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 amitraz. This RED was initially approved by the Agency in March 1995. Subsequently, the RED was circulated for review and comment in connection with an international harmonization project. 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 ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses 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 CP Moran (703) 308-8590. 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, another DCI letter will be enclosed listing such requirements. Complete the two response forms provided with each DCI letter by following the instructions contained in each DCI. **You must submit the response forms for each product and for each DCI within 90 days of the date you receive the RED; 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 data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. 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 RED issuance date (the cover letter 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.

You may request an original EPA Form 8570-1 from:

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 delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer 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; 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 Citation of Data**. Complete and sign this form (EPA form 8570-29) for each product. **Cite-all is not a valid option for reregistration.**

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 ALL DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-0234)***
Office of Pesticide Programs (H7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-0234)***
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

***** the case code for this RED (see front cover of document).

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

AMITRAZ

LIST A

CASE 0234

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

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AMITRAZ REREGISTRATION ELIGIBILITY DECISION TEAM

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Linda S. Propst	Reregistration Branch
Mario F. Fiol	Reregistration Branch
Carol Stangel	Planning and Reregistration 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

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
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

Reregistration Decision

This Reregistration Eligibility Decision (RED) Document addresses the reregistration eligibility of the pesticide amitraz.

Based on the reviews of the generic data for the active ingredient amitraz, the Agency has sufficient information to make a reregistration eligibility decision on the health effects of amitraz and on its potential for causing adverse effects in humans, fish and wildlife and the environment. Based on this information, the Agency concludes that products containing amitraz for all registered uses are eligible for reregistration, provided certain risk mitigation measures required in this document are implemented.

The Agency, however, is concerned with the potential for the developmental/ neurological/ reproductive toxicity of amitraz to the general population, the acute neurotoxic effect on certain categories of workers, and the possible significant risk to terrestrial and aquatic species. In order to reduce these risks, the Agency is requiring an increase in the interval between amitraz application to pears (minimum of 35 days between applications); an increase in the restricted-entry interval (REI) for pears to 28 days, and for cotton an increase to 48 hours; specifying minimum (baseline) personal protective equipment (PPE) for all occupational uses, and requiring engineering controls for the pear use. Additionally, the Agency is requiring the submission of a confirmatory developmental/neurological/ reproductive study and confirmatory dislodgeable foliar residue (DFR) and exposure data.

In order to reduce the potential risk for chronic reproductive effects to avian species, risk mitigating measures were developed by the registrant, AgrEvo Co., and the Agency for amitraz use on pears. The label deletion of the pre-bloom use on pears will reduce the possible risk posed to on-site terrestrial animal species. In order to alleviate any concerns the Agency may have for the neurotoxicity effect of amitraz resulting from acute dietary exposure, the registrant must provide label amendments that will limit the use on pears to two applications of a WP formulation.

The scientific data base is adequate to support the reregistration of all registered uses of amitraz. The Agency is, however, requiring a life-cycle aquatic invertebrate study (Guideline 72-4(b)) with BTS-27271, one of the three amitraz degradates; concurrent dislodgeable foliar residue (DFR) data (Guideline 132-1(a)) and dermal exposure data (Guideline 133-3); batch equilibrium studies (Guideline 163-1) conducted with the amitraz degradates BTS-27271 and BTS-27919; droplet size spectrum (Guideline 201-1) and field drift studies (Guideline 202-1) which the registrant may elect to satisfy through the Spray Drift Task Force; dermal exposure data (Guideline 231); and inhalation exposure data (Guideline 232).

Background Information

Amitraz is a formamidine insecticide/acaricide used to control pear psylla on pears, whitefly and mites on cotton and pears; lice, livestock ticks, and mange mites on beef and dairy cattle and swine; and ticks on dogs. Currently, there are six active amitraz products. Bee mite strip and cattle collar uses were recently voluntarily canceled. Formulated amitraz products include an emulsifiable concentrate, wettable powder, soluble concentrate, and impregnated material. The registered formulations include an unspecified solid formulation for manufacturing (97%), three emulsifiable concentrates (12.5% and two 19.8%); a wettable powder (50%); and an impregnated dog collar/tag (9%). Currently maximum application rates range from 0.2 lb/50 gal of water to 3 lb ai/acre per season. Amitraz products can be applied with aerial and ground equipment, including airblast sprayers and hand sprayers, using dilute and concentrated solutions. There is also the 3-month dog collar.

Amitraz was first registered in 1975 as a technical to be used in the preparation of experimental miticide/insecticide formulations. In 1976, an application for registration for an end-use formulation to be used on apples and pears was submitted. In 1977, prior to any registration decision, the Agency published a notice in the Federal Register of a rebuttable presumption against registration (RPAR, now referred to as Special Review) on the basis that amitraz met the risk criteria for carcinogenic effects. It was concluded that amitraz was a possible human carcinogen and the proposed pear use would pose a risk of cancer, albeit very small, to certain exposed groups. It was further concluded that the benefits for use on pears outweighed the risks. The Agency conditionally registered amitraz on pears for four years. Since alternative products were available for apples, the benefits for apples did not outweigh the risks and apples were not registered.

One of the conditions of registration was the generation of a new mouse carcinogenicity study. This study was submitted and evaluated by the Agency's Cancer Assessment Group (CAG). Using both mouse studies, the CAG classified amitraz as a Group C (possible human) carcinogen. This cancer classification decision was reaffirmed by the Agency's Peer Review Committee in October 1990.

The Agency issued a Registration Standard for amitraz in October 1987 (PB-88-128665). The Registration Standard required product and residue chemistry, environmental fate and ecological effects data. No additional toxicology studies were required.

A Data Call-In issued September 30, 1991 required additional data for product chemistry, ecological effects, reentry protection, environmental fate, and nature of the residue in livestock. The Agency has now completed its review of the target data base for amitraz, including data submitted in response to the 1987 Registration Standard and the subsequent Data Call-In.

Supporting Rationales for Reregistration Decision

Acute toxicity studies indicate that amitraz is slightly toxic by the oral and inhalation routes (Toxicity Category III) and moderately toxic by the dermal route (Toxicity Category II). Amitraz is not a dermal irritant and only a slight irritant to the eyes (Toxicity Category IV) for both and is not a dermal sensitizer.

In a human study, acute exposure to amitraz was associated with central nervous system (CNS) toxicity symptoms of sedation, disorientation, and hypothermia. The Agency considers the NOEL for acute neurotoxicity in the human study, 0.125 mg/kg/day, to represent the toxicological endpoint for short-term occupational risk assessment and considers the Q_1* of 5×10^{-2} $(mg/kg/day)^{-1}$ to represent the toxicological endpoint for occupational carcinogenic risk assessment.

Amitraz may pose a concern for potential carcinogenic risks to certain categories of workers. Amitraz is classified as a Group C (possible human) carcinogen, based on findings of combined liver adenomas/carcinomas in female B6C3F1 mice. Estimates of human risk may be calculated from the unit risk, Q_1*, which is 5×10^{-2} $(mg/kg/day)^{-1}$, based on findings of combined hepatocellular adenomas and carcinomas in female mice. Additionally, there may also be a potential for a developmental, neurological and/or reproductive risk, based on available toxicology information. These issues will be assessed after a confirmatory combined developmental/neurological/reproductive study in rats is submitted and evaluated.

Dietary exposure due to published uses of amitraz may be associated with an estimated excess upper bound carcinogenic risk of 1.4×10^{-6}. The bulk of exposure was attributed to pears (58% of total exposure based on 14 days PHI). Except for honey, for which 100% crop treated value was used, the exposure estimates for all other published uses reflect all presently available refinements in both residue and percent crop treated information.

Using anticipated residues and percent treated crop data, chronic exposure to amitraz in the diet is only a small fraction of the RfD (1.1% of RfD for the overall U.S. population and 4.5% of RfD for "non-nursing infants <1 year old", the most highly exposed DRES subgroup) and does not appear to be a cause for concern. Based on the low % RfD's, it appears that chronic non-cancer dietary risk from exposure to amitraz is minimal. Additionally, using tolerance level residues for all commodities except pears, acute exposure to amitraz in the diet does not appear to be a cause for concern (MOE > 10, based on the human study). The acute anticipated residue used for amitraz and BTS-27271 is 0.42 ppm. At the 98th percentile of pear consumption, no population subgroup has acute dietary risk MOEs of <10.

Handlers using amitraz to treat pear orchards, cotton fields, and livestock on a long-term basis may be at risk from its carcinogenic effects. Estimated excess carcinogenic risks for handlers are 2.7×10^{-8} to 1.2×10^{-5}. MOEs were based on the NOEL from the human

study; handlers' exposure data for the pear use; and available PHED data for cotton and livestock use and foliar residue data for pear use.

The Agency has performed a comprehensive qualitative environmental fate assessment for parent amitraz. The available studies submitted and reviewed by the Agency show that parent amitraz rapidly degrades in the environment to form two primary transformation products BTS-27271 and BTS-27919 and a secondary transformation product BTS-24868. Because of its rapid degradation in the environment, amitraz is not expected to pose a concern for ground or surface waters. In contrast to parent amitraz, amitraz transformation products have been shown to be moderately persistent in aquatic and terrestrial environments and appear to be relatively immobile in soil column and field dissipation studies. An accurate quantitative assessment of these products in ground and surface water, though, cannot be made until additional mobility studies (batch equilibrium) are completed.

Amitraz use on pears and cotton may also pose a chronic risk to nontarget avian and mammalian species. The EECs calculated using maximum and typical Kenaga values and residues from a foliar field dissipation study exceed the lowest effect level (LEL) which is defined by the range of the NOEL to the LOEL. Amitraz use on pears may also pose a chronic risk to nontarget aquatic invertebrates because the EEC for the degradate BTS-27271 exceeds 0.01 EC_{50} for Daphnia magna.

For the pear use, amitraz exceeds the endangered species LOC (0.10 LD_{50}/day) (using a maximum scenario) for birds feeding on BTS-27271 residues. For the cotton use pattern, the endangered species LOC (0.10 LD_{50}/day) is exceeded for birds feeding on residues of BTS-27271 (also using a maximum scenario). However, no change in its classification is being imposed in this document because the Agency believes that the label modification deleting the use of amitraz on pears early in the spring will reduce the exposure to birds when they are in their nesting cycle and are feeding more frequently.

The Agency has determined that amitraz is a valuable tool to control pear psylla, whiteflies and mites. Considering the limited acreage where amitraz is used both on pears and cotton and the mitigating risk reduction measures in label modification as well as the previously described human risk mitigating measures to protect human health, the potential for adverse chronic risk posed by its continued use has been reduced.

