-days/week, 8-hour work days) and five males not exposed to the amitrole spraying were considered to be controls. The medical monitoring reportedly found "no remarkable findings based on palpating the thyroids of the control or exposed subjects." The results of the thyroid function tests showed slightly higher TSH levels, slightly lower T_4 levels with basically no change in T_3 levels through the two week follow up period. The authors reported that all the thyroid function values "were within normal limits."

b. Dermal Absorption

Amitrole (96.8% pure) and ^{14}-C-amitrole (4.03mCi/nmol (millicuries/nanomole), 94.1% pure) were tested in a dermal absorption study in Crl:CD®(SD)BR male rats. Groups of 20 rats were tested with 0.10, 1 or 10 mg amitrole/rat. Appropriate urine, feces, blood, skin and whole carcass samples were analyzed. Four rats/test group were sacrificed at 0.5, 1, 2, 4 or 10 hours after dosing. The dermal penetration study indicated that little or no ^{14}C-Amitrole was absorbed over a period of up to 10 hours at dose levels up to 10.0 mg/rat. Only 5/60 animals showed a level of 0.1% or more of the dose in the urine (a range of 0.1 - 0.5%). No animals showed 0.1% or more of the dose in the feces or carcass. However, significantly high percentages of the dose remained in or on the washed skin and may be available for absorption over a longer period of time. This study is acceptable for regulatory purposes (MRID 00151651).

c. Reference Dose

Since there is no food use pattern for amitrole, and since chronic or lifetime exposure is an unlikely scenario for amitrole, an RfD was not established. The Office of Pesticide Programs

Reference Dose (RfD)/Peer Review Committee stated that the dosing regimens used in the chronic studies for amitrole do not provide precise enough information to establish a NOEL/LOEL for use in a chronic risk assessment. The Committee further stated that for nonfood uses a margin of exposure (MOE) approach would be more appropriate and recommended that an acceptable MOE of at least 100 be used for the purposes of risk assessment.

d. Toxicological Endpoints of Concern

The Office of Pesticide Program's Health Effects Division Less Than Lifetime Committee (document dated July 25, 1995) concluded the following for amitrole:

For acute dietary exposure. There are no food uses for amitrole, therefore, there are no dietary exposure issues.

For short term occupational exposure (1 to 7 days) a risk assessment for inhalation exposure is appropriate. The maternal and developmental NOEL of 4.0 mg/kg/day from the oral developmental toxicity study in the rabbit is to be used for a risk assessment for inhalation (MRID 00159997).

For intermediate term occupational exposure (1 week to several months) a risk assessment for inhalation exposure is appropriate. The NOEL of 0.90 mg/kg/day from the 2-generation reproduction study in the rat is to be used for a risk assessment for inhalation (MRID 44016201).

For dermal short and intermediate term exposure, the maternal and developmental NOEL of 1,500 mg/kg/day from the dermal developmental toxicity study is so high that a risk assessment is not required for dermal exposure (MRIDs 40567701 and 40963701)

e. Carcinogen Classification

Amitrole has been classified as a Group B_2-probable human carcinogen by the Office of Pesticide Programs Carcinogenicity Peer Review Committee (document dated August 30, 1991). This classification is based on the thyroid tumors seen in the rat (both sexes, multiple strains), and mouse (both sexes, two strains) and on liver tumors seen in the mouse (both sexes, multiple strains) as described in the above studies. The Agency calculated a Q1* of 0.68 from the thyroid tumor effects as seen in the first long term toxicological study (MRID 00132445), described above.

f. Subchronic Toxicity

The requirement for the 90-day dermal study was waived. The Less-than-Lifetime Committee of the Agency's Office of Pesticide Programs determined (document dated July 20, 1995) that results from a dermal absorption study and from the oral and dermal rabbit developmental studies indicate that dermal absorption is very low (only up to 1-2%). Therefore, it is unlikely that a 90-day dermal study conducted with amitrole will provide any additional useful data. A 90-day feeding study will not be required in place of the 90-day dermal study because sufficient data are available to indicate that a 90-day oral study will not provide any additional useful data for the purposes of risk assessment. The primary target organ is the thyroid. Data from short term studies and chronic studies indicate that effects will appear in the thyroid at lower dose levels than any other target organ.

Eleven short term studies were conducted with amitrole in order to study the effects of amitrole on the thyroid. Although none of the studies can be categorized as being acceptable for a subchronic feeding study, the data can still be used for making regulatory decisions. The studies are summarized in Table 2. Some of the data were summarized from a review of the literature and some of the studies were reports from laboratory studies. Where available, the MRID numbers are provided. The subchronic data needed for risk assessment purposes is extracted from the limited chronic data and from the studies listed in the table.

Table 2. Amitrole: Nonneoplastic Effects in Short Term and Subchronic Oral Rat Studies

Dose Levels (mg/kg/day) & Length of Exposure	Strain	Effects	Study I.D.
0.75, 1.5, 3.0, 6.0 in diet for 2 weeks	Unspecified	Thyroid enlargement, ↓ radioiodine uptake at 3 & 6. No effects at 0.75 & 1.5. **NOEL: 0.75 mg/kg/day**	Jukes & Shaffer (1960)
0.01, 0.003 in diet for 11 weeks or 0.1, 0.5, 2.5 in diet for 13 weeks	♂: Blue Spruce Farms	↓ radioiodine uptake, ↓ protein-bound iodine at 0.1, 0.5, 2.5; disturbances in follicle size & depletion of colloid at 0.5 & 2.5; ↑ thyroid wts at 2.5; no effects at 0.01 or 0.003. **NOEL for protein-bound iodine & radioiodine uptake was 0.01 mg/kg/day; however, NOEL in 1-liner was 0.5 mg/kg/day because no microscopic changes observed at 0.01 mg/kg/day.**	Fregley (1968) MRID No. 00052658
1.5, 5, 15 in diet for 4 weeks	♂: Sprague-Dawley	↓ body wts, food consumption, T_3, T_4 at 5 or 15; sl. ↓ T_3, T_4 at 1.5; ↑ T_3/T_4 ratio for all groups. **NOEL: 1.5 mg/kg/day, LOEL: 5 mg/kg/day.**	Babish et. al. (1977) MRID No. 00052643
2.5, 12.5, 62.5 in drinking water for 15 weeks	♂: "albino"	Dose-related ↓ body wt, food consumption; enlarged thyroid & increase in vascularity, moderate stimulation of follicle epithelium at 2.5; ↓ liver catalase activity, hyperplasia, most follicles lack colloid at 12.5; ↓ liver catalase activity, hypertrophy, hyperplasia, no follicles with colloid at 62.5. **NOEL: < 2.5 mg/kg/day**	Bagdon et. al. (1956) MRID No. 00063601
35 for 32 days, 75 on alternate days for 32 days	♂: "albino"	↓ body wts & food consumption at 35 & 75 (alternate days); hyperemic & enlarged thyroids at 35; slightly hyperemic & not enlarged at 75 (alternate days). **NOEL: < 35 mg/kg/day**	Vidone et. al. (1958) MRID No. 00082174
0, 12.5, 25 for 28 days	♂	↓ body weight gain, enlargement and congestion of the thyroid at 12.5 and above. **NOEL: < 12.5 mg/kg/day**	Keller (1960) MRID No. 00028434
0, 5, 50, 500 for 63 days	♂+♀	At 50 mg/kg/day and above, cell injury in the liver. **Thyroid was not examined NOEL: 5 mg/kg/day, LOEL: 50 mg/kg/day.**	Fogelman (1954) MRID No. 00063598
125, 250 in drinking water for 16 weeks	♀: Wistar	Initial deformation of thyroidal follicular epithelium, ↓ colloid, dilation of endoplasmic reticulum, ↓ peroxidase activity. Later, adenomas of thyroid: not stated, but assume at both dose levels **NOEL: < 125 mg/kg/day**	Tsuda (1974)
0.04% in drinking water for up to 6 months.	♂: Sprague-Dawley	3 days: thyroid not enlarged; 1 week: thyroid twice normal size with ↓ colloid & structural changes, ↓ peroxidase activity; 6 months: a few functional follicles, thyroid increased 10 times normal size, continued ↓ peroxidase activity. **NOEL: < 0.04% in drinking water**	Strum & Karnovsky (1971)
0.04% in drinking water for 12, 20, 37 days	♂: Sprague-Dawley	↓ liver & kidney catalase activities, loss of colloid & hyperemia of thyroid, ↑ thyroid wts (12 days and beyond). **NOEL: < 0.04% in drinking water**	Alexander (1959)

g. Combined Chronic Toxicity and Carcinogenicity

Six long-term studies have been conducted on rats and mice with amitrole. When assessed separately, each of the studies is unacceptable according to the Agency testing guidelines. For chronic toxicity, the first two studies summarized below have been selected as containing the most relevant data for regulatory purposes and when taken together, the two studies are acceptable for regulatory purposes. For carcinogenicity, when all six studies are taken together, the studies are acceptable for regulatory purposes because they adequately characterize the potential chronic toxicity, and were considered by the Office of Pesticide Program's (OPP) Carcinogenicity Peer Review Committee to contribute to the weight of the evidence for carcinogenicity. The first study was used for carcinogenicity risk assessment.

In the first study, technical amitrole (94.59%) was tested in a chronic feeding study in male and female Fischer 344 rats. The chemical was administered as a pulse dose for either 115 weeks for males or 119 weeks for females. Group A, control animals received no test compound, Group B rats were fed amitrole in their diet at a constant level of 5 ppm during weeks 1-39 and 100 ppm during weeks 40-115 for males or 40-119 for females. Rats in Group C, D, E received amitrole in their diet at pulsed levels (alternate 4 weeks periods) of 1, 3, and 10 ppm, respectively, during weeks 1-39 and 20, 60, and 200 ppm, respectively, during weeks 40-115 for males or 40-119 for females. On alternate months, Groups C, D, and E were fed basal diets without amitrole. The average dose levels are calculated to be: 0.0 (A), 0.35 (C), 1.04 (D), 3.4 (B) or 3.5 mg/kg/day (E) for 115 - 119 weeks. This study had body weight, food consumption, hematology, clinical chemistry, urinalysis, gross necropsy and organ weight data that were close to what is requested in the testing guidelines. However, an incomplete list of organs was examined microscopically. At 0.35 mg/kg/day and above, there was an increase in thyroid follicular cell hyperplasia in both sexes ($p < 0.01$; 0/60, 12/57, 29/55, 38/58 and 25/60 for males and 0/52, 7/54, 25/50, 40/56 and 31/56 for females for increasing doses, respectively). At 1.04 mg/kg/day and above, larger thyroids were observed; and at 3.4 mg/kg/day and above, an increase in thyroid weight was observed ($p < 0.05$). Nothing else was observed in the study. Amitrole induced a statistically significant increase in thyroid follicular cell adenomas in both sexes at 1.04 mg/kg/day and above ($p < 0.01$ except for 1.04 mg/kg/day females in which $p < 0.05$). There was also an increasing trend in both sexes ($p < 0.01$). There was an increasing trend for thyroid follicular cell carcinomas in both sexes ($p < 0.01$ for males,$p < 0.05$ for females). For combined follicular cell adenomas and carcinomas, there was a statistically significant increase in both sexes at dose levels of 1.04 mg/kg/day and above ($p < 0.01$ for males; $p < 0.05$ at 1.04 mg/kg/day and $p < 0.01$ at the two higher dose levels for females). There was an increasing trend in both sexes ($p < 0.01$). Under the conditions of the study, the NOEL for chronic toxicity was less than 0.35 mg/kg/day based on an increase in thyroid follicular cell hyperplasia, larger thyroids and an increase in thyroid weight. This study is classified as Core Supplementary for a chronic feeding study in the rat and is determined to be unacceptable for a carcinogenicity study in the rat. However, for chronic toxicity, when combined with the following study, the study may be used for regulatory purposes. For carcinogenicity, when considered as part of the overall weight of the evidence with the results of the other

carcinogenicity studies conducted with amitrole and under the conditions of this study, amitrole is considered to be carcinogenic to the rat. In this particular study, inducing increases in thyroid follicular cell adenomas, combined thyroid follicular adenomas/carcinomas and an increasing trend in thyroid follicular cell adenomas, carcinomas and combined adenomas/carcinomas. (MRID 00132445).

In the second study, technical amitrole (96.4-97.0%) was tested in a lifetime study in male and female Wistar rats at the following dose levels in the diet: 0, 1, 10 or 100 ppm (0, 0.05, 0.5 or 5.0 mg/kg/day). The maximum number of days the animals received the test chemical was 1,021 days. No food consumption, hematology, clinical chemistry, urinalysis, organ weight or gross necropsy data were provided. However, a fairly complete microscopic examination was provided for most of the organs suggested by the Agency. There was a reduction in survival time at 5.0 mg/kg/day for both sexes combined ($p \leq 0.007$; mean survival times of 980, 971, 973 and 940 days for controls, low, mid- and high dose groups respectively; statistical analysis conducted on combined sexes at the high dose versus combined sexes and dose levels for all other groups, including controls). In addition, there was an increase in thyroid "cysts" at 5 mg/kg/day in both sexes as well (1/73 in controls versus 43/74 in males and 1/75 in controls versus 27/74 in females; $p<0.01$). There was an increase in the incidence of thyroid tumors (unspecified) in both sexes at the high dose when compared to controls ($p < 0.01$). There was also an increase in trend in both sexes ($p < 0.01$). In addition, there was an increase in the incidence of pituitary tumors (unspecified) in both sexes at the high dose ($p < 0.05$ for males and < 0.01 for females). There was an increase in trend in females ($p < 0.01$). Under the conditions of the study, the systemic NOEL is 0.5 mg/kg/day and the systemic LOEL is 5.0 mg/kg/day based on slight reduction in survival and an increase in thyroid "cysts". The study is classified as Core Supplementary for a chronic feeding study in the rat. However, for chronic toxicity, when combined with the preceding study, the study may be used for regulatory purposes. This study is unacceptable for a carcinogenicity study in the rat. However, when considered as part of the overall weight of the evidence with the results of the other carcinogenicity studies conducted with amitrole and under the conditions of this study, amitrole is considered to be carcinogenic to the rat; in this particular study inducing increases in thyroid and pituitary tumors in both sexes and an increasing trend in both thyroid and pituitary tumors in this particular study.
(MRID 00061351).

In the third study, amitrole (grade and purity unspecified) was tested in a feeding study in male and female rats (Charworth Farms) at dietary levels of 0, 10, 50, and 100 ppm (equivalent to 0, 0.5, 2.5, and 5.0 mg/kg/day) for two years; another group, 500 ppm (equivalent to 25 mg/kg/day) was treated for 19 weeks and then placed on a controlled diet due to poor weight gain; the weight loss was reversible, no pathology was reported for this group. This study suffers from serious conduct problems, particularly in the area of the histological examination and presentation of the data. Not all animals were examined, many were autolyzed and those which were examined were not well reported by the pathologist and the reproduction of the hard copy from microfiche was extremely poor. Entire sections were either totally missing or totally unreadable. Interim reports for the 13, 26 and 52 week sacrifices were also missing. Statistical

analysis of the data by the Exact Trend Test (conducted in the knowledge that interpretation is extremely limited) indicated that there were statistically significant dose-related positive trends in the incidence of thyroid gland tumors. There were also non-statistically significant numerical increases in the incidences of thyroid adenomas in the mid- and high dose groups and combined thyroid adenomas/carcinomas in the high dose group in both sexes at the terminal sacrifice. This study is unacceptable for a carcinogenicity study in the rat. However, when considered as part of the overall weight of the evidence with the results of the other carcinogenicity studies conducted with amitrole and under the conditions of this study, amitrole is considered to be carcinogenic to the rat; in this particular study inducing a significant dose-related increasing trend in the incidence of thyroid tumors (MRID 00082176).

In the fourth study, SPF-NMRI mice were fed 0, 1, 10 or 100 ppm (equivalent to 0, 0.15, 1.50 or 15.0 mg/kg/day) amitrole (96.4 - 97.0%) for 18 months. The authors reported that survival, body weights and food consumption were similar for all treatment and control groups throughout the study (no individual animal or group mean data were presented in the report). Increased thyroid weights were observed in the 10 ppm male treatment group when compared to controls at final sacrifice only. The high dose (100 ppm) male and female thyroid weights were reportedly increased throughout the study. A slight non-significant increase in incidence of hepatocellular neoplasia was observed for high dose females (100 ppm) when compared to controls. There were also statistically significant positive trends for hepatocellular carcinoma ($p = 0.019$) and combined adenoma/carcinoma ($p = 0.019$) in females. This study is unacceptable for a carcinogenicity study in the mouse. However, when considered as part of the overall weight of the evidence with the results of the other carcinogenicity studies conducted with amitrole and under the conditions of this study, amitrole is considered to be carcinogenic to the mouse; in this particular study inducing an increase in trend for liver tumors (MRIDs 00061348, 41317901, and 41462501).

In the fifth study, amitrole was used as a positive control in the screening of 120 compounds for tumorigenicity. C57BL/6 x C3H/Anf and C57BL/6 x AKR mice were administered by stomach tube 1000 mg/kg (6700 ppm) amitrole from day 7 to day 28 of age followed by 2192 ppm (equivalent to 329 mg/kg) in the diet for 18 months. All amitrole treated animals either died or were sacrificed in extremis between 53 and 60 weeks on test of a designed 126 week study. The early deaths of all the amitrole treated animals in this study indicate that the doses selected exceeded the Maximum Tolerated Dose (MTD) for these strains of mice. The authors reported that "hepatomas" were observed in 67 (of 72) mice treated with amitrole. In one of the article's footnotes, the authors also reported that "carcinoma of the thyroid were found in 64 [of 72] mice" treated with amitrole. This study is unacceptable for a carcinogenicity study in the mouse. However, when considered as part of the overall weight of the evidence with the results of the other carcinogenicity studies conducted with amitrole and under the conditions of this study, amitrole is considered to be carcinogenic to the mouse; in this particular study inducing increases in liver and thyroid tumors when used as a positive control in a screening study for tumorgenicity (MRID 00043595).

In the sixth study, B6C3F1 mice were fed 500 ppm amitrole (grade and purity unspecified, equivalent to 75 mg/kg/day) ad libitum as follows: Group 1 - "pregnant females from the 12th day of gestation to delivery" (mice exposed placentally in utero); Group 2 - "mothers with litters from delivery to weaning" (mice exposed preweaning through the mother's milk; Group 3 - "offspring from weaning through 90 weeks" (mice exposed postweaning through the diet). Non-treated controls were sacrificed at 52, 90 or 142 weeks. Since it is unclear as to which of the non-treated control groups (those sacrificed at 52, 90 or 142 weeks) were used to assess the carcinogenic activity of amitrole in groups 1 and 2, the study could not be evaluated for these 2 groups. However, adult males [Group 3] could be evaluated using the control group sacrificed at 90 weeks. This group responded to protracted amitrol treatment with development of benign and malignant liver tumors. The adult females [Group 3] showed only a marginal neoplastic response. This study, when considered as part of the overall weight of the evidence with the results of the other carcinogenicity studies conducted with amitrole and under the conditions of this study, amitrole is considered to be carcinogenic to the mouse; in this particular study, possibly inducing increases in liver tumors in both sexes (Vesselinovitch, 1983; no MRID number).

h. Developmental Toxicity

For developmental toxicity, four studies are available to the Agency. They consist of an oral developmental toxicity study in the rat, two oral developmental toxicity studies in the rabbit and a dermal developmental toxicity study in the rabbit. All studies are acceptable for regulatory purposes.

In the first study, technical amitrole (91.83%) was tested in a developmental toxicity study in CD®-Crl: COBS® CD®(SD)BR outbred albino rats. Amitrole was administered by gavage in a dosage volume of 10 ml/kg deionized water from gestational days 6 through 15 at the following levels: 0, 100, 500 or 1000 mg/kg/day. Thirty-eight females were selected for each dose group: 24 were sacrificed at gestation day, 21 and 14 were held to postnatal day 21. At 500 mg/kg/day and above, there were slight but statistically significant increases in mean absolute and relative thyroid weights at both gestation day 21 and at postnatal day 21 (p value ranging from < 0.05 to $p < 0.001$). There was also a slight, but statistically significant decrease in mean bodyweight gain for high dose dams during gestation days 6-18 (90.9% of controls, $p < 0.05$). The NOEL for maternal toxicity is considered to be 100 mg/kg/day and the LOEL is considered to be 500 mg/kg/day based on increased mean absolute and relative thyroid weights and decreased maternal body weight gain. Statistically significant increases in the number of litters with unossified cervical centra # 6 and proximal phalanges; bi-lobed cervical centra #'s 1, 2, 3 and/or 4; enlarged biparietal suture; poorly ossified proximal phalanges and maxillary and dark thyroids were observed in the high dose group when compared to the control group. In addition, the high dose group had a statistically significant lower mean bodyweight than the control group. Therefore, the NOEL for developmental toxicity is 500 mg/kg/day and the LOEL is 1000 mg/kg/day (HDT) based on skeletal variations, decreased mean fetal bodyweights and dark thyroids (MRID 00160448).

In the second study, technical amitrole (91.83%) was tested in a developmental toxicity study in rabbits. Timed-pregnant New Zealand White rabbits were administered amitrole by gavage in a volume of 2.0 ml/kg deionized water during gestation days 6-18 at the following dose levels: 0, 4.0, 40.0 or 400.0 mg/kg/day. No maternal effects were observed at 4.0 mg/kg/day. At 40.0 mg/kg/day and above there was a statistically significant decrease in body weight gain during the dosing period (121 grams in controls versus -219 and -436 grams in the mid- and high dose groups, respectively). At 400.0 mg/kg/day, there was a statistically significant increase in abortions (5 versus 0 in controls). The NOEL for maternal toxicity is 4.0 mg/kg/day and the LOEL is 40.0 mg/kg/day based on decreases in body weight gain during the dosing period and an increase in abortions. At 40.0 mg/kg/day and above, there were statistically significant increases in the number of litters with a variety of malformations and variations in external, visceral and skeletal examinations ($p < 0.05$ and $p < 0.01$). At 400.0 mg/kg/day, there were statistically significant decreases in fetal body weight (70% of controls) and in percent live fetuses/litter (62 versus 84%) and a statistically significant increase in postimplantation loss/litter (290% of controls). The NOEL for developmental toxicity is 4.0 mg/kg/day and the LOEL is 40.0 mg/kg/day based on increases in the number of litters with a variety of malformations and variations and decreases in fetal body weight and percent live fetuses/litter (MRID 00159997).

In the third study, technical amitrole (97.5%) was tested in a developmental toxicity study in rabbits. Naturally inseminated rabbits were administered the test chemical by gavage in water on gestation days 6-18, inclusive. The following dose levels were given: 0, 5, 20 or 80 mg/kg bodyweight/day. At 80 mg/kg/day, there were slight decreases in mean bodyweight of the does from days 6-9 of the gestation period (bodyweight gain from days 6-18 was 69% of controls, not statistically significant). There were also decreases in food consumption ($p < 0.001$ on days 6-10 and $p < 0.01$ on days 14-19). Therefore, the NOEL for maternal toxicity is 20 mg/kg/day and the LOEL is 80 mg/kg/day. The LOEL is a borderline NOEL because the effects were so slight and they were supported by thyroid follicular cell hypertrophy on a parallel maternal toxicity range-finding study. At 80 mg/kg/day, the only treatment-related developmental effect was a statistically significant ($p < 0.05$) decrease in male fetal bodyweight (91% of controls). This effect is considered to be minimal. Therefore, the NOEL for developmental toxicity is 20 mg/kg/day and the LOEL is 80 mg/kg/day. The LOEL is considered to be a borderline LOEL because the effect was so minimal (MRIDs 43643601 and 43643602).

In the fourth study, amitrole (93.9% pure) was tested in a dermal developmental toxicity study in Hra:(NZW) SPF rabbits at the following dose levels: 0, 1.0, 1.5 or 2.0 g/kg/day in a volume of 0.5 mg/g during gestation days 7-19. At 2.0 g/kg, there was an increase in does that were thin and anorexic and a statistically significant decrease in body weight gain during the latter days of the dosing period as well (days 14-20). By day 20, high dose females weighed 12% less than the controls ($p < 0.05$). Food consumption was also significantly decreased on days 10-20. There appeared to be an increase in the number of resorptions/doe, although a statistical analysis was not conducted and the mean number of live fetuses/doe was not significantly affected at this dose level. The NOEL for maternal toxicity is 1.5 g/kg/day and the LOEL is 2.0 g/kg/day based on decreases in body weight and body weight gain during the dosing period.

At 2.0 g/kg, a statistically significant decrease in mean fetal bodyweights for both sexes was observed. Increases in skeletal anomalies were also observed at this dose level, however, these increases were only seen in the number of fetuses affected and not in the number of litters affected. Therefore, the NOEL for developmental toxicity is 1.5 g/kg/day and the LOEL is 2.0 g/kg/day based on decreases in mean fetal bodyweights for both sexes (MRIDs 40567701, 40963701).

i. Reproductive Toxicity

A reproduction study conducted in the rat is available to the Agency. The study is acceptable for regulatory purposes.

In a 2-generation reproduction study, Amitrole (97-98% a.i.) was administered to 30-31 Sprague-Dawley rats/sex/dose in the diet at dose levels of 0.5, 2, 15 or 112.5 ppm. The mean achieved dose levels were 0, 0.03, 0.12, 0.90 or 5.88 mg/kg/day (males) and 0, 0.04, 0.16, 1.23 or 7.83 mg/kg/day (females) in the F_0 generation and 0, 0.04, 0.16, 1.24 or 12.02 mg/kg/day (males) and 0, 0.05, 0.21, 1.64 and 15.64 mg/kg/day (females) in the F_1 generation. No toxicologically significant effects were observed at dose levels of 0.5, 2 or 15 ppm. At 112.5 ppm, the following effects were observed in parental animals: clinical signs (hypoactivity, piloerection, dyspnea, hypothermia), death, a decrease in mean body weight and body weight gain during the premating and gestation periods (mostly, $p < 0.001$), a decrease in mean food consumption and food efficiency, decreases in several absolute and relative organ weights and an increase in absolute and relative thyroid weight ($p < 0.01$), increases in thyroid activity (small follicles and decreased colloid content), thyroid follicular cell hypertrophy and hyperplasia, thyroid nodular hyperplasia and/or adenoma, uni- or bilateral atrophy of the adrenal cortex, a higher incidence of ceroid pigment accumulation in the adrenal cortical cells, hepatocellular hypertrophy, hepatic cell degeneration/necrosis and higher incidence and/or severity of perilobular steatosis, decrease in the number of acidophil cells in the pituitary, higher intensity of vacuolated cells in the pituitary, a high incidence of pseudopregnancy, a high incidence and/or severity of acinar and/or ductular epithelial cell vacuolation in the mammary gland, mineralization of urothelium and/or urinary gravel in the renal pelvis, retardation of renal maturity and a lower incidence of mononuclear cell aggregation, tubular basophilia and accumulation of acidophilic globules in the cortical tubular epithelium. Also at 112.5 ppm the following reproductive effects were observed: decreases in mating and fertility indices (not statistically significant, partly explained by high death rate and decrease in implantation sites), decreases in implantation sites/litter ($p< 0.001$), a slightly higher gestation interval (F_1: $p < 0.001$) and a decrease in the mean pup male/female ratio in the F_1 generation. The LOEL is 112.5 ppm (lowest of F_0 and F_1 generations of 5.88 mg/kg/day in males, 7.83 mg/kg/day in females), based on clinical signs, death, decreases in mean body weight, body weight gain, food consumption, food efficiency and selected absolute and relative organ weights, an increase in thyroid weight and activity, follicular cell hypertrophy and hyperplasia and nodular hyperplasia and/or adenoma, hepatocellular hypertrophy and other microscopic changes in the adrenals, liver, pituitary, mammary gland and kidney, a high incidence of pseudopregnancy, decreases in mating and

fertility indices, implantation sites/litter and mean pup male/female ratio and a slightly higher gestation interval. The NOEL is 15 ppm (0.90 mg/kg/day in males, 1.23 mg/kg/day in females; (MRID 44016201).

j. Mutagenicity

Amitrole has been tested in many mutagenicity studies, most of which are in the literature. Four submitted studies are summarized in this document. All four of the studies are acceptable for regulatory purposes. In addition to the summaries of the 4 submitted studies, a summary paragraph of the published mutagenicity literature on amitrole is given to provide a more complete picture for this chemical.

In the first study, amitrole was tested in a Salmonella typhimurium/mammalian microsome mutagenicity assay at doses ranging from 20 to 12,500 µg/plate. Under the conditions of the assay, amitrole was not mutagenic in S. typhimurium strains TA1535, TA1537, TA98 or TA100. Concentrations ≥2500 µg/plate with and without S9 were cytotoxic. Although the results were clearly negative, the rationale for the performance of the study with 30% S9 was not provided, and a direct acting positive control was not included in the study. Nevertheless, the study is acceptable and satisfies the guideline requirements for testing for gene mutation (MRID 42214601).

In the second study, amitrole (99.4%) was tested for mutagenic activity in Saccharomyces cerevisiae, strain D4 and in Salmonella typhimurium, strains TA-1535, TA-1537 and TA 1538 in a series of microbial plate tests. It was tested both with and without metabolic activation (enzymatic preparations from the liver, lungs or kidneys from the mouse, rat and monkey). The following positive controls were also tested: ethyl methanesulfonate, 2-nitrofluorene and quinacrine mustard (nonactivation) and dimethylnitrosamine, 2-acetylaminofluorene and 7,12-dimethylbenzanthracene (with activation). Amitrole was moderately toxic at 500 µg/plate and a concentration of 100 µg/plate was selected for the screen. Amitrole tested negatively both with and without metabolic activation. The positive controls induced a significant number of revertants/plate. It appears that the mouse, rat and monkey livers were best suited for metabolic activation, the monkey being the least suitable. The lung and kidney did not activate the positive control chemicals. This study is acceptable (MRID 00052646).

In the third study, amitrole was tested in an in vivo micronucleus assay in the mouse using a single oral gavage dose of 10,000 mg/kg. Amitrole did not induce overt toxicity in either males or females at this dose level. In addition, the test chemical did not induce cytotoxicity in the target organ, or cause a significant increase in the frequency of micronucleated polychromatic erythrocytes (MPEs) in bone marrow cells harvested 24, 48 or 72 hours posttreatment. Based on these findings, amitrole is not considered to be clastogenic in the mouse micronucleus assay. The study is acceptable and satisfies the guideline requirement for testing for structural chromosomal aberrations (MRID 42214602).

In the fourth study, amitrole was evaluated for its ability to induce cellular transformation in BALB/3T3 cells in vitro. The parental clone had been selected for its low spontaneous transformation rate and its high response to known carcinogens. For the first trial, a treatment range of 1- 1000 µg/ml was used. For trials 2 and 3, the dose levels were separated by two-fold serial dilutions between 0.6 and 5 mg/ml in an attempt to cluster the doses at the more active end of the dosage range. Toxicity was observed in all plates at the 5 mg/ml level and in 2 of the 10 plates set up at the 2.5 mg/ml level. The mitotic indices of these cells were not determined, but the treated cultures reached confluency at the same time as the untreated cultures; thus, the rates of division did not appear to be impaired by the test chemical. A positive response was observed at the 1 mg/ml and 0.01 mg/ml levels of the first trial, but not at any of the dose levels of the second or third trials. Amitrole induced cellular transformation in cells of one of three trials, and was interpreted as having a weak cellular transforming capacity in these cells. The study is acceptable (MRID 00052648).

A summary of the genotoxicity data base for amitrole was written in the published article by Richard N. Hill et al in Fundamental and Applied Toxicology 12: 629-697 (1989).
Although the published literature shows that amitrole does not induce positive results in a majority of mutagenicity assays, there does appear to be some evidence that amitrole may have some genotoxic activity. Most bacterial gene mutation assays are negative as well as the Drosophila sex-linked recessive lethal assay and the mouse lymphoma assay. Assays for chromosomal effects are generally negative, but there are in actuality very few test results (in human lymphocytes and a mouse dominant lethal). Two sister chromatid exchange assays were reported positive, there were some positive and some negative results for DNA damage and unscheduled DNA synthesis and all in vitro cell transformation assays were positive.

k. Metabolism

Metabolism studies are required only if the Agency determines that additional information on the metabolism of the chemical is necessary to clarify unusual effects observed in chronic or reproduction studies or to clarify issues concerning structure activity relationships. For amitrole, no issues that need further clarification are identified that warrant the need for metabolism data. Metabolism data were reviewed from the literature and from submitted studies. None of these studies, either singly or combined, provide a complete picture of the absorption, distribution, metabolism and excretion of amitrole. Nevertheless, as stated before, because the Agency does not have any issues that need to be further clarified, no additional studies are required. The available studies do provide useful information and are summarized here. When available, MRID numbers are provided. All studies are referenced in the bibliography (Appendix C).

Studies Conducted With Rats

Oral Exposure

Fang, 1964: Wistar rats were fed 1 mg C^{14}-amitrole (per rat) via stomach tube. The expired air, urine, feces and tissues were analyzed for radioactivity during a three day period following dosing. During the first 24 hours, 70-95.5% of the radioactivity was found in the urine; a small variable amount of activity was found in the feces. After absorption, amitrole was distributed throughout most body tissues. The maximum radioactivity was found in liver and kidney. Within three to four hours of dosing, the tissue levels began decreasing. Paper chromatography revealed both unchanged amitrole and one unidentified metabolite in rat liver slices taken at various times following dosing.

Franco and Municio, 1975: Male Wistar (number unspecified) rats "were treated with amitrole [unspecified amount] during 8 days by the method described elsewhere." The authors reported that "unaltered amitrole and three metabolites are present in the urine of treated animals." The metabolites were not identified or quantified.