Before reregistering the products containing amitraz, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. The product specific data include product chemistry for each registration and acute toxicity testing. After reviewing all

these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. However, those products which bear uses of this or any other active ingredients which have not been determined to be eligible for reregistration will be reregistered only when such uses and active ingredients are determined to be eligible for reregistration.

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 registration" 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 amitraz. The document consists of six sections. Section I is the introduction. Section II describes amitraz, 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 amitraz. Section V discusses the reregistration requirements for amitraz. 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 from the Office of Pesticide Programs, Public Response Section in the Public Response and Program Resource Branch, 401 M Street, S.W., Washington, D.C. 20460. Telephone number: (703) 305-5805.

II. CASE OVERVIEW

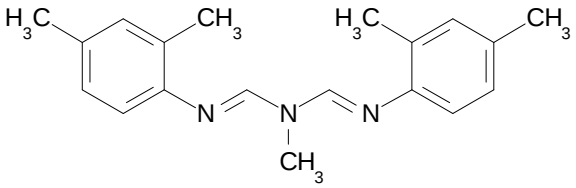
A. Chemical Overview

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

- **Common Name:** Amitraz or BAAM

  An insecticide/acaricide with registered food/feed uses on crops (cotton and pears), animals (cattle and hogs), and home use (pets).

- **Chemical Name:** N'-(2,4-dimethylphenyl)-N-(((2,4-dimethylphenyl)imino)methyl)-N-methyl-methanimidamide



- **Empirical Formula:** $C_{19}H_{23}N_3$
- **Molecular Weight:** 293
- **CAS Registry No.:** 33089-61-1
- **Shaughnessy No.:** 106201
- **Basic Manufacturer:** AgrEvo Chemical Company

Pure amitraz is an off-white crystalline solid, and technical amitraz is a straw-colored crystalline solid with a melting point of 86-87^0 C and a density of 1.13 g/ml. At 20-25^0 C, amitraz is soluble at <1 ppm in water, 66.6 g/100 ml in xylene, 50 g/100 ml in acetone, and 2.38 g/100 ml in methanol.

B. Use Profile

The following is information on the currently registered uses of amitraz. A detailed table listing the eligible and ineligible uses as well as methods, application rates, limitations, and use restrictions is included in Appendix A.

- **Type of Pesticide:**
  formamidine insecticide/acaricide

- **Mechanism of Action:**
  contact

- **Use Groups And Sites:**
  Terrestrial Food Crop: Pear
  Terrestrial Food and Feed Crop: Cotton
  Indoor Residential: Dogs/canines
  Indoor Food: Dairy cattle (lactating or unspecified), beef/range/feeder cattle (meat), hog/pig/swine (meat)

- **Pests:**
  Pear psylla and livestock ticks, lice and mange mites. Also lepidopteran pests, whiteflies and mites on cotton.

- **Formulation Types Registered:**
  Unspecified solid formulation for manufacturing: 97%
  Emulsifiable concentrate: 12.5%, and 19.8%
  Wettable powder: 50%
  Impregnated collar/tag (dog): 9%

- **Method and Rates of Applications:**
  Cotton: Up to 1 lb a.i./acre during the growing season with a maximum of 8 applications per year. Label indicates amitraz is often mixed with other insecticides.
  Pear: Up to 3 lb a.i./acre applied during dormancy and throughout the growing season excluding prebloom applications.
  Livestock (dairy cattle/beef cattle/swine): Spray or dip at up to 0.2 lb ai./ 50 gallons of water
  Dog collar: 3 month collar.

Application of product can be either by aerial or ground equipment, including airblast sprayers and hand sprayers delivering either dilute or concentrated applications. The dog collar, impregnated with amitraz, is considered a homeowner product.

- **Use Practice Limitations:** Refer to appendix A.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available of amitraz use. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. However, data were not available for the use of amitraz in dog collars.

U.S. Amitraz Use
Estimated Annual 1989 - 1992

Site	Grown Acres (000)	Treated Acres		a.i. lbs. (000)
		(000)	(%)	
PEAR				
California	25.8	2 - 6	10 - 25	2.5 - 8.0
Colorado	0.6	0.1 - 0.2	19 - 31	0.1 - 0.2
Massachusetts	0.1	N/A	N/A	N/A
Michigan	1.6	0.5 - 0.8	32 - 48	0.5 - 0.8
New Jersey	0.1	N/A	N/A	N/A
New York	3.2	1.3 -1.9	46 - 72	2.3 - 2.9
Ohio	0.1	0.002	2 - 3	0.001
Oregon	18.3	5 - 15	26 - 88	8 - 21
Pennsylvania	1.5	0.8 - 1.3	51 - 85	2.3 - 3.8
Washington	26.0	4 - 6	15- 23	6 - 8
Total for Pears *	77.3	16 - 31	19 - 37	21 - 71
COTTON				
California only	1040	0.07	0 - <1	0.06

(*) Total for pears also includes other states which are not listed above.

U.S. Amitraz Use Estimated Annual 1989 - 1992				
Livestock Commodity	**Millions**	**Millions**	**(% treated)**	**a.i. lbs.**
Cattle	96	2 - 3	2 - 3	N/A
Swine	111	11 - 22	10 - 20	N/A
Total for Livestock	207	13 - 25	6 - 12	N/A

N/A indicates not available.

D. Data Requirements

Data requested in the October 1987 Registration Standard for amitraz included studies on product chemistry, ecological effects, environmental fate, and residue chemistry. These data were required to support the uses listed in the Registration Standard. Additionally, a Data Call-In issued by the Agency in September 1991 requested product chemistry, ecological, environmental, and residue chemistry data that the Agency had determined were needed for reregistration. Appendix B lists all data requirements identified by the Agency as needed to support reregistration of currently registered uses.

E. Regulatory History

Amitraz was first registered in 1975 as a 93% technical to be used in the preparation of experimental miticide/insecticide formulations. The first application for registration of an end-use formulation was made in 1976 for a product to be used on apples and pears. In April 1977, prior to any registration decision on these uses, the Agency published a notice in the Federal Register (42 FR 18299) of a rebuttable presumption against registration (RPAR, now referred to as Special Review) of pesticide products containing amitraz on the basis that amitraz met the risk criteria for carcinogenic effects. An 80-week mouse carcinogenicity study showed a significant increase in the incidence of lymphoreticular tumors in mice.

The RPAR or Special Review process resulted in the Agency conclusion that there is "weakly positive evidence" that amitraz is a possible human carcinogen. The Agency also concluded that the proposed use on apples and pears might pose a very small risk of cancer to certain exposed groups. A review of the benefits and risks surrounding the proposed uses resulted in the Agency determination that there would be significant benefits from the use on pears since amitraz will control pear psylla, a serious pest for which there were no viable alternatives. It was concluded however, that there were little or no benefits to the use on apples since alternative products were available. The Agency's decision was published in the Federal Register in October, 1979 (44 FR 59939-59946) where it was also announced that the Agency intended to conditionally register amitraz on pears for four years. The registration

was issued in January, 1980 with the conditions of the registration requiring the registrant to a) submit additional benefits data for the pear use, b) submit a new mouse carcinogenicity study, c) label the product "Restricted Use," and d) add additional precautionary text to the label.

The conditional registration requirements for the use of amitraz on pears were satisfied. A new mouse carcinogenicity study was referred to the Agency's Cancer Assessment Group (CAG) for evaluation in 1986. The study showed an increase in the incidence of hepatocellular tumors in female mice. Based on the two studies, CAG concluded that amitraz has carcinogenic activity in the mouse, and should therefore be classified as a Group C, possible human carcinogen. Amitraz was referred to the FIFRA Scientific Advisory Panel (SAP) which recommended that it be classified as a Group D since the panel believed that the weight of the evidence was inadequate to clearly categorize the cancer potential. The Agency then reconsidered the classification but determined that amitraz would still be regulated as a Group C carcinogen. In 1986 amitraz was registered for use as an emulsifiable concentrate to control ticks on cattle and lice on hogs.

The Registration Standard ("Guidance for the Reregistration of Pesticide Products") was issued in October 1987 (EPA Case No. 234). The Standard reported that the Agency would continue the registration on pears, cattle and hogs, but stated that the tolerances for the proposed uses on apples and citrus would not be issued. The Standard also required that certain environmental fate and avian reproduction studies be conducted, and additional plant metabolism data be submitted. The Restricted Use classification for amitraz end-use products was lifted by the Standard, but a 24-hour reentry interval for pears was retained.

Subsequent registrations of amitraz-containing products were issued for use on dogs (1992), in beehives (1992), and on cotton (1993). End-use formulations include emulsifiable concentrates, a wettable powder, a dog collar, and an impregnated strip to control parasitic mites in beehives. There are a total of six active amitraz registrations, including one technical product. The technical product is not produced domestically. Also, an import tolerance for hops was recently proposed in the Federal Register.

In October 1990, the Agency's Office of Pesticide Programs, Health Effects Division, Peer Review Committee met to discuss amitraz and evaluate its carcinogenic potential. The Committee considered the weight-of-the-evidence and reaffirmed the Group C classification, and additionally recommended that the risks be quantified by unit risk.

On January 13, 1994, one of the amitraz registrants requested voluntary cancellation of two of his products: the dairy cattle collar (EPA Registration Number 54382-4) and the impregnated strip controlling parasitic mites in beehives (bee mite strips), (EPA Registration Number 54382-5).

III. SCIENCE ASSESSMENT

The Agency has conducted a thorough review of the scientific data base for amitraz for the purpose of determining the reregistration eligibility of amitraz.

A. Physical Chemistry Assessment

The physical and chemical properties of amitraz are as follows:

Amitraz Technical

Color:	either off-white or straw-colored
Physical State:	crystalline solid
Odor:	slight amine odor
Melting Point:	86 - 87^0 C
Specific Gravity:	1.128 g/ml at 20^0 C
Solubility:	at 20-25^0 C, soluble at 1 ppm in water, 66.6 g/100 ml in xylene, 50 g/100 ml in acetone, and 2.38 g/100 ml in methanol
Vapor Pressure:	3.4 x 10^{-4} Pa @25^0 C
pH:	N/A (product has low solubility and decomposes in water).
Stability:	stable at ambient temperature

There is a single registered manufacturing-use product (MP): the AgrEvo Chemical Company 97% technical amitraz (T; EPA Registration Number 45639-51).