Inhalation Exposure

MacDonald, Hazleton, 1976, (MRID 00052644): Rats (5/sex; Charles River Ltd.) were exposed by inhalation to an estimated dose of 25.8 ug/L for "whole body" or 49.2 ug/L for "head only" radiolabelled amitrole for one hour. Blood samples were taken at specified intervals and urine, feces and carcasses were examined for radioactivity. The results were reported as follows:

"Head Only": the blood plasma half life was estimated to be 20 hours; approximately 75% of the radioactivity was found in urine; the level of radioactivity is "substantially lower in females" and no appreciable quantities of radioactivity were found in the carcasses.

"Whole Body": the blood plasma half life was estimated to be 23 hours; the major route of excretion was the urine and no appreciable quantities of radioactivity were found in the feces and carcasses.

Turner, Hazelton, 1976, (MRID 00052645): As a supplement to the "whole body" and "head only" inhalation metabolism study (discussed above), metabolites in the urine and feces were identified by using chromatography. The results were reported as follows:

Urine: 60% of the dose was presumed to be unchanged amitrole; 15-20% was retained at the origin and 5-8% were unidentified.

Feces: 56% was of the dose was presumed to be unchanged amitrole and 25% was retained at the origin.

Studies Conducted With Rabbits

Dermal Exposure

Shah, 1977: This preliminary study in female New Zealand white rabbits (3 animals/pesticide) was designed to obtain a comparative rate of dermal penetration of 5 radiolabelled pesticides, including amitrole. The pesticides were "applied in 0.1 ml of acetone containing 1 mg of non-radioactive pesticide per kilogram body weight." Blood samples were taken at specified intervals up to 24 hours following treatment. Urine and feces were collected and "various organs" removed and assayed for radioactivity. After 24 hours, the site of application was swabbed with cotton and acetone. The authors reported that "after 15 minutes, the order of penetration into blood was aminotriazole > carbaryl = parathion > malathion > DDT > dieldrin." Although the percent of dose was not reported, "appreciable quantities of aminotriazole was found in the urine, feces and gall bladder." The amount of amitrole remaining at the site of application was estimated to be "fifty percent or more."

Studies Conducted With Mice

Oral and/or Intravenous Exposure

Tjalve, 1975, MRID 00052659: Male and female mice (7/sex; "C57/B1" strain) were either intravenously injected or administered by gavage 5 uCi (microCuries) of C^{14} amitrole and sacrificed from 5 minutes to 5 days following treatment. Whole body radiography showed a "high accumulation of radioactivity in tissues with rapid cell turnover such as the bone marrow, the spleen, the thymus, the lymph nodes and the gastrointestinal mucosa." The results appeared to be similar for both routes of exposure. The authors reported the following for liver and thyroid:

Liver: "The radioactivity in the liver is irregularly distributed, being highest in the peripheral parts of the liver lobules around the portal spaces;" "radioactivity was also present in the mitochondrial and microsomal fractions."

Thyroid: "A moderate accumulation of radioactivity was found in the thyroid."

2. Exposure Assessment

a. Dietary Exposure

There are no food uses for amitrole. Therefore, there are no known dietary exposures to amitrole and a dietary exposure assessment is not required.

b. Occupational Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering sites after application is complete.

Although the Agency has identified inhalation as an appropriate route of exposure on which to conduct short term and intermediate term risk assessment, the Agency also believes that in reality there is little likelihood of actual inhalation exposure from mixing/ loading/ applying of amitrole. The inhalation exposure estimates are very conservative because (1) amitrole is not volatile, (2) amitrole is only packaged in water soluble bags (which greatly reduces the chance for incidental inhalation exposure), (3) the inhalation exposure values presented in Table 3 reflect data from the Agency's Pesticide Handlers Exposure Database (PHED V1.1), which for the water soluble packaging data set includes some instances where detections were not found but a value of half the limit of detection was assumed, and (4) the Agency assumed 100% adsorption of inhalation exposure from both the oral developmental toxicity study and the reproduction study. The assumption of half the limit of detection is a common Agency practice in establishing exposure/residue values.

As previously discussed, the registrant voluntarily restricted the use patterns of amitrole to reduce the exposure of amitrole to handlers. The wettable powder and liquid concentrate formulations were voluntarily restricted by the registrant to water soluble packets and "no-glug" containers, respectively. The only current application method is for fixed-boom sprayers attached to ground equipment such as tractors, trucks or railroad wagons. The registrant has recently requested the voluntary cancellation of the liquid formulation (in no-glug container) and has also requested the use deletion of the only use currently within the scope of the Worker Protection Standard, ornamental plant nurseries.

Occupational-use products

All products containing amitrole are for occupational use. There are no homeowner use products containing amitrole.

Handler (Mixers, Loaders, Applicators) Exposures and Assumptions

The three exposure scenarios identified for amitrole are:

(1) Mixing/loading the liquid concentrate formulation (packaged in no-glug containers) to support ground application. As noted previously, the registrant has requested voluntary cancellation of this product. The Agency has included the mixer/loader, exposure/risk estimates for this formulation since the voluntary cancellation is still in process.

(2) Mixing/loading the wettable powder formulation (packaged in water soluble bags) to support ground application, and

(3) Applying as a spray with fixed-boom ground equipment. (Exposure data for groundboom equipment is used as a surrogate for the fixed-boom ground equipment).

Table 3 presents the short-term (1 - 7 days) and intermediate-term (1 week to several months) dermal and inhalation exposure scenarios, while Table 4 summarizes the caveats and parameters specific to each exposure scenario.

Post-Application Exposures and Assumptions

Post-application reentry and residue dissipation data have not been submitted to the Agency in support of the amitrole reregistration, based on the agreements reached in the Special Review. The potential for post-application exposure to amitrole residues is low because of the use patterns for this chemical (i.e., herbicide used in areas where reentry exposure is not expected to be problematic such as rights-of-way).

Table 3. Short-Term and Intermediate-Term Baseline Exposures to Amitrole

Scenario/Exposure	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (ug/lb ai)	Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres/day)	Daily Absorbed Dermal Exposure[e] (mg/day)	Daily Inhalation Exposure[f] (mg/day)	Total Absorbed Daily Exposure (mg/day)[g]
Mixer/Loader Exposures							
Scenario (1) Mixing Liquid Groundboom Treatment Application	2.9	1.2	Max: 8.0	Max: 80	Max: N/A	Max: 0.77	Max: N/A
			Typical: 2.5	Typical: 40	Typical: 1.5	Typical: 0.12	Typical: 1.6
Scenario (2) Mixing Wettable Powder (water soluble packets) for Groundboom Treatment Application	0.02	0.2	Max: 3.6	Max: 80	Max: N/A	Max: 0.058	Max: N/A
			Typical: 2.5	Typical: 40	Typical: 0.01	Typical: 0.02	Typical: 0.03
Applicator Exposures							
Scenario (3) Groundboom Tractor-Open cab	0.01	0.7	Max: 8.0	Max: 80	Max: N/A	Max: 0.45	Max: N/A
			Typical: 2.5	Typical: 40	Typical: 0.005	Typical: 0.07	Typical: 0.075

[a] Workers wearing single layer clothing and no gloves while open pouring liquids, using water soluble packets for wettable powders, and open cab for applicators.
[b] No respirator.
[c] Maximum values are from Label Reg Nos. 33688-6 and 33688-7.
[d] Values represent the maximum or typical area which can be treated in a single day for each exposure scenario of concern.
[e] Daily absorbed dermal exposure (mg/day) = Exposure (mg/lb ai) x Dermal Absorbed (0.5 percent) x Typical Appl Rate (lb ai/A) x Typical Treated (acres).
[f] Daily inhalation exposure (mg/day) = Exposure (ug/lb ai) x (1mg/1000ug) conversion x Max or Typical Appl Rate (lb ai/A) x Max or Typical Treated (acres); maximum values are used for the short-term and intermediate-term inhalation MOE calculations. The typical values are used for the carcinogenic risk assessment.
[g] Total absorbed daily exposure (mg/day) = typical daily absorbed dermal exposure (mg/day) + typical daily inhalation exposure (mg/day).

Table 4. Exposure Scenario Descriptions for Uses of Amitrole

Exposure Scenario	Data Source	Clothing Scenarios		Equipment	Standard Assumptions (8-hr work day)[a]	Comments[b]
		Baseline	Additional PPE			
Mixer/Loader Exposures						
Scenario (1) Mixing Liquid	PHED V1.1	Long pants, long-sleeved shirt, no gloves	Coveralls over long pants and long-sleeved shirt, chemical resistant gloves	Open mixing liquid formulations. The PHED data used had no restrictions, however, amitrole is packaged in No-Glug containers	80 acres maximum and 40 acres typical	**Baseline:** Dermal and Inhalation grades acceptable. Dermal = 53 to 122 replicates; Inhalation = 85 replicates; High confidence in dermal and inhalation data. **Additional PPE:** Dermal grades acceptable. Dermal = 59 to 122 replicates; High confidence in dermal data. PHED data used for baseline no protection factors (PFs) were necessary. Additional PPE values calculated from PHED data using a 50 percent PF for the addition of coveralls.
Scenario (2) Mixing Wettable Powder	PHED V1.1	Long pants, long-sleeved shirt, no gloves	NA	Mixing wettable powder packaged in water soluble packets	80 acres maximum and 40 acres typical	**Baseline:** Dermal acceptable grades, inhalation all grades. Dermal = 5 to 15 replicates; inhalation = 15 replicates; Low confidence in dermal and inhalation data. PHED data used for baseline no PFs were necessary.
Applicator Exposures						
Scenario (3) Groundboom	PHED V1.1	Long pants, long-sleeved shirt, no gloves	NA	Open cab tractors	80 acres maximum and 40 acres typical	**Baseline:** Dermal and inhalation grades acceptable. Dermal = 23 to 33 replicates; inhalation = 22 replicates; High confidence in dermal and inhalation data. PHED data used for baseline, no PFs were necessary.

[a] Standard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.
[b] "Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines are grades A and B. All grades that do not meet OREB's SOP are listed individually.

3. Risk Assessment

a. Dietary

Based on the current use patterns and exposure profiles for amitrole, residues in/on food and/or feed are not expected to occur. Therefore, the Agency did not conduct a dietary risk assessment.

b. Occupational

Daily Dose exposure is calculated using the following formula:

$$\text{Daily dose (mg ai/kg bw/day)} = \frac{\text{unit inhalation exposure (mg ai/lb ai) x use (lb ai/A) x daily acres treated (A/day)}}{\text{body wt (kg)}}$$

The following assumptions are made:

- Some mixers, loaders, and applicators are exposed more than 7 days per year (reasonable worse-case estimate). Therefore, the exposure/risk assessment must consider both short-term (less than 7 days per year) and intermediate-term (7 or more days per year) exposure scenarios.

These calculations of daily dose to amitrole by handlers are used to assess the inhalation risk to handlers. A risk assessment for dermal exposure is not necessary because of the lack of systemic effects seen in the dermal developmental toxicity study.

The following equations are used for determining the margin of exposure (MOE) from short-term and intermediate-term exposures.

$$\text{Short-Term Inhalation Exposure MOE} = \frac{\text{NOEL}}{\text{Inhalation Dose}} = \frac{4\ \text{mg/kg/day}}{\text{Maximum Inhalation Daily Dose}}$$

$$\text{Intermediate-Term Inhalaltion Exposure MOE} = \frac{\text{NOEL}}{\text{Inhalation Dose}} = \frac{0.9\ \text{mg/kg/day}}{\text{Maximum Inhalation Daily Dose}}$$

With regard to cancer risk, the Agency included both dermal and inhalation exposure. The lack of significant systemic effects from the dermal developmental toxicity study would not bear on the cancer risk assessment. The following equation is used for determining the carcinogenic risk:

$$\text{Risk} = \text{LADD (mg/kg/day)} \times Q_1^* \text{ (mg/kg/day)}^{-1}$$

where:

LADD (mg/kg/day) = [Daily Total Dose (mg/kg/day)] x [(10 Work Days Per Yr)/(365 Days Per Year)] x [(40 working Yrs/75 lifetime Yrs)]

LADD = Lifetime Average Daily Dermal and Inhalation Dose

Risk From Handler Exposures:

Risks from Short-Term and Intermediate-Term Exposures

The Agency conducted an assessment of the inhalation risks associated with amitrole following short-term and intermediate-term exposures to occupational handlers. The Agency has determined that a risk assessment is not required for short-term and intermediate-term dermal exposures. Margins of exposure (MOE) for occupational inhalation exposures were calculated for handlers using the NOELs of 4 mg/kg/day for short-term and 0.9 mg/kg/day for intermediate-term exposure. The calculated MOEs are presented in Table 5. Amitrole is not marketed to homeowners (only application method is fixed-boom sprayer), therefore the sole exposure concern is for occupational handlers. The calculations indicate that with the exception of one scenario, all of the MOEs for short- and intermediate-term inhalation exposures at baseline protection (i.e., no respirator) exceed 100 indicating acceptable risk. The exception is the intermediate-term inhalation exposure of Scenario 1 (mixing/loading the liquid concentrate, which has an MOE of 82). However, the registrant is voluntarily cancelling this formulation.

Carcinogenic Risks

The Agency conducted an assessment of the carcinogenic risks associated with amitrole following exposures to occupational handlers (Table 6) including all currently registered uses, which includes the liquid concentrate formulation (packaged in a no-glug container) for which the registrant has recently requested a voluntary cancellation.

The calculations indicate that the risks at baseline protection (i.e., long-sleeve shirt, long pants, shoes, and socks) are in the 10^{-5} range for mixing/loading wettable powders (contained in water-soluble packaging) and application using open-cab groundboom sprayers, the surrogate for fixed-boom ground sprayers. The calculations indicate that the risks at baseline protection

are greater than 10^{-4} for mixing/loading liquid formulations. These calculations do not reflect the exposure reduction expected to be realized from the mandatory use of "no-glug" containers for liquid formulations. However, the registrant has recently requested voluntary cancellation for this formulation.

The risk assessment indicates that the risks at baseline protection are approximately 10^{-5} for mixing/loading the wettable powder formulation packaged in water soluble bags. Since the risk assessment was conducted using this assumption, the Agency is requiring that the wettable powder formulation continue to be marketed only in water-soluble packaging. In addition, since the Agency has low confidence in the data used to assess exposure to mixers and loaders using water-soluble packaging and amitrole is a relatively potent carcinogen, additional risk reduction measures for mixers and loaders are being required. The following risk mitigation measures for mixers and loaders handling the wettable powder amitrole formulations, should adequately mitigate risk to these workers:

- mandatory use of water-soluble packaging for wettable powder amitrole formulations, and
- requiring mixers and loaders to wear a chemical-resistant apron, long-sleeve shirt, long pants, shoes, socks and chemical-resistant gloves.

Table 5. Short-Term and Intermediate-Term Inhalation MOEs for Workers Exposed to Amitrole

Exposure Scenario	Baseline Inhalation Dose[a] (mg/kg/day)	Daily Inhalation MOE[b] (Short-Term)	Daily Inhalation MOE[c] (Intermediate Term)
Mixer/Loader Exposure			
Scenario (1) Mixing Liquid Groundboom Treatment Application	0.013	308	82
Scenario (2) Mixing Wettable Powder (water soluble packets) for Groundboom Treatment Application	0.001	4,000	1125
Applicator Exposure			
Scenario (3) Groundboom Tractor-Open cab	0.0075	533	141

[a] Daily inhalation dose = (maximum daily inhalation exposure)/(60 kg)
[b] Short term inhalation MOE = NOEL (4.0 mg/kg/day))/daily inhalation dose (mg/kg/day).
[c] Intermediate term inhalation MOE = NOEL (0.9 mg/kg/day) daily inhalation dose (mg/kg/day).

Table 6. Cancer Risks to Handlers Exposed to Amitrole

Exposure Scenario	Baseline[a]			Additional PPE[b]		
	Total Daily Dose[c] (mg/kg/day)	LADD[d] (mg/kg/day)	Total Risk[e]	Total Daily Dose[c] (mg/kg/day)	LADD[d] (mg/kg/day)	Total Risk[e]
Mixer/Loader Exposure						
Scenario (1) Mixing Liquid Groundboom Treatment Application	0.027	3.9×10^{-4}	4.4×10^{-4}	0.002	2.9×10^{-5}	2.2×10^{-5}
Scenario (2) Mixing Wettable Powder (water soluble packets) for Groundboom Treatment Application	0.0005	7.3×10^{-6}	8.2×10^{-6}	NC	NC	NC
Applicator Exposure						
Scenario (3) Groundboom Tractor-Open cab	0.0013	1.9×10^{-5}	2.1×10^{-5}	NC	NC	NC

NC = Not calculated for this scenario.

[a] Baseline = long pants, long-sleeved shirt, and no gloves while open mixing liquids, using water soluble packets for wettable powder, and open cab tractor.

[b] Additional PPE for mixer/loaders (liquids) = coveralls over long pants, long-sleeved shirts, and chemical resistant gloves (0.02 mg/lb ai unit exposure).

[c] Total daily dose = Total daily exposure (mg/kg/day)/(60 kg)

[d] LADD (mg/kg/day) = [Daily Total Dose (mg/kg/day)] x [(10 Work Days Per Yr)/(365 Days Per Year)] x [(40 working Yrs/75 lifetime Yrs)].

[e] Risk = LADD (mg/kg/day) x Q_1^* $(mg/kg/day)^{-1}$

Where: $Q_1^* = 0.68(mg/kg/day)^{-1}$

Risk From Post-Application Exposures

There are no amitrole-specific post-application exposure data available. For many amitrole use scenarios, the Agency believes that the risks from post-application exposures will not pose an unacceptable risk to persons entering treated areas because, in general, amitrole is used in areas, such as rights-of-way, industrial areas, permanent landscape plantings, and other non-crop areas, where frequent or routine prolonged contact with treated surfaces is unlikely. Therefore, the Agency has determined that post-application exposures do not appear to pose an unreasonable risk to persons entering treated areas, as long as entry is not permitted until sprays have dried.

C. Environmental Assessment

The environmental assessment consists of the following sections: Ecological Toxicity Data; Environmental Fate and Transport Data; Ecological Exposure and Risk Assessment; and, Environmental Risk Characterization. The first two sections describe the ecological effects and environmental fate and transport data from appropriate field and laboratory studies, analyzes the impact to water resources, and details the environmental fate assessment; and the third and fourth sections estimate ecological and environmental exposures and assess the effects to non-target terrestrial and aquatic organisms, plants and endangered species. The section on environmental risk characterization integrates the exposure and effects assessments to determine the extent and potential for risk to the environment.

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

Although there are several unfulfilled data requirements, the Agency can partially determine the hazard of amitrole to nontarget terrestrial and aquatic organisms.

(1) Birds, Acute and Subacute

In order to establish the toxicity of amitrole to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} mg/kg	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	91.83	> 2150	00160451 Fletcher/1985	practically non-toxic	Yes

Avian Subacute Dietary Toxicity Findings					
Species	**% A.I.**	**LC_{50} ppm**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Northern Bobwhite	91.83	> 5000	00160452 Fletcher/1985	practically non-toxic	Yes
Mallard	91.83	> 5000	00160476 Fletcher/1985	practically non-toxic	Yes
Mallard	Technical	> 5000	00022923 Hill/1982	practically non-toxic	Yes
Pheasant	Technical	> 5000	00022923 Hill/1982	practically non-toxic	Yes

These results indicate that amitrole is practically non-toxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled. (GLN 71-1, MRID 00160451; GLN 71-2, MRIDs 00160452, 00160476)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed to amitrole repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Amitrole has a half-life exceeding four days, can be applied in multiple applications and has chronic effects on mammals at relatively low levels. Based on these conditions, avian reproduction studies are required, with the bobwhite quail and mallard duck. Guideline 71-4 will be fulfilled when adequate avian reproductive studies with both species of birds are submitted, reviewed and found acceptable.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD_{50} (reported below) from the Office of Pesticide Program's Health Effects Division is used to determine toxicity to mammals.

Mammalian Acute Oral Toxicity Findings			
Species	**LD_{50} g/kg**	**MRID #**	**Toxicity Category**
Rat (small mammal surrogate; males only)[1]	24.6 g/kg	00063601	practically non-toxic
Rat (small mammal surrogate; male and female)[1]	4.08 g/kg	Gaines et al., 1973 (no MRID)	practically non-toxic

1. Data from HED RED chapter.

The available mammalian data indicate amitrole is practically non-toxic to small mammals on an acute oral basis.

In an acceptable two-generation rat reproduction study (MRID 44016201), the LOEL is 112.5 ppm (lowest of F_0 and F_1 generations of 5.88 mg/kg/day in males and 7.83 mg/kg/day in females) and the NOEL is 15 ppm (0.90 mg/kg/day for males, 1.23 mg/kg/day for females).

Additionally, a developmental study with New Zealand white rabbits also gives pertinent mammalian toxicity data because the study reported developmental effects (MRID 00159997). The pregnant rabbits were administered amitrole by gavage for 12 days during gestation. The NOEL for developmental toxicity is 4.0 mg/kg/day and the LOEL is 40 mg/kg/day based on increases in the number of litters with a variety of malformations and variations in external, visceral, and skeletal examinations, and decreases in fetal body weight, and percent live fetuses/liter.

(4) Insects

A honey bee acute contact LD_{50} study is required since the use patterns for amitrole (terrestrial nonfood and outdoor residential sites) are expected to result in exposure to honeybees.

Nontarget Insect Acute Contact Toxicity Findings

Species	% AI	LD_{50} μg a.i./bee	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Honey Bee	Technical	> 12.09	00036935 Atkins/1975	relatively non-toxic	Yes

There is sufficient information to characterize amitrole as relatively non-toxic to bees. The guideline requirement is fulfilled. (GLN 141-1; MRID 00036935)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

o Acute

To establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

Freshwater Fish Acute Toxicity Findings					
Species	**% A.I.**	**LC_{50} ppm a.i.**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Bluegill sunfish	96.5	> 1000	00160453 McAllister/1985	practically non-toxic	Yes
Rainbow Trout	96.5	> 1000	00160454 McAllister/1985	practically non-toxic	Yes
Bluegill sunfish	90	> 180	43923702 McCann/1976 (USEPA lab)	practically non-toxic	Yes
Fathead minnow	90	> 100	40094602 Johnson/1980	practically non-toxic	Yes
Channel catfish	90	> 160	40094602 Johnson/1980	practically non-toxic	Yes
Rainbow trout	90	> 180	43923701 McCann/1976	practically non-toxic	Yes
Rainbow trout	formulated product (Fenavar)	65 ppm	00024959 McCann/1972	slightly toxic	No (supplemental)

The results of the 96-hour acute toxicity studies indicate that amitrole is practically non-toxic to fish. The guideline requirements are fulfilled. (GLN 72-1, MRIDs 00160453 and 00160454)

o Chronic

Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and if any one or more of the following conditions apply:

- if the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or
- if any acute LC_{50} or EC_{50} is greater than 1 mg/l; or
- if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or,
- if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist:

- studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected; or

- physicochemical properties indicate cumulative effects; or the pesticide has a half-life of greater than 4 days in water.

Amitrole exceeds a half-life of four days (aerobic soil metabolism half-life of ≈22-26 days; terrestrial field dissipation half-lives of 17-21 days) and multiple applications are listed on the label. Based on these conditions, either a fish early life-stage (72-4(a)) study or aquatic invertebrate life-cycle (72-4(b)) study is required. Using the acute toxicity data for aquatic species (refer to the Estuarine and Marine Animals section), the most sensitive aquatic species is the marine/estuarine invertebrate *Daphnia magna*. Therefore, to complete the chronic hazard assessment for amitrole, an aquatic invertebrate life-cycle (Guideline 72-4(b)) with *Daphnia magna* study is required.

The fish life-cycle test is required when an end-use product is intended to be applied directly to water or is expected to transport to water from the intended use site, when any of the following conditions apply: the EEC is equal to or greater than one-tenth of the NOEL in the fish early life-stage or invertebrate life-cycle test; or if studies of other organisms indicate the reproductive physiology of fish may be affected.

The Agency is reserving the requirement for a fish life-cycle test study (Guideline 72-5). The requirement of a fish life-cycle study will depend on the results from an acceptable aquatic invertebrate life-cycle study.

The risk to aquatic species (on a chronic basis) will be determined once the registrant submits the fish early life-stage (Guideline 72-4(a)) or aquatic invertebrate life-cycle studies. Exposure to aquatic enviornments may occur by runoff or spray drift. The aquatic invertebrate life-cycle study with *Dapnia magna* is being required.

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Freshwater Invertebrate Toxicity Findings					
Species	**% A.I.**	**EC_{50} (ppm)**	**MRID NO. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Daphnia magna	91.8	18	00160455 Forbis/1985	slightly toxic	Yes
Daphnia magna	technical	23 (26hr)	00017800 Crosby/1966	slightly toxic	No (supplemental)
Daphnia magna	Amitrol-T (formulated product)	30	05001497 Sanders/1970	slightly toxic	No (supplemental)

There is sufficient information to characterize amitrole, on an acute basis, as slightly toxic to aquatic invertebrates. The guideline requirement is fulfilled. (GLN 72-2; MRID 00160455)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The terrestrial non-food use of amitrole may result in exposure to the estuarine environment since roadsides and rights-of-way could occur close to estuaries.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

Estuarine/Marine Acute Toxicity Findings					
Species	**% A.I.**	**LC_{50} or EC_{50} (ppm)**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Eastern oyster shell deposition *(C. virginica)*	98.22	110	42837401 Dionne/1993	practically non-toxic	Yes
Mysidopsis bahia	98.22	2.8	42818201 Collins/1993	moderately toxic	Yes
Sheepshead minnow *(C. variegatus)*	98.22	>1000	42817801 Collins/1993	practically non-toxic	Yes

There is sufficient information to characterize amitrole as moderately toxic to marine/estuarine crustaceans, and practically non-toxic to marine/estuarine finfish and bivalves on an acute basis. The guideline requirement is fulfilled. (GLN 72-3; MRIDs 42837401, 42818201, 42817801)

c. Toxicity to Plants

(1) Terrestrial Plants

Currently, terrestrial plant testing (seedling emergence and vegetative vigor) is required by the Agency for herbicides which have terrestrial non-residential outdoor use patterns and appear to move off site of application through volatilization (vapor pressure $\geq 1.0 \times 10^{-5}$mm Hg at 25°C) or drift (aerial or irrigation); and/or which may have endangered or threatened plant species associated with the site of application. The above testing requirements apply for amitrole because it has terrestrial non-food crop use, and the sites of application may have endangered species present.

Limited Tier II toxicity data on the technical/TEP material for the most sensitive species are listed below (Note - the seed germination and vegetative vigor data were submitted in a single study report under one MRID number.)

Nontarget Terrestrial Plant Toxicity Findings

Species		**MRID No.**	**Fulfills Guideline Requirements**	**% A.I.**	**Seed Germination EC_{25} (lbs ai/A)**	**Vegetative Vigor EC_{25} (lbs ai/A for each parameter)**		
Mono	Dicot					Dry Weight	Leaf Length	Shoot Height
---	Cucumber	42813702	No for GLN 123-1(a) (supplemental for seed germination/ seedling emergence tests); Yes for GLN 123-1(b) (acceptable for vegetative vigor tests)	98.22	>8	nd[1]	nd	0.740
Wheat	---				>8	0.005	nd	nd
---	Pepper				>8	0.008	nd	nd
Corn	---				>8	nd	6.445	nd
Leek	---				nd	1.613	7.742	nd
---	Sunflower				>8	0.347	3.444	nd
---	Lettuce				0.28	0.269	0.425	nd

[1] nd indicates values were not determined.

The results indicate amitrole adversely affects the vegetative vigor of both monocots (wheat) and dicots (pepper). The guideline requirements for the vegetative vigor tests (GLN 123-1(b)) are fulfilled. However, the guideline requirement Guideline 123-1(a) is not fulfilled since the study was classified as supplemental and does not fulfill the guideline requirement.

(2) Aquatic Plants

Currently, aquatic plant testing is required for any herbicide which has outdoor non-residential terrestrial uses that may move off-site of application by runoff (solubility >10 ppm in water), by drift (aerial or irrigation), or is applied directly to aquatic use sites (except residential). Amitrole meets the runoff condition for aquatic plant testing. The following species

should be tested: *Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and a freshwater diatom.

Tier II toxicity data on the technical material are listed below:

Nontarget Aquatic Plant Toxicity Findings				
Species	**% A.I.**	**MRID No. Author/Year**	**Fulfills Guideline Requirements**	**EC_{50}**
Selenastrum capricornutum	98.22	42813701 Cross/1993	No (supplemental)	>5.7 mg/l

The five listed aquatic plant studies are required to complete the aquatic plant risk assessment. Only the study on *Selenastrum capricornutum* was submitted; therefore, the guideline requirements are not fulfilled (GLN 123-2).

2. Environmental Fate and Transport Data

a. Environmental Fate Assessment

Acceptable and supplemental information from environmental fate studies with respect to the persistence and mobility of amitrole under laboratory and field conditions has been reviewed. Persistence classes discussed in the following sections were based on the groupings (ranging from non-persistent to persistent) published in Goring et al., (1975) and McEwen and Stephenson (1979). The environmental fate data base for amitrole with terrestrial nonfood crop use is essentially complete.

The following information is derived from acceptable environmental fate studies reviewed by the Agency. The studies determining laboratory persistence (degradation and metabolism processes) indicate amitrole is slightly to moderately persistent [aerobic soil half-life ($t_{1/2}$) ≈22-26 days; aerobic aquatic half-life of ≈57 days] with degradation primarily through biotic processes such as microbial-mediated metabolism. Abiotic hydrolysis is not a significant degradation process. Amitrole was reportedly stable to photodegradation in water and was shown to photodegrade slowly on soil with a $t_{1/2}$ of >30 days. Results of the anaerobic aquatic metabolism study demonstrate that amitrole is persistent with a $t_{1/2}$ of >1 year. In an aerobic aquatic metabolism study, amitrole was moderately persistent with an experimentally-determined $t_{1/2}$ of ≈57 days for a flooded sandy loam sediment. Results of terrestrial field dissipation studies in Washington and Oregon show amitrole dissipating fairly rapidly under field conditions with DT_{50}s ranging from ≈17-21 days.

The mobility of amitrole was evaluated with batch equilibrium studies and amitrole was determined to be mobile in silty clay, sandy loam, sand, and silt soils (K_ds ranged

from 0.152-0.922 ml/g). The reported vapor pressure of amitrole is 4.4×10^{-7} mm Hg (5.9×10^{-5} Pa) and the estimated Henry's Law Constant of 1.6×10^{-10} atm-m^3/mol are low; therefore, volatilization and subsequent photodegradation in air are not considered probable routes of dissipation.

The bioaccumulation in fish study was not submitted; however, the high solubility (280 g/l) and low octanol/water partition coefficient (log K_{ow} = -0.15) indicate limited potential for bioaccumulation in fish.

Amitrole is mobile, somewhat persistent and may have the potential to contaminate ground water. This assessment is based on the acceptable environmental fate studies which indicate amitrole has a significant number of characteristics in common with pesticides that are known to leach to ground water. Amitrole is stable to hydrolysis, and aerobic soil and anaerobic aquatic metabolism and field dissipation data indicate that it is somewhat persistent. Amitrole is classified as mobile because the low K_d and K_{oc} values indicate it will not strongly absorb to soil. Pesticides with similar properties have been found in ground water.

Amitrole may contaminate surface water from runoff or spray drift associated with ground spray application. Amitrole is stable to degradation from abiotic hydrolysis and aqueous photolysis, and is slightly to moderately persistent (aerobic soil metabolism $t_{1/2}$ ≈22-26 days; aerobic aquatic metabolism $t_{1/2}$ ≈57 days) in aerobic environments. Amitrole does not adsorb significantly to soil particles and may be transported in the dissolved phase by runoff to surface water bodies. Amitrole's primary route of dissipation is microbial-mediated metabolism; however, amitrole is stable in anaerobic environments.

b. Environmental Fate and Transport Data

(1) Degradation

(a) Abiotic Hydrolysis

Amitrole does not degrade by abiotic hydrolysis and was stable in the sterile test solutions. Amitrole did not degrade in filter-sterilized aqueous buffer solutions (pH 5, 7, and 9) during 30 days of incubation in the dark at approximately 25° C. Amitrole comprised 100% of the recovered radioactivity at all sampling intervals. The half-life was not calculated because hydrolytic degradation was not observed. In another study, amitrole was stable to hydrolysis in aqueous buffered pH 5, 7, and 9 solutions that were incubated in the dark for 34 days at 25 ± 1 °C (Accession #153181). The guideline requirement is fulfilled. (GLN 161-1; MRID 42843801)

(2) Photodegradation in Water

Amitrole is considered stable to degradation by aqueous photolysis. Amitrole did not substantially photodegrade in filter-sterilized aqueous buffer solutions (pH 5, 7, and 9) during 30 days of artificial light exposure (UV glass-filtered xenon arc lamp) at approximately 25° C. For the pH 5 test solutions, amitrole comprised 100% of the recovered radioactivity at all sampling intervals; therefore, the half-life at pH 5 was not determined. In the pH 7 and 9 test solutions after 30 days irradiation, amitrole was measured at 96.77% and 97.83% of the initial concentrations, respectively. The half-lives for the pH 7 and pH 9 test conditions were calculated to be 204 and 761 days, respectively; however, the accuracy of these estimated half-lives is uncertain because the data were extrapolated beyond the 30-day study duration. In another study, amitrole did not photodegrade in sterile pH 7 buffer solutions irradiated for 31 days (Accession #153182). The guideline requirement is fulfilled. (GLN 161-2; MRID 42943201)

(3) Photodegradation on Soil

Based on acceptable study results, amitrole is considered moderately resistant to photodegradation on soil. Amitrole photodegraded with an observed half-life of >30 days on sandy loam soil that was irradiated on a 12-hour photoperiod with artificial light (xenon arc lamp) for 30 days at 25° C. In contrast, amitrole did not degrade on sandy loam soil incubated for 30 days at 25° C in darkness. The only degradate identified in the samples was 1,2,4-triazole (maximum concentration of 9.9% at 30 days). The photolysis half-life on soil for amitrole was estimated to be 73 days; however, the accuracy of this estimated half-life is uncertain because the data were extrapolated beyond the 30-day study duration. In another study, amitrole applied to a sandy loam soil irradiated with sunlight degraded with a registrant-calculated half-life of ≈22 hours (Accession #153183). The guideline requirement is fulfilled. (GLN 161-3; MRID 42676601)

(4) Photodegradation in Air

No studies were required. The reported vapor pressure of amitrole at 20° C is 4.4×10^{-7} mm Hg (5.9×10^{-5} Pa) and estimated Henry's Law Constant of 1.6×10^{-15} atm-m^3/mol are low; therefore, volatilization and subsequent photolysis in the atmosphere are not considered probable routes of dissipation.