The product chemistry data base for amitraz is adequate and will support the reregistration eligibility of amitraz as a food use pesticide. References (MRIDs) for all studies submitted in support of the product chemistry data requirements are listed in the data tables, Appendix B, part of this document.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base of amitraz is adequate and will support reregistration as a food use pesticide. Although a confirmatory study (a combined developmental/neurological/ reproductive toxicity study in rats) is required for continued registration of amitraz, the information available is sufficient to evaluate the chemical's toxicity.

a. Acute Toxicity

The acute toxicity data for the technical grade of amitraz are summarized below:

Test	Results LD_{50}	Category
(81-1) Oral LD_{50} - rat	531 mg/kg (M); 515 mg/kg (F) (MRID 00041539)	III
(81-2) Dermal LD_{50} - rabbit	> 200 mg/kg (MRID 00040862)	II
(81-3) Inhalation LC_{50} - rat	2.4 mg/L (MRID 00029963)	III

The table below presents additional amitraz acute toxicity information. Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

Test	Results LD_{50}	Category
(81-4) Eye Irritation - rabbit	Non-irritating (MRID 00040861)	IV
(81-5) Dermal Irritation - rabbit	Non-irritating (MRID 00040862)	IV
(81-6) Dermal Sensitization - guinea pig	Negative (MRID 00029965)	N/A
(N/A) in vitro acetylcholinesterase inhibition study - housefly	Negative (MRID 00040324)	N/A

N/A = Not applicable

b. Subchronic Toxicity

In a subchronic oral toxicity study, mice were administered amitraz by gavage, at levels of 0, 3, 12, 50, or 200 mg/kg/day for 90 days. The systemic NOEL was 3 mg/kg/day. Higher doses produced reduced body weight gain and liver toxicity (increased serum glutamic pyruvate transaminase activity, increased liver weight, hepatocyte enlargement, bile duct proliferation, and focal necrosis). The systemic LOEL was 12 mg/kg/day (MRID 00028715).

In another subchronic oral toxicity study, Beagle dogs were administered amitraz, by capsules, at levels of 0, 0.25, 1.0, or 4.0 mg/kg/day for 90 days. The systemic NOEL was 0.25 mg/kg/day. At the LOEL (1.0 mg/kg/day) there were slight enlargement of the central and midzonal hepatocytes of the liver and slight hyperplasia of the zona glomerulosa of the adrenals. Both the LOEL and the high dose (4 mg/kg/day) produced transient CNS (central nervous system) depression, decrease in pulse rate, glucosuria, neutrophilia of the bone marrow and recurrent hypothermia of short-lasting duration that appeared within three hours after dosing and only lasted a few hours. The high dose additionally produced ataxia, emesis, and catarrhal conjunctivitis. (MRIDs 00040345, 00028716).

In a 21-day dermal toxicity study in rabbits, doses of 50 or 200 mg/kg/day were applied to the skin of rabbits (6 hours/day for a total of 15 times over the 21-day period).

Moderate erythematous reactions with desquamation of the skin and subcutaneous hemorrhage, along with anorexia, sedation, hyperglycemia, testicular degeneration, lymph node nodular hyperplasia, and generalized neutrophilia of various organs occurred at both doses. The NOEL was less than 50 mg/kg/day (MRID 00029972).

c. Chronic Toxicity

The required chronic toxicity study in rodents is satisfied by a chronic/carcinogenicity feeding study in rats (MRID 00044585).

In a 2-year chronic toxicity study, amitraz was administered to dogs, by oral capsule, at doses of 0, 0.1, 0.25 or 1.0 mg/kg/day. The systemic NOEL was 0.25 mg/kg/day. The LOEL was 1.0 mg/kg/day, based upon central nervous system depression, increased blood glucose levels, and hypothermia (MRID 00044586).

d. Carcinogenicity

Carcinogenic effects were not observed in a combined chronic/carcinogenicity study. Wistar rats were fed levels of 0, 15, 50, or 200 ppm (0, 0.77, 2.5 or 10.18 mg/kg/day for males and 0, 0.97, 3.13 or 12.59 mg/kg/day for females) for two years. The systemic NOEL was 15 ppm. The systemic LOEL was 50 ppm, based upon findings of aggressive or excitable behavior, clinical signs, and reduced weight gain at this level and at 200 ppm. (MRID 00044585).

In a carcinogenicity feeding study, CFLP mice were fed diets containing 0, 25, 100, or 400 ppm amitraz (0, 3.75, 15, or 60 mg/kg/day) for 80 weeks. Amitraz produced lymphoreticular tumors in females at 400 ppm, the highest level studied. Tumors were not evident at the mid dose level of 100 ppm. The systemic NOEL was 25 ppm, due to a reduction in body weight gain at higher doses (MRID 00111886).

In another carcinogenicity feeding study, B6C3F1 mice were fed diets containing 0, 25, 100, or 400 ppm amitraz for 104 weeks. Amitraz produced liver adenomas and carcinomas as well as lung adenomas at the highest dose level studied, 400 ppm (50.1 mg/kg/day for females and 44.7 mg/kg/day for males). Tumors were not evident at the next dose level (100 ppm; 15 mg/kg/day). The systemic NOEL was less than the lowest level tested. The systemic LOEL was 25 ppm (the lowest level tested; 2.6 mg/kg/day for females and 2.3 mg/kg/day for males), based upon stomach hyperkeratosis, spleen hematopoiesis, and liver changes (nodules, and telangietactic and basophilic foci). Hyperactive or aggressive behavior, reduced weight gain, and a reduced myeloid/erythroid ratio in bone marrow were observed at the 100 and 400 ppm levels (MRID 00013952).

Amitraz is currently classified by the Agency's Health Effects Division Cancer Peer Review Committee (October 1990) as a "Group C" (possible human) carcinogen, based on the

finding of combined hepatocellular adenomas and carcinomas in female B6C3F1 mice. A quantification of the risks was recommended by the Committee. The upper bound (95%) of the estimated potency (Q_1*) for amitraz was calculated to be 5 x 10^{-2} (mg/kg/day)$^{-1}$. This new classification reflects a change from previous evaluations. In 1986 the Office of Research and Development's Cancer Assessment Group concluded that amitraz should be classified as a "Group C" carcinogen, with no risk quantification, based on the same carcinogenic evidence. In the same year (02/24/86), the FIFRA Scientific Advisory Panel concluded amitraz should be classified in Group D (not classifiable as to human carcinogenicity).

e. Developmental Toxicity

In two developmental toxicity studies, Wistar rats were dosed with amitraz at 0, 1, 3, or 12 mg/kg/day, by gavage (assumed route). No treatment related maternal or developmental effects were observed in one study. In the other study, the maternal and developmental NOELs were 3 mg/kg/day. Both maternal and reproductive LOELs were 12 mg/kg/day, based on decreased weight gain. These studies do not satisfy the data requirements for developmental toxicity, but together they can be used for risk assessment (MRIDs 00029959; 00029960).

In another developmental toxicity study, New Zealand White rabbits were dosed with amitraz at 0, 1, 5, or 25 mg/kg/day, from gestation days 6 through 18. The NOEL for both maternal and developmental effects was 5 mg/kg/day. The LOEL for both maternal effects (reduced body weight and increased abortions on gestation days 17 to 20) and developmental effects (decreased litter size and weight, and reduced implantation and viability indices) was 25 mg/kg/day. This study does not meet the present Agency standards for a developmental toxicity study, but the information is adequate for risk assessment purposes (MRID 00029961).

f. Reproductive Toxicity

In a multi-generation reproduction study, (MRID 00029962), Boots-Wistar rats were fed diets containing 0, 15, 50, or 200 ppm amitraz. The systemic toxicity NOEL was 50 ppm (4.84 mg/kg/day/ male and 5.22 mg/kg/day/female) and the LOEL was 200 ppm (16.41 mg/kg/day/male and 20.06 mg/kg/day/female), based on reduced body weight gain and food consumption in F_0 animals. The reproductive toxicity NOEL (15 ppm; 1.47 mg/kg/day/male and 1.69 mg/kg/day/female) was lower than the systemic NOEL. The reproductive toxicity LOEL (50 ppm; 4.84 mg/kg/day/male and 5.22 mg/kg/day/female) was also lower than the systemic LOEL and was based on reduced litter size and pup survival in all 3 generations (F_1, F_2, and F_3), and a slight reduction in pup weights in the F_1 and F_2 generations. Further reproductive toxicity was observed at the high dose (most of the F_1 generation rats died, and there were not enough animals left for subsequent matings). This

study was unacceptable and does not satisfy the data requirements for Guideline 83-4 (Reproductive Toxicity). A study addressing the developmental neurotoxicity and reproductive toxicity potential of amitraz in the rat is required as confirmatory of the present data.

g. Mutagenicity

Results of mutagenic studies (table below) indicate that amitraz is not mutagenic.

Guideline	Study Type	Results
84-2(a)	Salmonella Reverse Gene Mutation (Ames Assay)	Negative at ≤ 10 mg/plate, with/ without metabolic activation. (Accession 253131)
84-2(a)	Forward Gene Mutation Assay mouse L5178Y lymphoma cells)	Negative at 0.06-20 ug/ml w/wo activation. HDT is highest non-cytotoxic dose. (Accession 253131).
84-2(b)	In-vitro Structural Chromosome Aberration (human lymphocytes)	Negative up to cytotoxic and/or insoluble concentrations. (MRID 4179501)
84-4	Unscheduled DNA Synthesis (human embryonic lung fibroblast)	Negative up to cytotoxic concentrations, w/wo activation. (Accession 161011)
84-4	Morphological Transformation (C3H/10T1/2 cells derived from mouse embryo fibroblast	Negative up to cytotoxic concentrations, w/wo activation. (Accession 161010)

Two metabolites of amitraz [N-(2,4-dimethylphenyl)-N-methyl formamidine (BTS-27271)] and [2,4-dimethylformanilide (BTS-27919)] were also shown to be negative for reverse gene mutation in the Salmonella assay (MRID 00161008). A third metabolite [2,4-dimethylaniline (BTS-24868)] was reported to be positive for forward gene mutation in the mouse lymphoma assay with metabolic activation (MRID 00161012).

h. Metabolism

Extensive metabolism studies have been conducted with amitraz in several species, including humans, baboons, dogs, rats, and mice. In all species, amitraz was rapidly metabolized in the stomach, following oral administration, to form at least six metabolites, among which are the three cited above. Metabolites BTS-27271 and BTS-27919 (which are formed via hydrolysis at the C-N [N-methylmethanimidamide] bond) are the primary metabolites of amitraz. Excretion of metabolites occurred mainly in the urine over 48 hours (62%-82% in all species) and to a lesser extent in feces (9%-39%), with no unchanged parent compound observed in urine. The proportion of various metabolites recovered in the urine of all species was also similar. The highest levels of ^{14}C tissue residues in animals were found over 3 to 4 days in the liver, bile, kidney, adrenal glands, and pigmented areas of the eye. (MRID 00160964)

i. Dermal Adsorption

Male rats were given a dermal dose of 91 ug/cm^2 of amitraz. The material remaining on the skin or in urine, feces, skin, digestive tract, and remaining carcass was analyzed at 24 hours and 120 hours after dosing. The mean percents of dose absorbed were 6.67% at 24 hours post-dosing and 7.79% at 120 hours post-dosing, indicating continued absorption with time (MRID 42133501). A dermal adsorption rate of 7.79% was recommended for oncogenic risks assessment.