(5) Aerobic Soil Metabolism

Amitrole is slightly persistent ($t_{1/2}$ ≈22-26 days) to metabolism in soil under aerobic conditions when incubated at 20-24 °C. Amitrole is metabolized more slowly at lower temperatures (registrant-calculated half-life of ≈64-69 days for soil incubated at 7° C). Triazole ring-labeled [3-^{14}C]amitrole (1H-1,2,4-triazol-3-ylamine; radiochemical purity >98%), at 0.8 μg/g, degraded fairly rapidly ($t_{1/2}$ ≈22-26 days) in loamy sand soil that was continually aerated in the dark at 21-24 °C for up to 52 weeks. Microbial-mediated metabolism of amitrole to carbon

dioxide is an important biotransformation process because $^{14}CO_2$ totaled >50% after 26 weeks. Two unidentified [^{14}C]degradates, isolated at <4% of the applied radioactivity, were minor constituents in the degradation pathway of amitrole under aerobic conditions. Unextracted [^{14}C]residues reached a maximum of 43.11% at 13 weeks and decreased slightly to 38.31% at 52 weeks which suggests substantial amounts of amitrole are incorporated as "bound residues" in soil. In another study, amitrole degraded rapidly (observed half-lives of ≈1-7 days, dependent on sampling intervals) in German sandy soil (standard soil 2.2) and English loam soil (Study # 153487). The guideline requirement is fulfilled. (GLN 162-1; MRID 43457801)

(6) Anerobic Soil Metabolism

No studies were required. Information on degradation of amitrole under anaerobic conditions is discussed in the anaerobic aquatic metabolism study.

(7) Anerobic Aquatic Metabolism

Based on acceptable study results, amitrole is considered stable to metabolic transformations under the anaerobic aquatic conditions of this study. Triazole ring-labeled [3-^{14}C]amitrole (1H-1,2,4-triazol-3-ylamine; radiochemical purity 98.20%), at 1.27 mg/container, degraded very slowly in flooded sandy loam sediment (150 g water:24 g soil) that was incubated under anaerobic conditions in the dark at 5-9 ºC and 21-24 ºC for up to 52 weeks. Two unknown [^{14}C]degradates were isolated at <10% of the applied (maximum concentration of "Unknown A" was ≈7% at 39 weeks, decreasing to ≈1% by 52 weeks; "Unknown B" was ≈2% at 26 weeks only). In another study, amitrole at 1.25 mg/l degraded with an observed half-life of ≈56 days in non-sterile sandy soil that was incubated anaerobically in the dark at 25 ± 1 ºC. In the present study, the study authors concluded "the half-life is greater than one year." The guideline requirement is fulfilled. (GLN 162-3; MRID 43570301)

(8) Aerobic Aquatic Metabolism

Amitrole is considered moderately persistent ($t_{1/2}$ ≈57-74 days) to metabolism under aerobic aquatic test conditions. Triazole ring-labeled [3-^{14}C]amitrole (1H-1,2,4-triazol-3-ylamine), at 8.4-8.5 μg/mL, degraded slowly in flooded sandy loam sediment that was continually aerated in the dark at 21-24 ºC for up to 30 days. Two [^{14}C]degradates were isolated at <5% of the applied, but were not identified. Using HPLC data from the first 21 days of the study, the registrant-calculated half-life was 57 days (r^2 = 0.97, n = 8). The half-life was estimated to be ≈74 days (r^2 = 0.91, n = 9) using TLC analyses and data through 30 days post-treatment. The guideline requirement is fulfilled. (GLN 162-4; MRID 43099801)

(9) Mobility

(a) Adsorption/Desorption

Based on batch equilibrium experiments, amitrole (in 1% sodium azide solutions) was determined to be mobile in silty clay, sandy loam, sand, and silt soils, with Freundlich K_{ads} values of 0.152-0.922 ml/g. Freundlich K_{ads} values were 0.714 (1/n = 0.7671) for the silty clay soil, 0.223 (1/n = 0.8549) for the sandy loam soil, 0.152 (1/n = 0.8722) for the sand soil, and 0.922 (1/n = 0.8590) for the silt soil; corresponding K_{oc} values were 11.6, 29.7, 20.2, and 51.2. Amitrole was mobile in these same soils when the soils were acidified to approximately pH 4.5; Freundlich K_{ads} values ranged from 0.575-2.28. In another batch equilibrium study, amitrole was determined to be mobile to slightly mobile in Plainsfield sand (K_{ads} = 0.685, 1/n = 0.7975), CA sandy loam (K_{ads} = 3.52, 1/n = 0.6487), Kewaunee silty clay loam (K_{ads} = 1.57, 1/n = 0.8563), and Plano silt loam (K_{ads} = 3.79, 1/n = 0.7739) soils (Study #153186). No discernible correlation between adsorption and either organic carbon content or CEC of the soils was observed. The guideline requirement is fulfilled. (GLN 163-1; MRID 42676602)

(b) Soil Thin Layer Chromatography

In a previously-reviewed study using soil TLC methods, uncharacterized [^{14}C]amitrole residues aged for 5 days were determined to be of low mobility (R_f = 0.1; mobility class 2) in a sandy loam soil treated with residues of [3,5-^{14}C]amitrole (radiochemical purity >85%) at 3.37 mg/kg. (GLN 163-1; Study #153185)

(c) Volatility - Laboratory and Field

No studies were required. The reported vapor pressure of amitrole is 4.4×10^{-7} mm Hg (5.9×10^{-5} Pa) and estimated Henry's Law Constant of 1.6×10^{-15} atm-m^3/mol are low; therefore, volatilization is not considered a probable route of dissipation.

(10) Field Dissipation - Terrestrial

Based on acceptable study results, the terrestrial field dissipation studies indicate amitrole is slightly persistent (DT_{50}s of 17-21 days) for the tested sites. Amitrole (1H-1,2,4-triazol-3-ylamine; *AMIZOL*®) dissipated with a registrant-calculated DT_{50} and DT_{90} of 17 and 55 days, respectively, from the upper 15 cm of a bare-ground test plot of loam soil in Hillsboro, OR after application of amitrole at approximately 9.170 kg ai/ha(≈8.2 lb ai/A). In Moses Lake, WA, amitrole applied at approximately 8.212 kg ai/ha (≈7.3 lb ai/A) dissipated with registrant-calculated DT_{50} and DT_{90} of 21 and 70 days, respectively, from the upper 15 cm of a bare-ground test plot of loam soil. Amitrole was detected in several samples to a maximum depth of 15-30 cm. The degradate, cyanamide was detected at both study locations (maximum concentration of 0.020 mg/kg); however, cyanamide concentrations dissipated rapidly (within

3 days after application) and were below the limits of quantification (0.010 and 0.025 mg/kg for OR and WA, respectively). The guideline requirement is fulfilled. (GLN 164-1; MRID 43646801)

In two previously-reviewed terrestrial field dissipation studies, amitrole, applied at 12 lb ai/A, dissipated with an observed half-life of ≈23 days from the 0-15 cm depth in plots of Common Bermuda grass on a Norfolk sandy loam soil in North Carolina. For a silt loam soil at an Iowa test location, amitrole applied at a nominal application rate of 12 lb ai/A, dissipated with an observed half-life of <3 days from the 0-15 cm soil depth in soybean plots (MRID 40595901).

(11) Bioaccumulation in Fish

The reported solubility of amitrole in water is 2.80×10^8 mg/L at 20° C and the log K_{ow} of -0.15 support the assumption of limited bioacummulation in fish.

(12) Spray Drift

No amitrole-specific studies were reviewed. Droplet size spectrum (GLN 201-1) and drift field evaluation (GLN 202-1) studies may be required for amitrole, since the different formulations may be applied by ground boom spray equipment and it is estimated that there will be detrimental effects to non-target organisms due to drift. However, to satisfy these requirements the registrant in conjunction with other registrants of other pesticide active ingredients formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. During 1996 the Agency plans to evaluate these studies. In the interim and for this assessment of amitrole, the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The estimated drift rates at 100 feet downwind of the treated sites are 1% at the applied spray volume from ground applications and 5% from aerial applications. After review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks of the application of amitrole products to outdoor industrial areas, nonagricultural right-of-ways/fencerows/hedgerows, nonagricultural uncultivated areas/soils, and ornamental and/or shade trees.

c. Water Resources

(1) Ground Water

Amitrole is mobile, somewhat persistent and may have the potential to contaminate ground water. This assessment is based on the acceptable environmental fate studies which indicate amitrole has a significant number of characteristics in common with pesticides that are known to leach to ground water. Amitrole is stable to hydrolysis and anaerobic aquatic

metabolism, and aerobic soil metabolism and field dissipation data indicate that it is somewhat persistent. The low K_d and K_{oc} values indicate that amitrole will not strongly bind to soil; therefore amitrole is mobile. Because pesticides with similar properties have been found in ground water, the Agency is requiring a ground water label advisory to be placed on all amitrole labels.

(2) Surface Water

Amitrole may contaminate surface water from spray drift associated with ground application or in the dissolved phase during surface runoff. Transport of amitrole in the dissolved phase during surface runoff events which occur soon after application could be considerable because of amitrole's slight-to-moderate persistence (aerobic soil metabolism half-life of ≈22-26 days; aerobic aquatic metabolism half-life of 57 days), low soil/water partitioning coefficient (K_ds <1), and, less importantly, it's high solubility (280 g/L). Amitrole is less persistent in aerobic (i.e., well-drained) soil environments due to microbial-mediated metabolism (aerobic soil metabolism half-lives of ≈22-26 days; terrestrial field dissipation half-lives of 17-21 days) and incorporation into soil-bound residues. In anaerobic environments such as very poorly drained soils, and sediments in stream and lake bottoms, amitrole is persistent (anaerobic aquatic metabolism half-life >1 year). The low soil/water partitioning coefficients for amitrole (K_ds of 0.152-0.922 ml/g) indicate amitrole in surface runoff would occur primarily dissolved in the runoff water and would not be adsorbed onto eroding soil or entrained sediment.

In well-mixed, receiving surface water bodies, amitrole is predicted to be moderately persistent (aerobic aquatic metabolism half-life of 57 days). Volatilization of amitrole from surface waters is not considered an important route of dissipation based on the low vapor pressure (4.4×10^{-7} mm Hg) and low Henry's Law constant (1.6×10^{-15} atm-m^3/mol, estimated). The high solubility in water (280 g/L) and the low octanol/water partitioning coefficient (log K_{ow} = -0.15) indicate amitrole should not significantly bioaccumulate.

Although amitrole has the potential to contaminate surface water from runoff and spray drift, several published surface water monitoring studies using multi-residue analytical methods did not detect amitrole (Baker, 1988; Moyer and Cross, 1990; Goolsby et al., 1993; Jordan and Stamer, 1991). In addition to these studies, amitrole detections for surface waters were not found in a search of the Agency STORET database. Results of the monitoring studies suggest a low potential for amitrole to contaminate surface water. Lastly, amitrole is not regulated under the Safe Drinking Water Act (SDWA) and a Maximum Contaminant Level (MCL) has not been established.

3. Ecological Exposure and Risk Assessment

a. Ecological Exposure and Risk Characterization

The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOCs. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC_{50}. The acute effect levels typically are:

- EC_{25} (terrestrial plants),
- EC_{50} (aquatic plants and invertebrates),
- LC_{50} (fish and birds), and
- LD_{50} (birds and mammals)

The chronic test results are the:

> NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOCs.

Levels of Concern (LOCs) and Associated Risk Presumption

Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	Acute risk
acute RQ>	0.2	Risk that may be mitigated through restricted use
acute RQ>	0.1	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk, endangered species may be affected chronically,

Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	Acute risk
acute RQ>	0.1	Risk that may be mitigated through restricted use
acute RQ>	0.05	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk, endangered species may be affected chronically

Plants *

IF THE	LOC	PRESUMPTION
RQ>	1	Risk
RQ>	1	Endangered plants may be affected

***** Currently, no restricted use or reproductive effects criteria for plants have been established.

b. Exposure and Risk to Nontarget Terrestrial Animals

(1) Birds

Pesticide residues found on avian dietary food items following application are compared to LC_{50} values to predict hazard for birds. The Agency estimates the day 0 residues on vegetation based on the work of Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994). For amitrole, LC_{50} values were not available; therefore, the LC_{50}s were characterized as greater than 5000 ppm. The maximum concentration of residues of amitrole which may be expected to occur on selected avian dietary food items following both single and multiple foliar applications (2 appl. at 4 lbs ai/acre) are reported in the table below along with the RQs calculated from LC_{50} values of 5,000 ppm (the maximum dose):

Estimated Environmental Concentrations on Avian Dietary Food Items						
Food items	**3.6 lbs ai/A**		**4.0 lbs ai/A**		**8.0 lbs ai/A**	
	EEC (ppm)	RQ	EEC (ppm)	RQ	EEC (ppm)	RQ
Short Grasses	864	<0.17	960	<0.19	1920	<0.38
Long grasses	396	<0.08	440	<0.08	880	<0.17
Broadleaf plants, leaves and leafy crops, forage e.g. alfalfa	486	<0.09	540	<0.10	1080	<0.21
Fruit, Pods, and Seeds	54	<0.01	60	<0.01	120	<0.02

At the 3.6 - 4.0 lbs ai/A use rates for amitrole with LC_{50}s of 5,000 ppm, the RQs based on the EEC for short grass exceed the LOCs for the acute risk to endangered species (0.1).

At the 8.0 lbs ai/acre use rate, the RQ based on the EEC for long grass exceeds the LOC for the acute risk to endangered species (0.1). Additionally, the RQ at the 8.0 lbs ai/A use rate based on the EECs for short grass and broadleaf plants exceeds the restricted use LOC (0.2) for acute risk to non-target avian species.

Since there was little or no mortality at the highest concentration in the avian dietary toxicity test (5000 ppm) used to calculate the above RQs, amitrole is considered to represent low acute risk to birds.

Chronic risk to birds cannot be assessed because avian reproduction data are not available.

(2) Mammals

Results of the mammalian LD_{50} study indicate that amitrole is practically non-toxic to small mammals on an acute oral basis. From the LD_{50} of 4,080 mg/kg (Office of Pesticide Programs' HED RED Chapter dated 12/26/95), the following formula was used to estimate a 1-day concentration of toxicant in food expected to be lethal to 50% of the test population (LC_{50}).

$$\text{1-day } LC_{50} = \frac{LD_{50} \text{ in mg ai per kg}}{\text{\% body wt consumed (expressed as a decimal)}}$$

Estimated 1-Day LC_{50}s For Mammals Of Vareid Sizes And Food Consumptions		
Mammal Body Weight (g)	% Body Wt Consumed in a Day[1]	Estimated LC_{50} (ppm)
46 (meadow vole or herbivore)	61%	6,688
35 (field mouse or granivore)	16%	25,500
5 (least shrew or insectivore)	110%	3,709

[1] Davis and Golly, 1963

Acute Risk Quotients For Small Mammals Consuming Estimated Residues						
Mammal Type and Diet	Maximum EEC (ppm) at 8 lbs ai/A	RQs	Maximum EEC (ppm) at 4 lbs ai/A	RQs	Maximum EEC (ppm) at 3.6 lbs ai/A	RQs
Small herbivore consuming short grass	1920	0.29	960	0.14	864	0.13
Small granivore consuming seeds	120	0.00	60	0.00	54	0.00
Small insectivore consuming insects	1080	0.29	540	0.15	486	0.13

At 8 lbs ai/A, the RQs for small herbivores consuming short grass and small insectivores consuming insects exceeded the LOCs for acute risk that may be mitigated through restricted use (0.2). The RQs for small granivores consuming seeds do not exceed any LOCs (0.1-1).

For the 4.0 and 3.6 lbs ai/A use rates, the RQs for both small herbivores and small insectivores exceeded the LOC for acute effects on endangered species (0.1). The RQ for small granivores did not exceed any LOCs (0.1-1).