A subsequent dermal absorption study (MRID 43396801) has been submitted to the Agency for review. Although the California Environmental Protection Agency, Department of Pesticide Regulation (CEPA DPR), reviewed and found the study acceptable, the Agency has determined the study to be supplementary. However, the Agency has concluded that the study still supplies valuable information and concurs with California EPA that the dermal absorption of 13.8% be used to estimate absorbed doses.

j. Special Studies

Animal Study: Amitraz was investigated for its effects on estrous cycles in female rats and mice, and on hormone levels in female mice. In 8 week old rats, administration of 20 mg/kg/day amitraz in the feed for 18 weeks resulted in a significant prolongation of the estrous cycle length (length = 4.3 days in control animals and 6.1 days in treated animals) (MRID 00040323). In mice, administration of 3.75 mg/kg/day (NOEL) for 28 weeks caused no effects on the estrous cycle or on hormone levels. Higher doses of 15 and 60 mg/kg/day given for the same time period produced increases in blood dehydroepiandrosterone sulfate levels, reductions in progesterone and prolactin levels, and an elevated liver weight. At the 60 mg/kg/day dose there was also reduced body weight gain, decreased urea and glucose levels, and prolonged proestrus with reduction of the duration of diestrus; thus, there was no overall effect on the total estrous cycle length.

Human Study: In a human double blind randomized crossover study of acute neurotoxicity, 6 male volunteers were given sequential oral doses of amitraz by capsule, at 0.0625 or 0.125 mg/kg with a placebo control. There were at least 14 days between treatments. Vital signs (pulse, respiration rate, blood pressure, and body temperature) and ECGs were taken. Pupil responsiveness and psychomotor performance were evaluated. Urine was collected for testing. Minimal and transient changes in blood pressure, temperature, ECG rate, and psychomotor performance were observed at 0.125 mg/kg. In another human metabolism study, 2 male volunteers given 0.250 mg/kg by oral route experienced sedation, disorientation, and hypothermia. For the purpose of risk assessment, the human acute oral doses of 0.125 mg/kg and 0.25 mg/kg (for effects in two human subjects, should be used for the NOEL and LOEL, respectively.

k. Other Toxicological Considerations

Neurotoxic signs were observed in chronic oral toxicity studies in rodents (aggressive or excitable behavior in mice and rats; MRIDs 00013953, 00044585) as well as in subchronic and chronic oral toxicity studies in non-rodents (CNS depression and hypothermia in dogs; MRIDs 00040345, 00028716, 00044586). Acute signs (hypothermia, drowsiness, disorientation) consistent with an effect on the CNS were also observed in human volunteers.

l. Reference Dose (RfD)

A RfD for amitraz was determined to be 0.0025 mg/kg/day, based on a NOEL of 0.25 mg/kg/day from the chronic oral toxicity study in dogs (MRID 00044586). An uncertainty factor of 100 (a factor of 10 each for interspecies extrapolation and intraspecies variance) was used. The critical effects were increased blood glucose concentration, hypothermia and CNS depression. An ADI for amitraz was established by WHO (1990) at 0.003 mg/kg/day, based on the same chronic dog study and using the same uncertainty factor.

The Agency's RfD Committee additionally concluded that developmental (MRID 00029959) and reproductive (MRID 00029962) toxicity studies in rats were supplementary, and, therefore, neither should be considered as a reliable assessment of the developmental or reproductive toxicity potential for amitraz. Since there was some evidence that amitraz was associated with reproductive and developmental toxicity at relatively low dose levels, and neurotoxicity was observed in both rodents and non-rodents, the registrant should 1) submit a new, confirmatory combined developmental, neurological, and reproduction toxicity study in rats and 2) consult with the Agency on the protocols for this study.

2. Exposure Assessment

a. Dietary Exposure

The residue chemistry data base for amitraz is adequate and will support reregistration as a food use pesticide.

Plant Metabolism: The qualitative nature of the residue in plants is adequately understood. The metabolism of amitraz in plants occurs via hydrolysis at the C-N [N-methyl-methanimidamide] bond to yield BTS-27271 and BTS-27919. Both of these metabolites are further degraded by a break of either the C=N or the C-N bond to form 2,4-dimethylaniline (2,4-DMA or BTS-24868). Amitraz may also be demethylated to form N,N'-bis (2,4-dimethylphenyl) methanimidamide (BTS-28037). Oxidation of the 4-methyl group on 2,4-DMA yields 4-amino-m-toluic acid (BTS-28369), and oxidation of the 4-methyl group on N-(2,4-dimethylphenyl)formamide yields 4-formamido-m-toluic acid (BTS-39098); another toluic acid metabolite is 4-acetamido-m-toluic acid (FBC-31158). The terminal residues of

concern are amitraz and its metabolites containing the 2,4-DMA moiety (BTS-27919 and BTS-27271); these are the residues which are presently included in the tolerance expression (MRIDs 00028664, 00028666, 00055718, 00161022, 00161023, 40590601,40590801, 40999502, 41206701).

Animal Metabolism: The qualitative nature of the residue in poultry and ruminants following oral dosing is adequately understood. Studies involving laying hens and dairy cows have indicated that amitraz metabolism is fairly rapid and that the major route of elimination is via the excreta. The metabolic pathway in poultry and ruminants is similar to that in plants. The terminal residues of concern in animals, based on oral feeding studies, are amitraz and its metabolites containing the 2,4-DMA moiety (BTS-27919 and BTS-27271). The results of a swine dermal metabolism study (MRIDs 42969301, 43287101) indicated that the nature of the residue in swine following dermal application is similar to the nature of the residue following oral dosing. In both ruminant oral and swine dermal metabolism studies, residues in tissues consisted primarily of the (unregulated) acidic metabolites, and lower levels of the regulated metabolites.

Residue Analytical Method: There are two adequate methods listed in FDA's Pesticide Analytical Manual (PAM Vol. II) for purposes of data collection and enforcement of tolerances for residues of amitraz and its metabolites containing the 2,4-DMA moiety. Methods I (designed for animal tissues and milk) and II (designed for plant commodities) are both GLC methods with electron capture detection, and convert residues of amitraz to 2,4-DMA by acid and base hydrolysis, respectively. The detection limits of the methods are 0.01 ppm for milk and 0.05 ppm for plant and other animal commodities. Amitraz and its metabolites containing the 2,4-DMA moiety have been tested using FDA's Multiresidue Method Protocol D; the metabolite BTS-27919 was the only compound which could be analyzed by this protocol (MRIDs 00046030, 00051929, 00051930, GS00234013, 40811310, 40811311, 40811312).

Storage Stability: Adequate storage stability studies have been conducted using fortified samples of citrus fruits, cow tissues and milk, and cottonseed. Residues of BTS-27271 and BTS-27919 are stable in/on citrus fruits stored at -20°C for up to 18 months. Residues of amitraz, BTS-27271, and BTS-27919 are stable in cow tissues and milk stored at -20°C for up to 12-15 months. Residues of amitraz are stable in cottonseed for over one year of frozen storage. The storage intervals and conditions from the magnitude of the residue studies in plants are adequately supported by storage stability data (MRIDs 00046029, GS00234014, 40811308, 40811309, 40999508).

Magnitude of the Residue in Plants: The magnitude of the residue data in food/feed crops for which there are presently registered uses (pears and cotton) are adequate. The residue chemistry data for honey and honeycomb are also adequate (MRIDs 00046029, 00051717).

Processed Food/Feed: There are no processed commodities associated with the use of amitraz on pears. Adequate cotton processing studies indicate that the amitraz residues of concern do not concentrate in the hull meal, crude oil, refined oil, and soapstock processed from cottonseed following application at exaggerated rates (MRIDs 41444201, 41444202, 41444203, 41478901).

Magnitude of the Residue in Meat, Milk, Poultry and Eggs: It is highly unlikely that beef cattle would be exposed to amitraz via consumption of treated commodities; dairy cattle in milksheds in which cottonseed is readily available may be exposed to amitraz both dermally and in the diet. Residues of amitraz in meat, fat, and meat byproducts are likely to result from dermal application only, while amitraz residues in milk may be the result of dermal application and/or consumption of the treated feed commodity. Acceptable dairy cattle and poultry feeding studies have been submitted, evaluated, and accepted by the Agency in connection with several past or pending tolerance petitions. Magnitude of the residue studies in cattle following dermal application have been reviewed and found acceptable by the Agency in conjunction with past petitions. (MRIDs 40811306, 40811307, 40999504, 40999505, 41295501, 41295502, 41295503).

Confined/Field Rotational Crops: A confined rotational crop study was submitted in connection with the effort to register the 1.5 lb/gal SC/L formulation on cotton. The guideline requirement is satisfied.

Two field rotational crop studies were submitted and reviewed. These two studies together were adequate to satisfy the requirements of Guideline 165-2 for cotton. The data support the crop rotation restrictions of 44 days for "root and leafy vegetables" and of 60 days for "small grains and other crops" for amitraz when used on cotton (MRIDs 40999509, 41637302).

The published tolerance for pears (2 ppm) was based on a pre-harvest interval (PHI) of 14 days.

b. Occupational and Residential Exposure

An occupational and/or residential 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 treated sites after application is complete.

(1) Use Summary

Amitraz is an insecticide/acaricide used to control whitefly, pear psylla, dog and livestock ticks, lice, and mange mites. Amitraz is formulated into a wettable powder (WP) and emulsifiable concentrates (EC) for use on pears, soluble concentrate/liquid (SC/L) for use

on cotton, and impregnated collars for use on dogs. One EC formulation is also registered for dermal treatment of cattle and swine. Amitraz is applied as an airblast and concentrate spray to pears, by ground boom or aircraft to cotton, and as a dip or low pressure hand spray to swine, beef cattle, and dairy cattle. Impregnated collars are used to control ticks on dogs.

Application rates are as follow:

- **For pear use**, application rates range from 0.187 to 1.5 lb ai per acre, with a maximum seasonal rate of 3 lb ai/acre. The typical rate for pear treatment (1.49 lb ai/A;) is almost half the maximum seasonal rate.

- **For cotton use**, application rates are 0.125 to 1.0 lb ai per acre, with a maximum of 8 applications per year.

- **For livestock use**, an application rate of 0.2 lb ai/50 gallons (2 gal/animal), with a repeated application in 10 to 14 days recommended.

Some products containing amitraz are intended primarily for occupational use and one is primarily intended for homeowner use (pet collars).

(2) Summary of Toxicity Concerns Impacting Occupational and Residential Exposures

Acute Toxicity: The acute toxicological database for amitraz indicates toxicity category II for acute dermal toxicity, III for acute oral and acute inhalation toxicity, toxicity category IV for eye irritation potential and skin irritation potential. Amitraz is not a sensitizer. The vapor pressure for amitraz is low.

Other Adverse Effects: In a human study, acute exposure to amitraz was associated with central nervous system (CNS) toxicity symptoms of sedation, disorientation, and hypothermia. The NOEL for acute human neurotoxicity (0.125 mg/kg) was selected by the Agency's HED Toxicological Endpoint Selection Committee to be the acute toxicological endpoint for short-term occupational risk. Studies also indicate that amitraz causes cancer in animals. It is currently classified as a "Group C" (possible human) carcinogen, with an upper bound (95%) of the estimated potency (Q_1*) of 5×10^{-2} $(mg/kg/day)^{-1}$, based on findings of combined hepatocellular adenomas and carcinomas in female B6C3F1 mice. Amitraz may also cause neurological, developmental, and/or reproductive adverse effects in animals but the data are incomplete. Studies indicate that a dermal absorption rate of 13.8% and an inhalation absorption rate of 100% should be used to estimate occupational/residential exposures.

(3) Summary of Potential Occupational and Residential Exposures

Handlers (Mixers, Loaders, Applicators, etc.) Exposures: The Agency has determined that there is an exposure potential for handlers (mixers, loaders, applicators, etc.) during the usual use-patterns associated with amitraz. Exposures to mixer, loaders and applicators are likely when liquid (emulsifiable concentrate) and wettable powder formulations are used.

Post-Application Exposures: The Agency has determined that there is a potential for an exposure risk for persons entering treated sites after application is complete, especially for entry into treated pear orchards and cotton fields.

(4) Mixer/Loader/Applicator Exposure

Mixer/loader/applicator (M/L/A) exposure data were submitted for the end-use product Mitac® WP that is applied by open cab/airblast to pear trees (pear orchards) (MRID 42496003). In the study, the applicator also performed the mixing and loading activities. The monitoring period ranged from 13 to 17 mix/load/spray cycles per day over a period of approximately 6 to 7 hours. Each cycle consisted of applying 1.5 lb ai in 400 gallons of water per acre.

No exposure data were submitted for the cotton and livestock uses. Consequently surrogate data from the Pesticides Handlers Exposure Data Base (PHED) are used to assess handlers' exposure from these two uses.

Based on amitraz pattern of use, several exposure scenarios are plausible as defined by the types of application equipment and procedures that may be employed by amitraz handlers. These include the mixing, loading, and application activities associated with the use of amitraz to treat pear orchards, cotton fields, and livestock. The routes of exposure are both dermal and inhalation. The exposure scenarios are presented in the attached Table 1 along with the corresponding exposure assessment. The data have been normalized to simulate workers wearing a single layer of clothing (coveralls or long pants plus long-sleeve shirts) and chemical-resistant gloves. Shoes and socks are assumed.

Handlers' exposure may be expressed as the daily dose (DD), according to the following equation:

$$DD = \frac{A/day \times lb\ ai/A \times Unit\ Exposure \times absorption\ rate}{handler's\ kg\ body\ weight}$$

where:

- the unit of exposure = mg/lb ai handled
- absorption rates are 13.8% (dermal) and 100% (inhalation)
- handler's body weight = 76 kg
- handlers wear a single layer of clothing (coveralls or long pants plus long-sleeve shirts) and chemical resistant gloves
- Shoes and socks are assumed.

The exposure assessment for pear uses used the exposure data from the registrant-submitted studies (MRIDs 42496003, 43396801) and the following assumptions:

- 17 acres are treated per day,
- Application rate = maximal/typical rate for all M/L/A exposure scenarios (1.5 lb ai/A; twice/year) + minimal rate (0.187 lb ai/A; once/year) for scenario I on Table 1, and
- M/L/A Dermal (D) and Inhalation (I) Exposure Units in mg/lb ai handled as follows:

  . 4.13/0.03 (M/L/A; open bag; open cab; air blast)
  . 0.2/0.0037 (M/L; open bag)
  . 0.02/0.003 (M/L; water soluble pack).
  . 1.8/0.0037 (A; open cab; air blast)
  . 0.02/0.0037 (A; closed cab; air blast)

The exposure assessment for cotton uses used surrogate data from PHED, the high application rate (1 lb ai/acre), and the following assumptions:

- A liquid formulation is used,
- A ground boom applicator can treat 100 acres per day and aerial applicators can treat 350 acres per day. For the aerial applications, the mixer/loader and application functions are assumed to be conducted by separate individuals. For the ground boom application, these functions may be performed by the same or by separate individuals, and
- D/I Exposure Units in mg/lb ai handled as follows:

  . 0.113/0.0037 (M/L/A; ground boom; open pour)
  . 0.0046/0.00007 (M/L; ground boom; closed system)
  . 0.014/0.0004 (A; ground boom; open cab)
  . 0.0046/0.00006 (M/L; aerial support; closed system)
  . 0.004/0.001 (A; pilot)

The exposure assessment for livestock uses used surrogate data from PHED. A scenario was selected in which a low pressure sprayer was used to spray manure and poultry litter indoors. The following assumptions were used:

- application rate = 0.5 lb ai/100 gallons (2 gal/animal),
- exposure rate = 10 hrs/day; 3 days/yr; 500 heads treated manure (maximal exposure),
- A handler is exposed to 0.2 mg/lb ai handled by the dermal route and 0.03 mg/lb ai handled by inhalation route.

Handlers's dermal, inhalation, and total (dermal & inhalation) daily doses are shown in Table 1 of this section. Pear use is associated with the highest total exposure (0.022 mg/kg/day), followed by cotton use (0.024 mg/kg/day), and lastly, by livestock use (0.004 mg/kg/day). Within the pear use handlers' group, exposures are highest when the mixing/loading is accomplished using an open system and the application is by open cab/airblast (exposure scenario I) (0.22 mg/kg/day). Total exposure is low when the mixing/loading is accomplished using water soluble packs (exposure scenario III) (0.0011 mg/kg/day), and the application is by closed cab/air blast (exposure scenario V) (0.0011 mg/kg/day).

These calculations of daily exposure to amitraz by handlers are used to assess the risk to those handlers.

Table 1.

AMITRAZ HANDLERS' DAILY DOSES

Crop	Handler	Formulation, Equipment and Clothing	Application rate	Daily Dose (mg/kg/day)		
				Dermal (D)	Inhalation (I)	Total (D + I)
Pears	M/L/A	**Scenario I** Wettable Powder; open bag, open cab, airblast; LS, P, G.	max & typ	0.21	0.011	0.22
			min	0.026	0.0014	0.027
	M/L	**Scenario II** WP; open bag; C, G.	max	0.01	0.0013	0.011
	M/L	**Scenario III** WP; water soluble pack	max	0.001	0.0001	0.0011
	A	**Scenario IV** WP; open cab, airblast; C, G.	max	0.09	0.0013	0.091
	A	**Scenario V** WP; closed cab, airblast	max	0.001	0.0001	0.0011
Cotton	M/L/A	**Scenario VI** liquid formulation (LF); groundboom, open pour; C, G (other rates: 0.25 and 0.125 lb../A).	1.0 lb./A max	0.023	0.0012	0.024
			0.5 lb./A	0.01	0.0006	0.011
	M/L	**Scenario VII** LF; groundboom, closed system.	max	0.0009	0.0001	0.001
	A	**Scenario VIII** LF; groundboom, open cab; LS, P, G.	max	0.0028	0.0006	0.0034
	M/L	**Scenario IX** LF; aerial support, closed system.	max	0.003	0.0003	0.0033
	A	**Scenario X** pilot	max	0.0028	0.001	0.0038
Live-stock	M/L/A	**Scenario XI** low pressure spray; LS, P, G.	500 animals	0.002	0.002	0.004
			50 animals	0.0002	0.0002	0.0004

. LS = Long sleeve shirt; P = Pants; G = Gloves; C = Coverall.

(5) Post-Application Exposure

Post-application exposure is greatest during post-application tasks requiring substantial dermal contact with treated foliage (i.e., limb spreading and fruit thinning or harvesting). The significant route of exposure is dermal. Inhalation exposure during post-application activities is expected to be minimal, because amitraz has a low vapor pressure.

Foliar dislodgeable residue (FDR) data were submitted by the registrant for amitraz and its two metabolites BTS-27271 and BTS-27919 (MRID 42496002). In the study, two applications (14 days apart) of the wettable powder formulation, at the highest rate (1.5 lb./A), were applied to pear orchards located in the Yakima Valley, WA, a principal pear growing region. The residues remained constant for 21 days. Because of this lack of dissipation, it is possible that the residues measured are from both treatments.

The average daily exposure (ADE) is estimated based on only one application at the maximum rate and assuming a worker' body weight of 76 kg, an 8-hour work day, a dermal absorption rate of 13.8% and a transfer coefficient of 3800 cm^2/hr. ADEs are expressed as the systemic dose, which includes exposure to the foliar dislodgeable residues of amitraz and BTS-27271 (the residue of concern for neurotoxic effects). Systemic doses are estimated for various post-application time points up to 35 days. The estimated systemic doses are shown in Table 2 of this section.

Table 2
PEAR Use: Post-Application Exposures and MOEs

Days after Treatment	Amitraz Residues µg/cm^2	BTS 27271 Residues µg/cm^2	Combined Residues µg/cm^2	Systemic Dose mg/kg/day	MOE
0	0.33	0.06	0.39	0.222	5.7
1	0.345	0.06	0.405	0.023	5.4
2	0.335	0.065	0.40	0.022	5.7
5	0.31	0.055	0.365	0.020	6.2
7	0.40	0.05	0.45	0.025	5.0
14	0.30	0.045	0.345	0.019	6.6
21	0.32	0.045	0.365	0.020	6.2
28	0.115	0.035	0.15	0.008	15.0
35	0.135	0.03	0.165	0.009	14.0

Systemic Dose includes the dislodgeable residues from amitraz plus the metabolite BTS-27271. Residues reflect one application (½ the total residue for two treatments), the use of a transfer coefficient of 3,800 cm^2/hr and a 76 kg individual (CA standard).