The mammalian chronic risk assessment is based on the NOEL for the two-generation rat reproduction study. The NOEL is 0.90 mg/kg/day which is the most sensitive toxicological value. The following formula was used to estimate the NOEL and LOEL in ppm of diet. For the LOEL calculated in the formula below, the rat reproduction study value of 5.88 mg/kg/day was substituted for the NOEL.

$$\text{NOEL (ppm of diet)} = \frac{\text{NOEL (mg/kg/day)}}{\text{\% body wt consumed (expressed as a decimal)}}$$

Estimated NOELs For Mammals Of Varied Sizes And Food Consumptions			
Mammal Body Weight (g)	% Body Wt Consumed in a Day[1]	Estimated NOEL (ppm)	Estimated LOEL (ppm)
46 (meadow vole or herbivore)	61%	1.48	9.64
35 (field mouse or granivore)	16%	5.63	36.75
5 (least shrew or insectivore)	110%	0.82	5.35

Chronic Risk Quotients For Small Mammals Consuming Estimated Residues						
Mammal Type and Diet	Maximum EEC (ppm) at 8 lbs ai/A	RQs	Maximum EEC (ppm) at 4 lbs ai/A	RQs	Maximum EEC (ppm) at 3.6 lbs ai/A	RQs
Small herbivore consuming short grass	1920	1297	960	649	864	584
Small granivore consuming seeds	120	21	60	11	54	10
Small insectivore consuming insects	1080	1317	540	649	486	593

The RQs for all use rates exceed the chronic LOC (1.0) for small herbivores, granivores and insectivores. This assessment indicates use of amitrole at all application rates has the potential for chronic risk to mammalian species, and may also chronically affect endangered mammalian species.

(3) Insects

There is sufficient information to characterize amitrole as relatively non-toxic to bees.

c. Exposure and Risk to Nontarget Aquatic Animals

Aquatic Estimated Environmental Concentrations: The toxicity of amitrole to most aquatic organisms tested to date ranges from practically non-toxic (freshwater finfish) to moderately toxic (marine invertebrates). The Agency calculated generic EEC levels using the GENEEC program. The GENEEC program considers the results of required environmental fate studies and is applicable to the typical field runoff scenario. It assumes runoff for a 10 hectare field into a 1 hectare pond two meters deep. The following environmental fate information was used for the GENEEC simulations: K_{oc} = 30 ml/g; solubility = 280,000 mg/L; and the aerobic soil metabolism half-life = 26 days. For modeling, spray drift was assumed 1% from ground spray applications and the application rates varied from 3.6 to 8 lbs ai/A. In this assessment, the screening model GENEEC was used to model runoff from non-agricultural use sites for amitrole. The GENEEC model was based on an agricultural use scenario, and is a conservative estimate of exposure from surface runoff because agricultural land uses are intensive and may cover large areas.

Generic Estimated Environmental Concentrations (GEECs) For Amitrole						
Use Sites	Application Method	Application Rate in lbs a.i./A	Initial EEC (ppm)	4-day EEC (ppm)	21-day EEC (ppm)	56-day EEC (ppm)
Industrial areas Nonagricultural rights-of way/ fencerows/hedgerows	Boom Sprayer	3.6	0.173	0.173	0.172	0.172
Nonagricultural uncultivated areas/soils Ornamental and/or shade Trees		4.0	0.192	0.192	0.191	0.191
Ornamental woody shrubs and vines		8.0	0.384	0.383	0.382	0.381

1. The GENEEC model is a Tier 1 screening model and is not the refined EEC or Tier 2 evaluation.

The use rates for amitrole range from 3.6 to 8.0 lbs. ai/A. The GENEEC program calculated Generic Estimated Environmental Concentrations (GEECs) that ranged from 0.172 to 0.384 ppm for these use rates. The assumed method of application is ground treatment with a boom sprayer.

The results of the Tier 1 Aquatic EEC modeling with GENEEC are listed in Table the table above. The range of aquatic EECs was 0.173 mg/L for the 3.6 lb a.i. application rate and 0.384 mg/L for the 8.0 lb a.i. application rate. The Initial or maximum EEC varied by a factor of 0.048 mg/L for each pound increase in amitrole. Comparison of the Initial EEC estimates and the 4-day, 21-day, and 56-day EECs indicate limited degradation of amitrole occurs in aquatic environments. This conclusion is consistent with the moderate persistence noted in the surface water assessment.

(1) Freshwater Fish and Amphibians

The RQs for the 3.6 to 8.0 lbs. ai/A use rates of amitrole do not exceed any levels of concern for freshwater finfish (0.1-1).

Chronic risk to freshwater fish can not be assessed because the fish life-cycle data are not available.

Risk Quotients (RQ) for Freshwater Fish and Amphibians					
Use	Application Rate	Surrogate Species	EEC (ppm)[1]	LC_{50} (ppm)	Risk Quotients EEC/LC_{50}
Industrial areas Nonagricultural rights-of way/fencerows/hedgerows	3.6	Bluegill	0.172	1000	0.000
		Rainbow trout	0.172	1000	0.000
Nonagricultural uncultivated areas/soils Ornamental and/or shade Trees	4.0	Bluegill	0.192	1000	0.000
		Rainbow trout	0.192	1000	0.000
Ornamental woody shrubs and vines	8.0	Bluegill	0.384	1000	0.000
		Rainbow trout	0.384	1000	0.000

1. Initial EEC value (immediately after runoff event).

(2) Freshwater Invertebrates

Risk Quotients (RQ) for Freshwater Invertebrates					
Use	Application Rate	Surrogate Species	EEC (ppm)[1]	EC_{50} (ppm)	Risk Quotients EEC/EC_{50}
Industrial areas Nonagricultural rights-of way/fencerows/hedgerows	3.6	*Daphnia magna*	0.172	18	0.010
Nonagricultural uncultivated areas/soils Ornamental and/or shade Trees	4.0	*Daphnia magna*	0.192	18	0.011
Ornamental woody shrubs and vines	8.0	*Daphnia magna*	0.384	18	0.021

1. Initial EEC value (immediately after runoff event).

The RQs for the 3.6 to 8.0 lbs. ai/A use rates of amitrole do not exceed any LOCs for freshwater invertebrates (0.1-1). However, the chronic risk to freshwater invertebrates will be assessed once the invertebrate life cycle study is reviewed.

(3) Estuarine and Marine Animals

Risk Quotients (RQ) for Estuarine and Marine Species

Use	Application Rate	Surrogate Species	EEC (ppm)[1]	LC_{50} (ppm)	Risk Quotients EEC/LC_{50}
Industrial areas Nonagricultural rights-of way/fencerows/hedgerows Nonagricultural uncultivated areas/soils Ornamental and/or shade Trees Ornamental woody shrubs and vines	3.6	Sheepshead Minnow	0.172	1000	0.000
		Eastern Oyster	0.172	110	0.002
		Mysidopsis bahia	0.172	2.8	0.061
	4.0	Sheepshead Minnow	0.192	1000	0.000
		Eastern Oyster	0.192	110	0.002
		Mysidopsis bahia	0.192	2.8	0.069
	8.0	Sheepshead Minnow	0.384	1000	0.000
		Eastern Oyster	0.384	110	0.004
		Mysidopsis bahia	0.384	2.8	0.137

1. Initial EEC value (immediately after runoff event).

The RQs for marine finfish (sheepshead minnow) and mollusks (eastern oyster) do not exceed the LOCs for the three application rates. At the 8 lb ai/A use rate for amitrole, the RQ for marine/estuarine invertebrates (*Mysidopsis bahia*) exceeds the LOC for acute risk that may be mitigated through restricted use (0.1). The shrimp (*Mysidopsis bahia*) species are the most sensitive of the organisms tested. The RQs for 3.6 and 4.0 lbs ai/A use rates of amitrole exceed the LOCs for acute effects to endangered marine/estuarine crustaceans (0.05). There are currently no endangered marine or estuarine crustacean species. These exceedances represent relatively low acute risk.

Chronic risk to estuarine/marine animals will be assessed once the aquatic invertebrate life-cycle data is reviewed.

d. Exposure and Risk to Nontarget Plants

(1) Terrestrial and Semi-aquatic

Non-target terrestrial plants inhabit non-aquatic areas. Non-target "semi-aquatic" plants are plants that usually inhabit low-lying wet areas that may or may not be dry in certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously

aquatic environment. The terrestrial and "semi-aquatic" plants are exposed to pesticides from runoff, drift or volatilization.

From the information currently available, amitrole affects the vegetative vigor of both monocots and dicots at very low exposure levels (<0.01 lbs ai/A). The risks to non-target plants from sheet and channelized runoff was not determined with certainty because plant toxicity data was limited (seedling emergence data are not available). Qualitatively, amitrole's broad spectrum plant control due to its mode of action (i.e., inhibition of carotenoid synthesis) suggests exposure of amitrole may impact non-target plants.

Ground Spray Evaluation For Terrestrial And Semi-Aquatic Plant Species

Use Site	Maximum Application Rate (lbs. ai/A)	Type of EEC	EEC (lbs ai/A)	EC_{25}[1] (lbs ai/A)	Risk Quotient (EEC/EC_{25})
Industrial areas Nonagricultural rights-of way/fencerows/hedgerows	3.6	drift based on ground spray application (assumed 1% drift)	0.036	0.005 (pepper) 0.008 (wheat)	7.2 4.5
Nonagricultural uncultivated areas/soils	4.0		0.04	0.005 (pepper) 0.008 (wheat)	8.0 5.0
Ornamental and/or shade trees Ornamental woody shrubs and vines	8.0		0.08	0.005 (pepper) 0.008 (wheat)	16.0 10.0

1. EC_{25} is based on dicot (pepper) and monocot (wheat) dry weights.

Drift from Ground Spray Application: Based on the 3.6 to 8.0 lbs. ai/A use rates of amitrole, risk quotients exceed the levels of concern for terrestrial and semi-aquatic plants (1.0). Risk quotients are based on EC_{25}s from the dry weight parameter for wheat (monocot) and pepper (dicot) from the vegetative vigor study. The wheat and pepper plant EC_{25}s were the most sensitive plants tested and the lowest levels for the available plant toxicity data.

(2) Aquatic Plants

Exposure to non-target aquatic plants may occur through runoff and/or drift from terrestrial applications. The risk assessment for aquatic plants is usually conducted for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Assessing risk to algae and diatom species is a useful indicator to determine potential impact to these food sources on aquatic organisms because algae and diatom species are the base of the food chain in aquatic environments.

RQ and EEC Values for Aquatic Plant Species						
Use Site	Maximum Application Rate (lbs ai/A)	Type of Plant	Type of EEC	EEC (ppm)	EC_{50}[1] (ppm)	Risk Quotient (EEC/EC_{50})
Industrial areas Nonagricultural rights-of way/fencerows/hedgerows	3.6	algae[1]	runoff	0.172	5.7	0.03
Nonagricultural uncultivated areas/soils	4.0	algae	runoff	0.192	5.7	0.03
Ornamental and/or shade Trees Ornamental woody shrubs and vines	8.0	algae	runoff	0.384	5.7	0.07

1. Only the test with *Selenastrum capricornutum* was provided and EC_{50} was >5.7 mg/l.

For algae, none of RQs for the three application rates exceed the levels of concern (1.0). However, this risk assessment is incomplete for vascular plants because only one of the five required plant species has been tested. Risk is unknown for the other species of aquatic plants.

e. Endangered Species

The risk assessment indicates that the use of amitrole may effect endangered mammals and plants.

4. Environmental Risk Characterization

a. Environmental Fate and Transport Assessment

Following review of acceptable and supplemental information in the environmental fate data base, amitrole appears to be slightly to moderately persistent in aerobic soil environments and persistent in anaerobic soil environments. Amitrole was mobile in four soils of widely-varying textures ranging from sand to silty clay. Amitrole dissipates fairly rapidly in aerobic soil environments (half-lives of 22-26 days) principally by microbial degradation and incorporation in soil-bound residues. In anaerobic soil environments, amitrole dissipates slowly (estimated half-life of "greater than 1 year"). Abiotic processes such as hydrolysis, photolysis, and volatilization are not important degradation mechanisms for amitrole. In terrestrial field studies conducted in Oregon and Washington, amitrole was slightly persistent with DT_{50}s of 17 and 21 days, respectively. The terrestrial field dissipation times (DT_{50}s) show good agreement with the laboratory-derived aerobic soil metabolism half-lives. The environmental fate assessment has a high level of certainty because it is based on acceptable laboratory and field studies which report consistent dissipation times and half-lives.

Based on the environmental fate information, amitrole is mobile, somewhat persistent and has the potential to leach to ground water. There is no evidence of groundwater contamination from amitrole residues; however, data for groundwater sampling of amitrole is extremely limited.

Amitrole may also contaminate surface water both from spray drift associated with ground spray applications and may be transported in the dissolved phase by runoff to surface water bodies. Amitrole is not regulated under the Safe Drinking Water Act; therefore, an MCL has not been established. The groundwater and surface water assessments have a medium level of certainty because of very limited monitoring information.

b. Risk to Nontarget Animals

The acute risk to nontarget animals (birds, insects, mammals, fish and aquatic invertebrates) is predicted to be low. Chronic risk to mammals was identified; however, the chronic risk to other nontarget animals (birds, fish and aquatic invertebrates) was not determined because chronic ecological effect data were not available.

Acute Risk

The acute risk to nontarget avian species and insects from applications of amitrole is expected to be low. For birds, it is important to note that the LC_{50} values used to calculate the RQs were greater than the highest dose tested (5,000 ppm). At the 5,000 ppm dose, little or no mortality was observed. Based on the Kenaga residue values, the maximum residues on avian food items (1080 and 1920 ppm) do not approach the concentration (5,000 ppm) at which zero or low mortality occurred. It is concluded that amitrole poses minimal acute risk to birds, including endangered species.

The acute risk from applications of amitrole is expected to be low to freshwater and marine/estuarine organisms. The risk quotients determined from application rates ranging from 3.6-8.0 lbs ai/A are less than the levels of concern for the tested aquatic animals at all use rates, except for marine/estuarine invertebrates. The RQ for mysid shrimp was 0.137 (8 lbs ai/acre) which exceeded the LOCs for endangered species (0.05) and restricted use (0.1) by a small margin. In this assessment, the screening model GENEEC was used to model runoff from non-agricultural use sites for amitrole. The GENEEC model was based on an agricultural use scenario and is a conservative estimate of exposure from surface runoff because agricultural land uses are intensive and may cover large areas.

The conclusion of low acute risk to estuarine crustaceans is based not only on the fact that the LOCs were exceeded by a small margin, but also because amitrole is used on non-agricultural use sites (outdoor industrial areas, nonagricultural rights-of-way/ fencerows/ hedgerows, nonagricultural uncultivated areas/soils, ornamental and/or shade trees, ornamental woody shrubs and vines). In addition to marginal LOC exceedances and non-agricultural uses, the amount of amitrole applied annually in the United States is relatively small. It is probable that total usage

of amitrole is between 40,000 and 60,000 pounds of active ingredient on an annual basis. Furthermore, endangered estuarine invertebrates are not currently listed by the USFWS.

The acute risk to nontarget mammals from applications of amitrole is also expected to be low. The RQs for small herbivores and insectivores (0.13 to 0.29) exceeded the LOCs for endangered species (0.1) and restricted use (0.2) by small margins. Some of the use areas (e.g., rights-of-ways), however, may be typical habitat for small mammals.

Chronic Risk

Mammals

Amitrole may be hazardous to mammalian reproduction in localized areas. Using the acceptable two-generation rat reproduction study, the risk assessment indicates use of amitrole has the potential for chronic risk to mammalian species, and may also chronically affect endangered mammalian species.

Assessment of the data from an acceptable toxicological developmental study (MRID 44016201) also indicates amitrole causes small mammals to produce smaller litters and deformed young. The developmental study, which was acceptable, used gavage to administer amitrole directly to pregnant rabbits. Amitrole affected fetal development in rabbits at 40 mg/kg/day by causing malformations in external appearance, viscera and skeletons of fetuses, and decreasing the percent of live fetuses per litter. These effects occurred with only 12 days of exposure during pregnancy. If these developmental effects occur in the environment, affected mammals may not survive and reproduce.

The estimated residues on mammalian food items exceed the NOEL of 4 mg/kg/day. For two mammal groups (small herbivores and insectivores), the estimated residues also exceed the LOEL (lowest observed effect level) of 40 mg/kg/day. Using the maximum EECs, the risk quotients calculated using the LOEL would be as follows:

Risk Quotients For Small Mammals Using The LOEL

Mammal Type and Diet	8 LBS/A	4 LBS/A*	3.6 LBS/A
Small herbivores consuming short grass	29	14	13
Small granivores consuming seeds	<1	<1	<1
Small insectivores consuming insects	30	15	3

* May be applied twice a year to a maximum of 8 lbs ai/A

From the LOEL risk quotient analyses, pregnant herbivores and insectivores may consume food items containing residues exceeding the level that, in the laboratory study, caused deformed fetuses and reduced litter sizes.