The US EPA performed regression analysis for amitraz and its metabolites and agrees with the California Environmental Protection Agency, Department of Pesticide Regulation (CEPA DPR) regarding the length of time required between applications when based solely on the natural log of the dissipation rate. In the study submitted by the registrant (both Federal and State agencies agree was not of high quality), there was no apparent dissipation until 21 days after the second application. After the 21st day, residue levels drop-off by about two thirds and remain constant until the 25th day (the last day of sampling). This "tailing-off" of data coupled with linear regression analysis can suggest some very slow dissipation rates. Additionally, the Agency determined that for pears a 28-day interval is required for a Reentry Interval (REI) because MOEs are greater than 10 only after 28-days, and with amitraz an MOE greater than 10 is acceptable because the NOEL was determined on a human study.

What is most notable about the data is the sudden drop-off, which coincidentally or not, is 35 days after the first application. Thus, rather than over-interpreting the marginal data, US EPA decided to use the most significant aspect of the study, the sudden drop-off. The Agency has also requested confirmatory data because the current study was conducted in the absence of concurrent dermal exposure data. In a recent meeting with representatives of US EPA, CEPA DPR, and Health Welfare Canada, it was agreed that the 35 days between applications (with confirmatory data) is preferred over the use of linear regression.

Potential exposure resulting from the cotton use, use in livestock buildings and on animal collars is minimal.

Cotton Use: Potential exposure is minimal because of the lower application rate and the mechanical harvesting of cotton.

Livestock Buildings: Since livestock buildings are often well ventilated or have controlled environments with adequate ventilation, inhalation exposure is minimal.

Animal Collars: The Agency has assumed that the potential for contact with amitraz to children exposed to pets wearing animal collars is negligible because of the type of formulation (impregnated plastic), the low duration and frequency of exposure. In a previous Agency assessment addressing potential exposure to children resulting from impregnated pet collars, these exposures were also considered negligible.

(6) Additional Occupational/Residential Exposure Studies

Mixer/loader/applicator (i.e., handler) exposure study requirements are addressed by Subdivision U of the Pesticide Assessment Guidelines. Additional confirmatory exposure studies for handler (mixer, loader, applicator) exposure are required at this time. Due to the limited data available reflecting applications to livestock, the Agency is requiring confirmatory dermal exposure (Guideline 231) and inhalation exposure data (Guideline 232) to support the reregistration of the livestock spray and dip treatments.

Post-application exposure study requirements (i.e., reentry) are addressed by Subdivision K of the Pesticide Assessment Guidelines. Additional confirmatory exposure studies for post-application exposures are required at this time. Due to the uncertainties associated with using a generic transfer coefficient and the minimum quality data submitted by the registrant, The Agency is requiring concurrent DFR (Guideline 132-1a) and dermal exposure (Guideline 133-4) data to support the reregistration of amitraz on pears.

3. Risk Assessment

a. Dietary Risk

The following data were used to assess amitraz's dietary risk:

(1) Toxicological Endpoints

- An estimated unit risk (Q_1*) of 0.05 $(mg/kg/day)^{-1}$, for carcinogenic dietary risks assessment,
- A RfD of 0.0025 mg/kg bodyweight (bwt) per day, for chronic dietary risk assessment, and
- A NOEL of 0.125 mg/kg bwt, for acute dietary risk assessment, based on a human acute neurotoxicity study.

(2) Residue Information

Food uses evaluated in the DRES analysis are the published non-zero tolerances listed in 40 CFR 180.287 and in the Tolerance Index System (TIS) for the combined residues of amitraz and its metabolites BTS-27271 and BTS-27919, expressed as the parent compound. All published non-zero tolerances for amitraz are being supported through reregistration. Although the registration for honey has been voluntarily canceled, it should be noted that the tolerance still exists and existing stocks are still being used.

For chronic and carcinogenic risk assessment, the DRES analysis uses anticipated residues (ARs) and percent crop treated data. AR values for pears reflect a 14-day PHI and use of the WP formulation. The DRES analysis uses mean ARs for pears. The chronic ARs for pears reflect the amitraz parent, BTS-27919, BTS-27271, and 2,4-DMA. All other ARs used in the chronic exposure analysis and cancer risk assessment are based on field trial data, processing studies, plant and animal metabolism studies, livestock feeding and direct dermal application studies. Average values, not maxima, were used for the chronic analysis if both were available. A default of 100 percent crop treated is assumed for honey, since an estimate was not available from the data. Chronic risk is also assessed based on tolerance levels and 100% crop treated information.

The DRES acute analysis uses high end residues for pears associated with the currently required 14-day PHI. The review of a new pear field trial submission (MRID 43370301) reflecting residues at the 14-day PHI, supports the registrant's contention that total amitraz residues resulting from application of the WP formulation are generally lower that those resulting from application of the EC formulation. Residues of concern for neurotoxic effects (i.e. amitraz and BTS-27271) were lower overall than those of the currently regulated (determined using the common moiety) residues. The acute AR (pears) for amitraz plus BTS-27271 is 0.42 ppm.

(3) Results

Chronic Dietary Risks: The DRES chronic exposure analysis assumes tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Refinements in residue and percent crop treated information were considered in calculating the Anticipated Residue Contribution (ARC) for those same population groups. The ARC is considered the more accurate estimate of dietary exposure. These exposure estimates were then compared to the RfD for amitraz to get estimates of chronic dietary risk.

Based on tolerance level residues and 100% crop treated data, the TMRC for the overall U.S. population is 0.000795 mg/kg bwt/day (32% of RfD), with a 14-day PHI for pears. The TMRC for non-nursing infants less than one year old, the DRES subgroup most highly exposed, is 0.005556 mg/kg bwt/day (222% of RfD), with a 14-day PHI for pears.

Based on average ARs and percent crop treated data, the ARCs for the overall U.S. population is 0.000028 mg/kg bwt/day (1.1% of RfD) with a 14-day PHI for pears. The ARCs for non-nursing infants less than one year old, the DRES subgroup most highly exposed, is 0.000113 mg/kg bwt/day (4.5% of RfD) with a 14-day PHI for pears. Based on the low ARCs, it appears that chronic, non-cancer dietary risk from exposure to amitraz is minimal.

Carcinogenic Dietary Risk: The upper bound carcinogenic risk from amitraz may be estimated for the overall U.S. population using the following equation:

Upper Bound Cancer Risk = Dietary Exposure (ARC) x Q_1*

A Q_1* of 5.0 x 10^{-2} $(mg/kg/day)^{-1}$ and a 70 year lifetime exposure were assumed in this calculation. Upper bound cancer risks by commodity are listed in the following table:

Table 3 - Upper Bound Estimates of Cancer Risk by Commodity	
Commodity	**Upper Bound Cancer Risk**
pears (PHI = 14 days)	8.4×10^{-7}
poultry and eggs	2.7×10^{-7}
honey	1.3×10^{-7}
milk	6.8×10^{-8}
beef	8.7×10^{-8}
hogs	2.2×10^{-8}
cottonseed	8.0×10^{-10}
TOTAL 14-day PHI for pears	1.4×10^{-6}

The bulk of exposure is attributed to one commodity, pears; (58% of total exposure based on 14-day PHI). Upper bound cancer risk is 1.4×10^{-6} from published uses.

Acute Dietary Risk: The DRES detailed acute exposure analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures of consumers through the diet for the U.S. population and certain subgroups. The analysis assumes uniform distribution of amitraz in the commodity supply. Because neurotoxicity is the endpoint of concern, exposure and risk are calculated for all standard DRES subgroups.

The Margin of Exposure (MOE) is a measure of how closely exposure comes to the NOEL (the highest dose at which no effects were observed in the study), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). In general, an MOE of 10 or greater is considered acceptable when the NOEL is based on a human study.

For this analysis, MOEs are calculated using both high end exposure and 98th percentile exposure for all five of the standard DRES subgroups (U.S. population - 48 states, Infants < 1 yr., Children 1 through 6 years, Females (13+ years) and Males (13+ years).

The acute anticipated residues (pears) for amitraz + BTS-27271 (the residue of concern for neurotoxic effects) is 0.42 ppm. Based on the 14-day PHI and at 98th percentile consumption values for pears, MOEs are greater or equal to 10 for all U.S. population subgroups.

The registrant submitted pear processing data (MRID 43396902) in support of the Canadian registration and continued U.S. registration and to determine if the data should be included in the Agency's risk assessment. The Agency concluded that the processing data not be included in the dietary risk assessment, since inadequate information was provided

regarding sampling and the analytical method used. The Agency does not typically use monitoring data to assess the acute risk.

b. Occupational/Residential Risk

(1) Toxicological Endpoints

The toxicological endpoints of concern for occupational exposure are (1) acute neurotoxicity resulting from short-term (one day to one week) and (2) the classification of amitraz as a "Group C" (possible human) carcinogen, with an upper bound (95%) of the estimated potency (Q_1*) of 5 x 10^{-2} $(mg/kg/day)^{-1}$.

(2) Calculating Risk

Risk of Excess Cancer: Upper bound (95%) carcinogenic risk may be estimated using the following equation:

Upper Bound Cancer Risk = LADD x Q_1*

where Q_1* = 5 x 10^{-2} $(mg/kg/day)^{-1}$ and

$$\text{LADD} = \text{Total daily dose (from Table 1)} \times \frac{\text{days/year}}{65 \text{ days}} \times \frac{35 \text{ years}}{70 \text{ years}}$$

Risk of Neurotoxicity: Acute neurotoxicity risk may be expressed by the margin of exposure (MOE), according to the following equation:

Margin of Exposure (MOE) =

$$\frac{\text{NOEL (mg/kg/day)}}{\text{Exposure (mg/kg/day)}}$$

where the NOEL = 0.125 mg/kg/day, and exposures are the total (dermal + inhalation) exposure values from Table 1. The MOEs take into consideration all currently required PPE. Because the toxicity endpoint is from a human study, MOEs less than 10 would trigger an acute neurotoxicity risk concern.

(3) Risk to Handlers (Mixers, Loaders, Applicators, etc.)

Risk of Excess Cancer from Long-Term Exposures: Handlers using amitraz to treat pear orchards, cotton fields, and livestock on a long-term basis may be at risk from its carcinogenic effects. Handlers' estimated upper bound cancer risk are shown in Table 4 of this section.

The highest carcinogenic risk is associated with the pear use (1.2×10^{-5}), followed by cotton use (1.6×10^{-5}), and lastly, by livestock use (8.2×10^{-7}). It is the Agency's policy to seek risk reduction for non-dietary cancer risk to the greatest extent possible, preferably to the negligible level.

Therefore, the Agency expects to reduce these risks as a result of the following measures required in this document. These measures include increasing the interval between amitraz applications to pears, increasing the restricted-entry interval (REI) for both pears and cotton, specifying minimum (baseline) personal protective equipment (PPE) for all occupational uses, and requiring engineering controls.

Additionally, in order to refine the risk assessment the registrant is required to submit a developmental/neurological/reproductive study and a dislodgeable foliar residue (DFR) study as confirmatory data.

Risk of Neurotoxic Effects from Short-Term Exposures: MOEs associated with the pear, cotton, and livestock uses are shown in Table 4. MOEs are greater than 10 for most exposure scenarios. MOEs are less than 10 for only three scenarios of handler exposure including 1) Scenario I (pear-use involving the wettable powder formulation mixed/loaded via open bag and applied via open cab/air blast) applied at both the maximal (and typical) and minimal rates, 2) Scenario IV (pear-use involving the wettable powder formulation applied via open cab/air blast) and 3) Scenario VI (cotton-use involving the liquid formulation mixed/loaded via open pour and applied at the maximal rate via ground boom).

The risk mitigation measures being imposed for handlers should mitigate these high risks to acceptable levels. These measures include those outlined in Section IV.B.4.

Table 4
AMITRAZ HANDLERS' MOES FOR ACUTE NEUROTOXIC RISK AND UPPER BOUND CANCER RISK

Crop	Handler	Formulation, Equipment and Clothing	Application rate	Total Daily dose mg/kg/day	days/yr	MOE	LADD	Cancer Risk
Pears	M/L/A	**Scenario I** WP; open bag, open cab, airblast; LS, P, G.	max & typ	0.22	2	0.6	6.0E-4	3.0E-5
			min	0.027	1	4.6	3.7E-5	1.8E-6
	M/L	**Scenario II** WP; open bag; C, G.	max	0.011	2	11	3.0E-5	1.5E-6
	M/L	**Scenario III** WP; water soluble pack.	max	0.0011	2	114	1.3E-6	6.5E-8
	A	**Scenario IV** WP; open cab, airblast; C, G.	max	0.091	2	1.4	2.5E-4	1.2E-5
	A	**Scenario V** WP; closed cab, airblast.	max	0.0011	2	114	3.0E-6	1.5E-7
Cotton	M/L/A	**Scenario VI** Liquid formulation (LF);groundboom, open pour; C, G.	max	0.024	10	5	3.3E-4	1.6E-5
			0.5 lb./A	0.011	10	11	1.5E-4	7.5E-6
	M/L	**Scenario VII** LF; groundboom, closed system.	max	0.001	10	125	1.3E-6	6.8E-7
	A	**Scenario VIII** LF; groundboom, open cab; LS, P, G.	max	0.0034	10	37	4.7E-5	2.3E-6
	M/L	**Scenario IX** LF; aerial support, closed system.	max	0.0033	10	38	4.5E-5	2.3E-6
	A	**Scenario X** pilot	max	0.0038	10	33	5.2E-5	2.6E-6
Livestock	A	**Scenario XI** low pressure spray; LS, P, G.	500 animals	0.004	3	31	1.6E-5	8.2E-7
			50 animals	0.0004	1	312	5.5E-7	2.7E-8

. LS = Long sleeve shirt; P = Pants; G = Gloves; C = Coverall. (roman numbers) are handlers's exposure scenario numbers.

(4) Risk from Post-Application Exposures

Risk of Excess Cancer from Long-Term Exposures: Reentry workers involved on a long-term basis with post-application tasks requiring substantial dermal contact with treated foliage resulting from the pear use (i.e., suckering, limb spreading and fruit thinning or harvesting) and resulting from the cotton use (i.e., harvesting and crop-advising) may also be at risk from amitraz carcinogenic effects.

Based on the foliar dislodgeable residue data obtained from application of amitraz to pears, and with an REI of 28 days, the estimated carcinogenic risk for the reeentry worker is not expected to exceed 1.0×10^{-4}. Again, because the Agency's policy intent is to seek risk reduction for non-dietary risks to the greatest extent possible, preferably to the negligible level, the Agency is increasing the restricted-entry interval (REI) for both pears (from 24 hours to 28 days) and cotton (from 24 to 48 hours) and mandating of minimum (baseline) personal protective equipment (PPE) for all occupational uses as well as engineering controls.

Risk of Neurotoxic Effects from Short-Term Exposures: MOEs for the pear use were 5.0 at 7 days following foliar applications and 6.6 at 14 days following foliar applications, based on the human acute neurotoxicity NOEL of 0.125 mg/kg/day and on exposure values representing the foliar dislodgeable combined residues of amitraz plus its two metabolites BTS-27271 and BTS-27919 (systemic dose values in Table 2).

The data the registrant has submitted for purposes of estimating reentry exposure consist of two-sided DFR (dislodgeable foliar residue) data collected from pear leaves on pear trees growing in eastern Washington state. DFR data were collected following two applications timed 14 days apart. The residues remained constant for 21 days. Because of this lack of dissipation, its possible that the residues measured are from both treatments. One major flaw with the DFR study however, is the fact that the residues were not dislodged from the leaf samples until up to 103 days after they were collected. Although, they were maintained in freezer storage during that time, some residues, that would have otherwise been dislodged, may have been absorbed into the foliar matrix.

Neurotoxicity risks resulting from the use of amitraz on cotton could only be roughly estimated, because of lack of data. The Agency roughly estimated risks to cotton harvesters and crop advisors (i.e., scouts) by using a dermal transfer coefficient similar to that for pears, prorating the dislodgeable foliar residue used for pears to reflect the lower application rate in cotton, and estimating 8 hours of daily exposure for harvesters and 6 hours of daily exposure for crop advisors. The MOE for cotton harvesters was unacceptable (less than 10) at both 24 and 48 hours after application. The roughly estimated MOE for cotton scouts was marginally acceptable (approximately 11) at 24 hours after application. Due to the low MOEs obtained from the rough risk assessment, the low MOE values for mixers, loaders, and applicators for cotton uses, and the lack of cotton-specific post-application exposure data, the Agency is

requiring worker safety measures to mitigate the post-application exposure risks to cotton workers. Refer to Section V for a listing of these.

Neurotoxicity risks resulting from the use indoors on livestock are considered negligible for reentry workers, since the expected inhalation and dermal exposures are assumed to be negligible. Additionally, neurotoxicity risks resulting from the use of amitraz in pet collars is also considered negligible for homeowners, including children, because the expected exposure is negligible.

Due to the uncertainties associated with using a generic transfer coefficient, and the questionable data submitted by the registrant, the Agency is requiring worker safety measures to mitigate risk to post-application workers. Refer to Section V for a listing of these measures.

C. Environmental Assessment

There are sufficient data for a comprehensive qualitative environmental fate assessment. The October 1987 Amitraz Registration Standard required the following environmental fate studies: hydrolysis, photodegradation in water and on soil, aerobic and anaerobic soil metabolism, leaching and adsorption/desorption, lab and field volatility studies, soil dissipation, and accumulation studies in fish and in aquatic non-target organisms.

At this time, however, only a preliminary quantitative assessment is possible. The environmental fate data base review indicates the following studies are still required: Droplet size spectrum (Guideline 201-1), and drift field studies (Guideline 202-1). Additionally, although the aged portion of the leaching/adsorption-desorption (Guideline 163) is fulfilled, batch equilibrium data on the amitraz degradates BTS-27271 and BTS-27919 are required to provide a more complete quantitative environmental fate and transport assessment.

The existing environmental fate studies show that parent amitraz degrades rapidly in the environment (aquatic and terrestrial) to form the primary transformation products BTS-27271 and BTS-27919 and a secondary transformation product BTS-24868. Even though parent amitraz is moderately mobile in sandy soil, it is of limited concern in ground and surface water because of its rapid degradation. In contrast, amitraz transformation products have been shown to be moderately persistent in aquatic and terrestrial environments and appear to be relatively immobile in soil column and field dissipation studies. Additional mobility studies (batch equilibrium) are needed in order to fully assess the mobility of amitraz transformation products in ground and surface waters.

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport Data

Hydrolysis: The major route of degradation of amitraz in the environment appears to be hydrolysis. Abiotic hydrolysis studies show that amitraz rapidly hydrolyzes to form the primary transformation products BTS 27271 and BTS 27919 and a secondary transformation product BTS 24868. The hydrolysis rate is inversely related to the pH of the medium, whereby amitraz hydrolyzes faster in slightly acidic environments ($t_{1/2}$ = 2 hours) than in alkaline environments ($t_{1/2}$ = 25.5 hours). Furthermore, one of the transformation products BTS 27271 hydrolyzes to form BTS 27919. In contrast to the primary degradation process, this secondary degradation is faster in slightly alkaline environments ($t_{1/2}$ = 5 hours) than in slightly acidic environments ($t_{1/2}$ = 2,280 days). Although BTS 27919 is stable to abiotic hydrolysis, it appears to break down to BTS 24868 in the environment, probably by microbial transformation (MRIDs 40780512, 42124616, 42124617).

Photodegradation: Photodegradation of amitraz in water occurred at approximately the same rate as the control, indicating that photodegradation is not the primary route of degradation. Photodegradation of amitraz in soil is even more rapid with a DT_{50} of less than 20 minutes (MRIDs 40780513, 41206703, 00407805, 4144420).

Aerobic and Anaerobic Soil Metabolism: In aerobic soil metabolism studies, parent amitraz had a half life of less than one day. The amitraz transformation products formed during aerobic soil metabolism were BTS 27271 (13% of applied), BTS 27919 (35% of applied), BTS 24868 (13% of applied), and CO_2 (35% of applied). The half-lives of BTS 27271 and BTS 27919 ranged from 67-82 days and 61-117 days, respectively. The amitraz transformation products have been found to be more persistent in soil metabolism studies than parent amitraz. Similar degradation rates and transformation products were observed in anaerobic soil metabolism studies (MRIDs 40798003, 42124620).

Aquatic Metabolism: In aquatic metabolism studies in microcosms, amitraz degrades rapidly with a 50% dissipation time (DT_{50}) of less than 6 hours. The primary transformation products BTS 27271 and BTS 27919 were more persistent than parent amitraz. The DT_{50} for BTS 27271 ranged from 6-7 days, while the DT_{50} for BTS 27919 ranged from 9-21 days (MRIDs 42124618, 42124622, 41444205).

Soil Adsorption: Parent amitraz had Freundlich adsorption coefficients of 1.69 (1/n=0.53) in a Shelby loamy sand soil, 3.01 (1/n=0.76) in a Speyer sand, 89.13 (1/n=1.22) in a Terling clay loam soil, and 16.31 (1/n=0.75) in a Shelford Field clay soil (MRIDs 41206704, 40780515).

Soil Column Leaching: Batch equilibrium studies indicated that amitraz was moderately mobile in sandy loam, silt loam, and clay soils and was very mobile in sandy soils. Although amitraz was considered moderately mobile in the environment, it degraded rapidly in the environment and is not expected to be a concern in ground and surface waters. The major

transformation products of amitraz BTS 27271 and BTS 27919 appeared to be relatively immobile in column leaching and field dissipation studies. However, soil TLC studies indicated that BTS 27271 was moderately mobile in sandy loam, silt loam, and clay textured soils (Rf 0.36-0.48) and very mobile in sand (Rf 0.91). It should be noted that the physiochemistry of BTS 27271 and BTS 27919 suggest that they should be in the cationic form (pK_b>9.0) in most soil environments and could electrostatically bind to soil. Additional mobility studies (batch equilibrium) are needed in order to fully assess the mobility of amitraz transformation products in ground and surface waters (MRIDs 40931501, 42124614, 42124615, 42124620, 40780516).

Volatility: Although the amitraz transformation products (BTS 27271, BTS 27919 and BTS 24868) have vapor pressures that exceed the 10^{-6} mm Hg trigger, laboratory soil volatility data indicate that BTS 24868 and CO_2 are the only volatile products (MRID 40780518).

Bioaccumulation in Fish: Amitraz and its primary transformation products do not appear to accumulate in fish. In bioaccumulation studies, the bioconcentration factors for viscera, flesh, and carcass of bluegill sunfish were 1821X, 588X, and 1838X, respectively. Residues were identified as BTS 27919, BTS 27271, and unidentified polar degradates. However, these residues were eliminated over a 14-day depuration period, indicating that amitraz residues do not bioaccumulate in fish (MRIDs 41444206, 42124623, 40780519, 00072503).

Terrestrial Field Dissipation: The existing environmental fate data indicated that amitraz breaks down rapidly in the environment ($t_{1/2}$ = 1 day) to form the transformation products BTS 27271 and BTS 27919 and a secondary transformation product BTS 24868. Field dissipation studies conducted in Florida, California, and Texas showed that these products were more persistent than parent amitraz under typical use conditions. Field dissipation half-lives for BTS 27271 ranged from 17-110 days and for BTS 27919 from 70-150 days. Although these studies indicated that amitraz residues for BTS-27271 and BTS 27919 were retained in the surface 15 cm of soil, false positive detections of these products were found in deep soil samples. BTS-27271, BTS 27919 and BTS 24868 were detected at depths of 30 cm (12 inches) in the Texas study. These data suggest that BTS 27271 and BTS 27919 are moderately persistent and appear to be relatively immobile under actual field conditions (MRIDs 40798004, 41637301).

Droplet Size Spectrum and Field Drift Studies: Droplet size spectrum (Guideline 201-1) and field drift studies (Guideline 202-1) are needed to support ground spray, aerial spray, and air-blast application methods for amitraz. Spray drift studies are required for aerially applied insecticides (*e.g.*, air blast, etc.) with Tox 1 or Tox 2 classifications; or if the insecticide is deemed as posing an environmental hazard. The registrant may elect to satisfy both data requirements through the participation in the Spray Drift Task Force.

b. Environmental Fate Assessment

There are sufficient data for a comprehensive qualitative environmental fate assessment of amitraz. Based on acceptable and supplemental environmental fate data from the Registration Standard to present, indicates that parent amitraz degrades rapidly in the environment ($t_{1/2}$=1 day) to form the primary transformation products N-2,4-dimethyl-phenyl-N-methylformanidine (BTYS-27271), 2,4-dimethylformanilide (BTS 27919) and the secondary transformation product 2,4-dimethylaniline (BTS-24868). Soil column leaching studies indicate that BTS 27271 and BTS 27919 are more persistent than parent amitraz under typical use conditions.

Even though the parent amitraz is moderately mobile in sandy loam, silt loam, and clay soils and very mobile in sandy soils, it is of limited concern in ground and surface waters because of its rapid degradation. The same cannot be said about the dissipation of amitraz degradates. The major transformation products, though have been shown to be relatively immobile in column leaching and field dissipation studies. Although there are acceptable laboratory and field data on the degradation of BTS-27919 ($t_{1/2}$ = 10 to 150 days) and BTS-27271 ($t_{1/2}$ = 7 to 110 days) and data requirements have been fulfilled for the mobility of these compounds, only qualitative conclusions can be drawn on the mobility of the amitraz degradates. The mobility of BTS-27271 and BTS-27919 has been addressed in soil column leaching, soil TLC, and field dissipation studies. These studies provide only a qualitative assessment of pesticide partitioning between soil and water.

Additional confirmatory data on the mobility of the primary amitraz degradates BTS-27271 and BTS-27919 is necessary to complete a quantitative environmental fate assessment. Without clearly defined partition coefficients (Kds) from acceptable batch equilibrium studies on BTS-27271 and BTS-27919, the relative rates of dissipation through transport to surface water or groundwater cannot be assessed. Therefore, batch equilibrium studies (Guideline 163-1) for BTS-27271 and BTS-27919 are required to allow for a complete quantitative environmental fate assessment. A more quantitative estimate of the fate of BTS-27271 and BTS-27919 would provide a more precise measurement of the aquatic effects of these degradates. However, based on acceptable field dissipation data, the amitraz degradates do not appear to be mobile under typical use conditions.

2. Ecological Effects

a. Ecological Effects Data

The October 1987 Amitraz Registration Standard required the following ecological effects data: avian subacute dietary, avian reproduction, freshwater and warmwater fish toxicity, acute toxicity to freshwater, estuarine and marine organisms, fish early life stage, and aquatic invertebrate life cycle.

There are sufficient studies on amitraz (the parent and its two primary degradates - BTS-27271 and BTS-27919) to permit a comprehensive ecological effects assessment.

(1) Terrestrial Data

Effects to Non-Target Birds: In order to establish the toxicity of amitraz to birds, the following tests were required for the pear, cotton and cattle/swine uses: 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 or ring-necked pheasant); one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail). For the dog use, which is considered indoor, one avian single dose oral and one eight-day dietary LC_{50} are required.

The Agency required studies on the two major metabolites (BTS-27271, BTS 27919) of amitraz because of their potential increased toxicity when compared to the parent compound.

Avian Acute Oral Toxicity Studies: The existing data demonstrate that parent amitraz is slightly toxic to mallard ducks. However, BTS-27271 is moderately toxic to the bobwhite quail and BTS-27919 is slightly toxic to the bobwhite quail.

Gdln. No.	MRID No.	Species	% A.I.	LD_{50}	Fulfills Gdln
71-1(a)	00030451	Mallard Duck	Technical	788 mg/kg	Yes
71-1(a)	42124602	Bobwhite Quail	BTS-27271 (99% a.i.)	71 mg/kg	Yes
71-1(a)	42124603	Bobwhite Quail	BTS-27919 (99.1% a.i.)	1827 mg/kg	Yes

Avian Subacute Dietary Toxicity Studies: Parent and Primary Degradates: The acceptable subacute dietary toxicity data for amitraz technical and degradates, BTS-27271 and BTS-27919, are listed below:

Gdln. No.	MRID No.	Species	% A.I.	LC_{50}	Fulfills Gdln
71-2(a)	00030452	Mallard	Technical	7000 ppm	Yes
71-2(b)	00030453	Japanese Quail	Technical	1800 ppm	Partial
71-2(a)	40780501	Bobwhite	98.2%	3081 ppm	Yes
71-2(a)	42124604	Bobwhite	BTS-27271 (99.91% ai)	1276 ppm	Yes
71-2(a)	42124605	Mallard	BTS-27919 (99. ai)	>5200 ppm	Yes
71-2(b)	42124606	Mallard	BTS-27271 (99% ai)	>5200 ppm	Yes
71-2(b)	42124607	Bobwhite	BTS-27919 (99% ai)	>5200 ppm	Yes

The existing data demonstrate that parent amitraz is practically nontoxic to the mallard duck and slightly toxic to the bobwhite quail. BTS-27271 is practically nontoxic to the mallard and slightly toxic to the bobwhite quail. BTS-27919 is practically nontoxic to both the mallard and the bobwhite on a subacute dietary basis.

Avian Reproduction Studies: Parent and Primary Degradate: Avian reproduction studies are required for the cotton and pear uses since amitraz may be applied in multiple applications. In addition, available laboratory and field data indicate that amitraz degradates may persist under certain environmental conditions: BTS-27919 $t_{1/2}$ = 10 to 150 days; BTS-27271 $t_{1/2}$ = 7 to 110 days.

The acceptable avian reproduction tests for amitraz technical and degradates (BTS-27271 and BTS-27919) are listed below:

Gdln. No.	MRID No.	Species	% A.I.	NOEL/LOEL	Fulfills Gdln
71-4(a)	00072412	Bobwhite Quail	Technical	ND*/40 ppm[1]	Partial
71-4(b)	00072411	Mallard Duck	Technical	ND*/40 ppm[2]	Partial
71-4(a)	40840301	Bobwhite Quail	97.5	40/160 ppm[3]	Partial
71-4(a)	42336001	Bobwhite Quail	98.9	24.6/50.5 ppm[4]	Yes
71-4(b)	42336002	Mallard Duck	98.9	24.6/50.5 ppm[5]	Partial
71-4(a)	42797801	Bobwhite Quail	BTS-27271 97.7 - 99.1%	25/100 ppm[6]	Partial
71-4(a)	42797802	Mallard Duck	BTS-27271 97.7 - 99.1%	5/25 ppm[7]	Partial

1. The specific impairments noted were increases in eggshell cracking and reduced percentages of three-week embryos that survived to become normal hatchlings at < 40 ppm. The mean body weights of chicks hatched were significantly affected in the 100 and 250 ppm groups, and egg weights and eggshell thickness were significantly reduced at 250 ppm.
2 Numbers of 14-day old survivors produced per week were significantly less than the control at <40 ppm. Reductions in percentage of viable embryos that survived to 3 weeks and percentage of 3-week embryos that survived to become normal hatchlings were noted at the 250 ppm level but not at 40 and 100 ppm.
3. Dietary concentrations of up to 40 ppm had no effect on adult birds or their reproductive performance. At 160 ppm, the adult birds ate marginally less food and the overall mean chick hatching weight was slightly low. However, these results must be considered in light of the high percentage of cracked eggs, particularly in the control group.
4. The NOEL was determined to be 24.6 ppm ai based upon reductions in viable embryos/eggs set at 50.5 ppm ai.
5. The NOEL was determined to be 24.6 ppm ai based upon reduced hatchling weight and increased male body weight (both growth effects) at 50.5 ppm ai. This study only partially fulfilled guidelines since it failed to detect reproductive effects.
6. The specific impairments noted were significant reductions at the 100 ppm test level in hatchlings as a percentage of eggs set, two-week survivors as a percentage of eggs set and two-week survivors as a percentage of eggs laid.
7. The specific impairments noted were significant increases at the 25 ppm test level in the total number of eggs cracked and in the number of eggs cracked as a percentage of eggs laid.