This exposure analysis uses residue levels which represent the maximum estimated values, and the residues are expected to be lower on most food items. Amitrole residues are predicted to decline by microbial-mediated metabolism or physical removal by washoff from rain and other routes of dissipation; however, the rate of foliar dissipation is not available for amitrole. Willis et al. (1980) reported foliar dissipation half-lives that were typically less than 10 days for several classes of pesticides. Results of the terrestrial field dissipation studies for amitrole indicate dissipation times (DT_{50}s) of 17 to 21 days on soil. Furthermore, the amitrole residue levels on insects and seeds in treated areas are not known because the food items may not be directly exposed to amitrole. The food items (insects, seeds) may not contain amitrole residues because the items were covered by vegetation during area treatment.

The extent of exposure depends, in part, on how many acres are treated, and the type of habitat that is exposed. For amitrole, the extent of treated acreage is unknown and was estimated to range from a minimum of approximately 5,000 acres to a maximum of 40,000 acres. The treated acreage estimate assumes 40,000 lbs ai are applied in the U.S. annually and the label application rates range from 1.0 to 8.0 lbs ai/A. Many of the treated areas, such as non-agricultural use sites, rights-of-way, fencerows, hedgerows and other may shelter a variety of mammal species. These areas may be prime habitat for small mammals including rabbits, voles, shrews, and other mammals. The mammals do not necessarily leave the treated areas and may feed on food items containing amitrole residues.

Birds

The risk to avian species on a chronic basis will be assessed once the avian reproductive data are submitted. Avian reproductive studies (preferably with the bobwhite quail and mallard duck) are required.

Aquatic Species

The risk to aquatic species (on a chronic basis) will be determined once the registrant submits the fish early life-stage (72-4(a)) or aquatic invertebrate life-cycle studies. Exposure to aquatic environments may occur by runoff or spray drift. The aquatic invertebrate life-cycle study with *Daphia magna* (water fleas) is being required.

c. Risk to Nontarget Plants

Terrestrial and Semi-aquatic Plants

The risk to nontarget terrestrial and semi-aquatic plants from applications of amitrole is expected to be moderate to high. Plant toxicity tests indicate amitrole affects vegetative vigor. The vegetative vigor study evaluates effects to plants from foliar exposure. However, seedling emergence data, which represent effects to seedlings from soil exposure, was not available. Amitrole is considered to affect a wide variety of plant species. The mode of action (inhibition of carotenoid synthesis and chlorophyll formation) results in non-selective weed control. The list of target plants on the label that are controlled suggests that amitrole is a "broad spectrum" herbicide.

The extent of impact beyond the treated sites is not known. While it is fairly certain that, to some extent, amitrole will drift and transport with runoff, the degree to which this occurs is uncertain. In addition to the uncertainty concerning extent of exposure, there is also uncertainty whether the magnitude of risk is adequately characterized because seedling emergence data were not available. The seedling emergence study provides data to assess risk to nontarget plants from amitrole in soil.

Aquatic Plants

Based on data for one species only, the LOC for aquatic plants has not been exceeded. However, risk to aquatic plants may occur from exposure by runoff and spray drift. Aquatic plant toxicity data for 5 species of plants, including a vascular species (*Lemna gibba*), are needed to determine risk to nontarget plants.

d. Risk to Endangered Species

Based on available mammalian data, amitrole may affect mammals (chronic effects), and terrestrial and semi-aquatic endangered plants. No data are available, however, to determine risk for endangered avian species and aquatic invertebrates (chronic effects), and aquatic plants.

When the Endangered Species Protection Program becomes final, limitations in the use of amitrole may be required to protect endangered and threatened species. These limitations may be formulation specific. The Agency anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

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 ingredients 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 amitrole active ingredients. 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 amitrole. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of amitrole, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of amitrole and to determine that amitrole can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore finds that all products containing amitrole as the active ingredient with the requirements and conditions specified herein, are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of amitrole (assuming the nursery stock use is deleted) 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 amitrole, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient amitrole, the Agency has sufficient information on the health effects of amitrole and on its potential for causing adverse effects in fish and wildlife and the environment. The generic data base supporting the reregistration of amitrole is substantially complete for all uses. However, the Agency is requiring the submission of two ecological studies and two handler exposure studies to be conducted with the generic active ingredient to complete the Agency's risk assessment and two plant testing ecological studies to confirm the Agency's risk assessment. Nevertheless, the Agency has determined that amitrole products not requested to be cancelled by the registrant prior to the issuance of this Reregistration Eligibility Decision document, labeled and used as specified in this

RED document, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that all uses of the wettable powder formulation packaged in water soluble bags are eligible for reregistration. The ornamental nursery stock use is being deleted.

2. Eligible and Ineligible Uses

The Agency has determined that all currently registered uses of amitrole (not including the uses associated with the liquid formulation which the registrant has requested voluntary cancellation and the ornamental nursery stock use which is being deleted), labeled and used as specified in this RED document as a terrestrial non-food crop herbicide are eligible for reregistration.

C. Regulatory Position - Summary of Risk Management Decisions

The following is a summary of the regulatory positions and rationales for amitrole. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

Because amitrole is only registered for nonfood uses, there are no tolerances for any food crop or water which will be used for irrigation, drinking, or other domestic purposes.

2. Cancer Risk Assessment

Amitrole has been classified as a Group B_2 (probable human carcinogen) by the Office of Pesticide Programs Carcinogenicity Peer Review Committee (document dated August 30, 1991). This determination is based on the thyroid tumors seen in the rat (both sexes, multiple strains), mouse (both sexes, two strains), and on liver tumors seen in the mouse (both sexes, multiple strains) as described in the appropriate toxicology studies. The Agency calculated a Q1* of 0.68 from the thyroid tumor effects as seen in the first long term toxicological study.

3. Restricted Use Classification (RU)

Amitrole was classified for Restricted Use through the Registration Standard, issued March 1984. In May 1984, a Special Review of Amitrole was initiated based on carcinogenic risk. In 1982, the Special Review of Amitrole was concluded with the following determination: "...because of the positive carcinogenicity studies, the Agency will continue to require that Amitrole remain a restricted use pesticide, that the cancer warning statement remain in place, that the current application method remain limited to boom sprayers and that the preset protective clothing requirements remain on labeling."

The registrant, CFPI requested that the Agency rescind the restricted use classification as part of the reregistration evaluation of amitrole.

After reviewing all the submitted data and comparing other pesticidal chemicals also classified as "restricted use," the Agency has determined that the restricted use classification could be rescinded for the following reasons and under the following conditions. Although the Agency's calculated cancer risk to mixers/loaders from amitrole packaged in water soluble bags is approximately 10^{-5}, (assuming handlers wear long sleeve shirts, long pants, shoes and socks) two thirds (2/3) of the estimated exposure/cancer risk is from inhalation exposure. As explained in this document, in the exposure assessment section, the Agency believes that actual inhalation exposure is likely to be practically non-existent. Focusing only on cancer risk from dermal exposure, the estimated cancer risk approaches 10^{-6} (1/3 X 8.2 X 10^{-5} from Table 6). Thus, with the low dermal absorption factor (0.5%), continued packaging in water soluble bags, the additional protection (although minimal because of the low dermal absorption) afforded by chemical resistant gloves and chemical resistant apron, and the conditions specified in the paragraph below, the Agency believes that a Restricted Use classification is no longer warranted.

In addition, the following conditions must be met: voluntary cancellation of the liquid formulation product (in process within the Agency), retention of the cancer warning label, limiting the sole application method to fixed-boom ground sprayers, retention of the same use profile as a non-food pesticide (non-cropland use only), and a commitment to provide the Agency with handler exposure studies to mixers/loaders of water soluble packages to confirm the Agency's risk assessment and conclusions. In addition, any proposed future expansion of their market will require that a separate risk assessment be performed for any new use/application method.

4. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through this RED document. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

5. Human Health

(a) Dietary

There are no food uses for amitrole. Therefore, there are no dietary exposures to amitrole and a dietary exposure assessment is not required.

(b) Worker (Mixer/Loader/Applicator)

Acute (Short Term) and Intermediate Term

The Agency conducted an assessment of the inhalation risks associated with amitrole following short-term and intermediate-term exposures to occupational handlers. The Agency has determined that a risk assessment is not required for short-term and intermediate-term dermal exposures. Margins of exposure (MOE) for occupational inhalation exposures were calculated for handlers using the NOEL for short-term exposure (4 mg/kg/day) and the NOEL for intermediate-term exposure (0.9 mg/kg/day). The calculated MOE's are presented in Table 5 of Section III(B)(b). Amitrole is not marketed to homeowners (the only application method is fixed-boom sprayer), and because of the nature of the use pattern, the sole exposure of concern is for occupational handlers. The calculations indicate that the MOEs for short- and intermediate-term inhalation exposures at baseline protection (i.e., no respirator) exceed 100 with the exception of Scenario I (mixing liquid to support groundboom application) which has a calculated MOE of 82. As previously stated, the registrant has requested voluntary cancellation of this product.

Amitrole is classified as a B_2-probable human carcinogen. The Agency will continue to require a cancer warning statement on all amitrole labels, continue packaging in water soluble bags, retain boom sprayers as the only application mode, require mixers and loaders to wear a chemical resistant apron and gloves, long sleeve shirts, long pants, shoes and socks. Additionally, the registrant has requested voluntary cancellation of the liquid formulation.

The restricted use classification is being rescinded since the Agency has determined that actual inhalation exposure is likely to be practically non-existent. Considering the low dermal adsorption factor, continued packaging in water soluble bags and the additional protection afforded by chemical resistant gloves and apron, the cancer risk from dermal exposure approaches 10-^{6}.

Post-Application

There are no amitrole-specific post-application exposure data available. For many amitrole use-scenarios, the Agency believes that the risks from post-application exposures will not pose an unacceptable risk to persons entering treated areas because, in general, amitrole is used in areas, such as rights-of-way, industrial areas, permanent landscape plantings, and other

non-crop areas, where frequent or routine prolonged entry by persons who contact treated surfaces is unlikely. Therefore, the Agency has determined that such post-application exposures do not appear to pose an unreasonable risk to persons entering treated areas, as long as entry is not permitted until sprays have dried.

6. Environmental

The acute risk to nontarget animals (birds, insects, mammals, fish and aquatic invertebrates) is predicted to be low. Chronic risk to mammals was identified; however, the chronic risk to other nontarget animals (birds, fish and aquatic invertebrates) was not determined because chronic ecological effect data were not available.

(a) Avian

Acute/Chronic

Studies indicate that amitrole is practically non-toxic to avian species on an acute oral and subacute basis. For birds, it is important to note that the LC_{50} values used to calculate the RQs were greater that the highest dose tested (5,000 ppm). The Agency considers amitrole to represent low acute risk to birds. At this time chronic risk to birds cannot be assessed, because avian reproduction data are not available.

(b) Mammals

Acute/Chronic

Amitrole is practically non-toxic to small mammals on an acute oral basis. The RQs for small herbivores and insectivores (0.13 to 0.29) exceeded by small margins the LOCs for endangered species (0.1) and restricted use (0.2). Amitrole however, may be hazardous to mammalian reproduction in localized areas. Using the acceptable two-generation rat reproduction study, the risk assessment indicates use of amitrole has the potential for chronic risk to mammalian species and may also chronically affect endangered mammalian species. The mammalian exposure asssessments use residue levels which represent the maximum estimated values, and the resiudes are expected to be lower on most food items. Amitrole residues are predicted to decline by microbial-mediated metabolism, physical removal by washoff and other dissipation pathways. The amitrole residue levels on food items in treated areas are not known because the treated areas are limited to nonagricultural use sites (rights-of way, fencerows, hedgerows, etc.) and the extent of exposure may be limited.

(c) Insects

There is sufficient information to characterize amitrole as relatively non-toxic to bees.

(d) Freshwater Fish and Amphibians

The toxicity of amitrole to most aquatic organisms tested to date range from practically non-toxic (freshwater finfish) to moderately toxic (marine invertebrates). Chronic risk to freshwater fish can not be assessed because the fish life-cycle data are not available at this time.

(e) Aquatic Invertebrates

There is sufficient information to characterize amitrole as slightly toxic to aquatic invertebrates. However, the chronic risk to freshwater invertebrates will be assessed once the invertebrate life cycle study is reviewed.

(f) Estuarine and Marine Organisms

The acute risk from applications of amitrole is expected to be low to freshwater and marine/estuarine organisms. The risk quotients determined from application rates ranging from 3.6-8.0 lbs ai/A are less than the levels of concern for the tested aquatic animals at all use rates, except for marine/estuarine invertebrates. The RQ for mysid shrimp was 0.137 (8 lbs ai/acre) which exceeded the LOCs for endangered species (0.05) and restricted use (0.1) by a small margin. In this assessment, the screening model GENEEC was used to model runoff from non-agricultural use sites for amitrole. The GENEEC model was based on an agricultural use scenario and is a conservative estimate of exposure from surface runoff because agricultural land uses are intensive and may cover large areas.

The conclusion of low acute risk to estuarine crustaceans is based not only on the fact that the LOCs were exceeded by a small margin, but also because amitrole is used on non-agricultural use sites. In addition to marginal LOC exceedances and non-agricultural uses, the amount of amitrole applied annually in the United States is relatively small. Usage information for amitrole in the U.S. provided by the registrant is between 40,000 and 60,000 pounds of active ingredient on an annual basis. Furthermore, endangered estuarine invertebrates are not currently listed by the United States Fish Wildlife Service (USFWS).

(g) Nontarget Plants (Terrestrial, Semi-Aquatic and Aquatic)

From the available information, amitrole affects the vegetative vigor of both monocots and dicots at very low levels (<0.01 lbs ai/A). The risks to non-target plants from sheet and channelized runoff was not determined with certainty because plant toxicity data was limited (seedling emergence data are not available). Qualitatively, amitrole's broad spectrum plant control due to its mode of action (i.e., inhibition of carotenoid synthesis) suggests exposure of amitrole may impact non-target plants. Based on the 3.6 to 8.0 lbs. ai/A use rates of amitrole, risk quotients exceed the levels of concern for terrestrial and semi-aquatic plants (1.0). Risk quotients are based on EC_{25}s from the dry weight parameter for wheat (monocot) and pepper (dicot) from

the vegetative vigor study. The wheat and pepper plant EC_{25}s were the most sensitive plants tested and the lowest levels for the available plant toxicity data.

Because the risk assessment is incomplete for non-target terrestrial and aquatic plants, terrestrial (seedling emergence) and aquatic plant (all five species) testing is being required to confirm and complete the Agency's risk assessment and conclusions.

(h) Surface Water

Even though amitrole exhibits some of the characteristics associated with chemicals that contaminate surface water from runoff or spray drift from with ground spray application, the Agency is not requiring surface water monitoring studies nor a surface water advisory because several published surface water monitoring studies using multi-residue analytical methods did not detect amitrole. In addition to these studies, amitrole detections for surface waters were not found in a search of the Agency's STORET database. Results of the monitoring studies suggest a low potential for amitrole to contaminate surface water. Lastly, amitrole is not regulated under the Safe Drinking Water Act (SDWA) and a Maximum Contaminant Level (MCL) has not been established.

(i) Ground Water

Amitrole is mobile, somewhat persistent and may have the potential to contaminate ground water. This assessment is based on the acceptable environmental fate studies which indicate amitrole has a significant number of characteristics in common with pesticides that are known to leach to ground water. Amitrole is stable to hydrolysis, and aerobic soil and anaerobic aquatic metabolism and field dissipation data indicate that it is somewhat persistent. Amitrole is classified as mobile because the low K_d and K_{oc} values indicate it will not strongly absorb to soil. Pesticides with similar properties have been found in ground water. There is no evidence of groundwater contamination from amitrole residues. Although the Agency is not requiring additional studies, it is requiring a ground water advisory to be included in all labels.

7. Labeling Rationale

a. Occupational and Residential Labeling Rationale/ Risk Mitigation Measures

(1) Compliance with the Worker Protection Standard (WPS)

(a) Uses of Amitrole and Scope of the 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 within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

At this time some of the registered uses of amitrole (nursery stock) are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). However, the registrant has indicated that they will voluntarily cancel the nursery stock use. Uses that are outside the scope of the WPS include use:

- On plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms are covered by the WPS).

- In a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other noncrop areas. The only remaining uses of amitrole will be as an industrial herbicide for use on "rights-of-way" and other similar uses not covered by the worker protection standard, once the voluntary cancellation of the liquid formulation bearing uses for nursery stock (as well as other uses) is formally requested and completed.

(b) Compliance With the WPS

The following discussion regarding compliance with worker prtoection standard is included since the nursery stock use is still technically registered, pending the Agency's receipt of the registrant's request for voluntary cancellation of nursery stock uses.

Any product whose labeling can be reasonably interpreted to permit use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

- After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the

requirements of the notices when the products are distributed or sold by the primary registrant or any supplementally registered distributor.

- After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by any person.

(c) Personal Protective Equipment/ Engineering Controls for Handlers

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If the Agency determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent Agency guidelines.

2. If the Agency determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

   - In the RED for that active ingredient, the Agency may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.

   - These minimum PPE requirements must be compared with the PPE that would be designated on the basis of 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.) must be placed on the label of the end-use product.

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.

(d) Occupational-WPS and Non-WPS Use Products

The Agency has determined that the establishment of active-ingredient-based minimum PPE and engineering-control requirements for occupational handlers must be taken for amitrole, because of the carcinogenic risk to mixers and loaders.

(e) Homeowner-Use Products

There are no homeowner uses of amitrole.

(f) Reentry Restrictions

WPS Uses

Uses covered by the Worker Protection Standard (i.e., the nursery stock use) is going to be, as noted above, voluntarily cancelled. Although the Agency has calculated risks for the handlers of the liquid formulation it has not determined reentry intervals or PPE for early entry for this use.

(g) Occupational-Use Products (NonWPS Uses)

Since the Agency has concerns about **immediate** post-application exposures to persons after nonWPS occupational uses of amitrole, it is establishing entry restrictions for all nonWPS occupational uses of amitrole end-use products. For specific requirements, refer to Section V of this document.

(h) Additional Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing amitrole. For the specific labeling statements, refer to Section V of this document.

8. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Spray Drift Task Force completes their studies, submits data, and the Agency evaluation is completed, there may be further refinements in spray drift management practices.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of amitrole for the above eligible uses has been reviewed and determined to be substantially complete for all uses. Nevertheless, the following studies are required to be conducted on the generic active ingredient:

o	Guideline 71-4(a) and (b)	Avian Reproduction studies
o	Guideline 72-4(b)	Aquatic Invertebrate Life Cycle with Daphnia Magna

The following confirmatory studies are required in order to complete the Agency's risk assessment and conclusions:

o	Guideline 123-1(a)	Terrestrial Plant Testing: Seedling Emergence only
o	Guideline 123-2	Aquatic Plant Testing: All five (5) species
o	Guideline 231 and 232	Handler exposure study to provide dermal and inhalation data on mixers and loaders during the use of water-soluble packages.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current Agency (EPA) regulations, PR Notices and applicable policies.

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "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)."

(b) "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)."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix D, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

a. Worker Protection Safety

- **PPE/Engineering Control Requirements for Pesticide Handlers**

For sole-active-ingredient end-use products that contain amitrole, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain amitrole, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

- **Products Intended Primarily for Occupational Use (WPS and nonWPS)**

<u>Minimum (Baseline) PPE/Engineering Control Requirements</u>

The Agency is establishing minimum (baseline) engineering controls for occupational uses of amitrole end-use products.

For the wettable powder packaged in water soluble packages (non WPS), the Agency is requiring that mixers/loaders and persons cleaning equipment wear:

long sleeve shirt and long pants,
chemical resistant gloves,
chemical resistant apron, and
shoes plus socks

For the wettable powder packaged in water soluble packages (non WPS), the Agency is requiring that applicators wear:

long sleeve shirt and long pants, and
shoes plus socks

- **Determining PPE Requirements for End-use Product Labels**

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

- **Determining Entry Restrictions**

For sole-active-ingredient end-use products that contain amitrole the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain amitrole the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

WPS uses

Since the registrant's voluntary cancellation of in-scope (nursery-stock, the only WPS use) use has been received by the Agency, an REI is not being presented.

NonWPS uses

The Agency is establishing the following entry restrictions for nonWPS occupational uses of amitrole end-use products:

"Do not enter or allow other employees to enter the treated area until sprays have dried."

Placement in labeling

Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading: "Entry Restrictions."

- **Other Labeling Requirements**

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing amitrole that are intended primarily for occupational use.

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."

User Safety Requirements

a. {Registrant: place this on the labeling if coveralls are required for pesticide handlers on the end-use product label:}

Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

b. {Registrant: place this on the labeling always:}

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

- "Users should remove clothing 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."

b. Environmental Hazard Statement

The following labeling statement must be added to the "Environmental Hazards" section on all amitrole end-use products:

Ground water label advisory

"This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

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 Reregistration Eligibility Decision (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 document. 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 registrants may distribute and sell amitrole products bearing old labels/labeling for 26 months from the date of issuance of this RED document. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED document. Registrants and persons other than registrants 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 REPORT
Case 0095[Amitrole] Chemical 004401[Amitrole]

The uses in Appendix A were evaluated for reregistration. These do not include changes in application rates, frequency or timing of applications, restricted entry intervals, etc. that may be mandated by this document.

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
INDUSTRIAL AREAS (OUTDOOR)				Use Group: TERRESTRIAL NON-FOOD CROP									
Spray, When needed, Boom sprayer	WP	NA	3.6 lb A	*	NS	NS	NS	3.6 lb	NS	NS			CAD, G99
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD CROP									
Spray, When needed, Boom sprayer	EC	NA	8 lb A	*	NS	NS	NS	8 lb	NS	NS			CAD, G99
	WP	NA	3.6 lb A	*	NS	NS	NS	3.6 lb	NS	NS			CAD, G99
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP									
Spray, When needed, Boom sprayer	EC	NA	8 lb A	*	NS	NS	NS	8 lb	NS	NS			CAD, G99
	WP	NA	3.6 lb A	*	NS	NS	NS	3.6 lb	NS	NS			CAD, G99
ORNAMENTAL AND/OR SHADE TREES				Use Group: TERRESTRIAL NON-FOOD CROP									
Spray, Foliar, Boom sprayer	EC	NA	8 lb A	*	NS	NS	NS	8 lb	NS	NS			CAD, G99
Spray, Nurserystock, Boom sprayer	EC	NA	8 lb A	*	NS	NS	NS	8 lb	NS	NS			CAD, G99
Spray, When needed, Boom sprayer	WP	NA	3.6 lb A	*	NS	NS	NS	3.6 lb	NS	NS			CAD, G99
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: TERRESTRIAL NON-FOOD CROP									
Spray, Foliar, Boom sprayer	EC	NA	8 lb A	*	NS	NS	NS	8 lb	NS	NS			CAD, G99
Spray, When needed, Boom sprayer	WP	NA	3.6 lb A	*	NS	NS	NS	3.6 lb	NS	NS			CAD, G99

APPENDIX A REPORT

Case 0095[Amitrole] Chemical 004401[Amitrole]

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LEGEND
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Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Re-Entry Intv.	: Reentry Intervals
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

EC	: EMULSIFIABLE CONCENTRATE
WP	: WETTABLE POWDER

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

APPENDIX A REPORT

Case 0095[Amitrole] Chemical 004401[Amitrole]

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USE LIMITATIONS CODES

CAD : Do not apply directly to water or wetlands.

G99 : Do not feed or graze animals on treated areas.

* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case amitrole covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to amitrole in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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 Guidelines, 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.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of AMITROLE

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ALL	00052652, 00052653
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00152463, 00157152
61-2B	**Formation of Impurities**	ALL	00152463, 00157152
62-1	**Preliminary Analysis**	ALL	00157152
62-2	**Certification of limits**	ALL	00157152
62-3	**Analytical Method**	ALL	00157152
63-2	**Color**	ALL	00152463
63-3	**Physical State**	ALL	00152463
63-4	**Odor**	ALL	00152463
63-5	**Melting Point**	ALL	00152463
63-6	**Boiling Point**	N/R	Not required. TGAI/MP is a solid at room temperature.
63-7	**Density**	ALL	00157152
63-8	**Solubility**	ALL	00152463, 00157152
63-9	**Vapor Pressure**	ALL	00157152
63-10	**Dissociation Constant**	ALL	00157152
63-11	**Octanol/Water Partition**	ALL	00160447
63-12	**pH**	ALL	00152463, 00157152
63-13	**Stability**	ALL	00157152

Data Supporting Guideline Requirements for the Reregistration of AMITROLE

REQUIREMENT		USE PATTERN	CITATION(S)
63-14	**Oxidizing/Reducing Action**	ALL	00160447
63-15	**Flammability**	N/R	Data not required. TGAI/MP is a solid at room temperature.
63-16	**Explodability**	ALL	00152463
63-17	**Storage stability**	ALL	00160447
63-18	**Viscosity**	N/R	Data not required. TGAI/MP is a solid at room temperature.
63-19	**Miscibility**	N/R	Data not required. TGAI/MP is a solid at room temperature.
63-20	**Corrosion characteristics**	N/R	00152463
63-21	**Dielectric breakdown volt**	NA	Not applicable.
64-1	**Submittal of Samples**	NA	Not applicable.
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**		00160451
71-2A	**Avian Dietary - Quail**		00160452
71-2B	**Avian Dietary - Duck**		00160476
72-1A	**Fish Toxicity Bluegill**		00160453
72-1B	**Fish Toxicity Bluegill - TEP**		RESERVED
72-1C	**Fish Toxicity Rainbow Trout**		00160454
72-1D	**Fish Toxicity Rainbow Trout- TEP**		RESERVED
72-2A	**Invertebrate Toxicity**		00160455
72-2B	**Invertebrate Toxicity - TEP**		RESERVED

Data Supporting Guideline Requirements for the Reregistration of AMITROLE

REQUIREMENT		USE PATTERN	CITATION(S)
72-3A	**Estuarine/Marine Toxicity - Fish**		42817801
72-3B	**Estuarine/Marine Toxicity - Mollusk**		42837401
72-3C	**Estuarine/Marine Toxicity - Shrimp**		42818201
72-3D	**Estuarine/Marine Toxicity Fish-TEP**		RESERVED
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**		RESERVED
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**		RESERVED
123-1A	**Seed Germination/Seedling Emergence**		42813702 SUPPLEMENTAL (GDLN NOT SATISFIED, NEW STUDY REQUIRED)
123-1B	**Vegetative Vigor**		42813702
141-1	**Honey Bee Acute Contact**		0036935
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**		00063601, Gaines et al. 1973
81-2	**Acute Dermal Toxicity - Rabbit/Rat**		00063599, Gaines et al. 1973
81-3	**Acute Inhalation Toxicity - Rat**		00127930
81-4	**Primary Eye Irritation - Rabbit**		00127930
81-5	**Primary Dermal Irritation - Rabbit**		00160450
81-6	**Dermal Sensitization - Guinea Pig**		00160449

Data Supporting Guideline Requirements for the Reregistration of AMITROLE

REQUIREMENT		USE PATTERN	CITATION(S)
82-1A	**90-Day Feeding - Rodent**		00052658, 00052643, 00063601, 00082174, 00028434, 00063598, Jukes, T.H. et al. (1960), Tsuda H. et al. (1974), Strum, et. al. (1971), Alexander, N.M (1959)
83-1A	**Chronic Feeding Toxicity - Rodent**		00061351, 00132445, Steinhoff et al. (1983)
83-2A	**Oncogenicity - Rat**		00127930, 00132445, 00052656, 00061351, 00082176, Steinhoff et al. (1983)
83-2B	**Oncogenicity - Mouse**		00043595 ,00061348, 41317901, 41462501, Innes et al. (1969), Vasselinovith (1983)
83-3A	**Developmental Toxicity - Rat**		00160448
83-3B	**Developmental Toxicity - Rabbit**		00159997, 40567701, 40963701, 43643601, 43643602
83-4	**2-Generation Reproduction - Rat**		44016201
84-2A	**Gene Mutation (Ames Test)**		00052646, 42214601
84-2B	**Structural Chromosomal Aberration**		42214602
84-4	**Other Genotoxic Effects**		00052648
85-1	**General Metabolism**		00052644, 00052645, 00052659, Fang, et al. (1964), Franco and Muncio et al. (1975), Shah, et al. (1977), IARC Monographs (1974), Dynamac (1982)
85-2	**Dermal Penetration**		00151651
86-1	**Domestic Animal Safety**		N/A

Data Supporting Guideline Requirements for the Reregistration of AMITROLE

REQUIREMENT		USE PATTERN	CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
No studies have been submitted or reviewed by the Agency.			
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**		42843801
161-2	**Photodegradation - Water**		42943201
161-3	**Photodegradation - Soil**		42676601
161-4	**Photodegradation - Air**		NOT REQUIRED
162-1	**Aerobic Soil Metabolism**		43457801
162-2	**Anaerobic Soil Metabolism**		NOT REQUIRED
162-3	**Anaerobic Aquatic Metabolism**		43570301
162-4	**Aerobic Aquatic Metabolism**		43099801
163-1	**Leaching/Adsorption/Desorption**		42676602
163-2	**Volatility - Lab**		NOT REQUIRED
163-3	**Volatility - Field**		NOT REQUIRED
164-1	**Terrestrial Field Dissipation**		43646801, 40595901
164-2	**Aquatic Field Dissipation**		RESERVED
164-3	**Forest Field Dissipation**		WAIVED
165-3	**Accumulation - Irrigated Crop**		WAIVED
165-4	**Bioaccumulation in Fish**		00061349

Data Supporting Guideline Requirements for the Reregistration of AMITROLE

REQUIREMENT	USE PATTERN	CITATION(S)

RESIDUE CHEMISTRY

There are no applicable guidelines or studies required because amitrole is a non-food use pesticide chemical.

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 (19??), 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.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC 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 A 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. 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 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Reqistrant'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. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

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 3-31-96).

This Notice is divided into six sections and seven 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 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
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, Data Compensation and Confidential Statement of Formula Forms

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 ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/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 the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes 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 (Telephone number: 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].

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

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and 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

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose 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 generic 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.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (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.

a. 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 completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms 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.

b. 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 Reqistrant's Response Form (Attachment 3), 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 under item 9 in the instructions for the Requirements Status and Reqistrant's Response Forms. 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 Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (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, is allowed only if the product bears an amended label.

c. 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 if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. 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:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). 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 responding to product specific data requirements.

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 requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not 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.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for 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.

2. Product Specific Data Requirements

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 choose 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.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). 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 also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. 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 Reqistrant'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.

a. 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 both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms 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.

b. 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.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Reqistrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select

one of the six options on the Generic 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 you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (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 upgradeable (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. 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 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

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 the 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, offer to share in the burden of producing the data upon terms to be agreed to 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 burden 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 normally will 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 '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, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must 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 usually are 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 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 upgradeable, 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

upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. 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 also should 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.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Reqistrant'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 upgradeable (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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, 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.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

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, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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 not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 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 low volume pesticides to be only those active ingredients 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 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 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 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:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, 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.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient 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.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past

five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) 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.

(vi) 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.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, 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 in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient 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.

b. Request for Waiver of Data

Option 9, under Item 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 requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must 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 are not appropriate 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.

2. Product Specific Data

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 product specific 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.

SECTION 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:

   i. 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 Reqistrant's Response Form.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. 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 GeneTox 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 generally would 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 also must 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 a 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 must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and 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 Generic and Product Specific Data Call-In Response Forms 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

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

AMITROLE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing amitrole.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of amitrole. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Compensation Forms in replying to this Amitrole Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for amitrole are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on amitrole are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible amitrole products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Nancy Tompkins at (703) 308-8172.

All responses to this Notice for the product specific data requirements should be submitted to:

Nancy Tompkins
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **AMITROLE**

AMITROLE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing amitrole.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of amitrole. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 5), and (5) the Cost Share and Data Compensation Forms in replying to this Amitrole Generic Data Call In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for amitrole are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on amitrole are needed. These data are needed to fully complete the reregistration of all eligible amitrole products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Mario F. Fiol at (703) 308-8049.

All responses to this Notice for the generic data requirements should be submitted to:

Mario F. Fiol, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **AMITROLE**

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE FORMS" FOR THE GENERIC AND PRODUCT SPECIFIC DATA CALL-IN

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 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.

The 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 suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, 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 FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** 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. **ON BOTH FORMS:** Check 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. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and 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.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data 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.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** 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."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do 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.

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.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** 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 initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled 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 FORMS" FOR THE GENERIC AND PRODUCT SPECIFIC DATA CALL-IN

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

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. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The 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 suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, 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 FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In 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. **ON BOTH FORMS:** 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 Reqistrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. 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. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	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 Indredient or Pute 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	Technical Grade Active Ingredient

TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** 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.

Option 1. **ON BOTH FORMS:** (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 protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (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-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency 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.

Option 3. **ON BOTH FORMS:** (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 also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. 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 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 apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date 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.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. 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.

Option 6. **ON BOTH FORMS:** (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. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, 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 the Agency 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). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 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.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. 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" form specifying 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.

Item 10. **ON BOTH FORMS:** 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. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

EPA'S BATCHING OF AMITROLE PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS

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 amitrole 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.

In conducting the batching PRS identified the following products:

- Technical Amitrole [(90.0% a.i.) (Id. No. 33688-5)].
- Amizol Industrial Herbicide [(90.0% a.i.) (Id. No. 33688-6)].
- Amitrol-T Liquid Herbicide [(21.6% a.i.) (Id. No. 33688-7)].

PRS has concluded that there are no acute tox data requirements for Technical Amitrole (33688-5) and/or Amizol Industrial Herbicide (33688-6). Amizol Industrial Herbicide is similar to Technical Amitrole.

Acute tox testing of Amitrol-T Liquid Herbicide (33688-7) should be provided by the registrant for PRS review.

List of All Registrants Sent this Data Call-In Notice
(Remove this page and insert mailing list)

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
Approval Expires 3-31-96

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

APPENDIX E - LIST OF RELATED DOCUMENTS

The following is a list of available documents for Amitrole that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Nancy Tompkins at (703) 308-8172.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for amitrole.

The following documents are part of the Administrative Record for amitrole 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 Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria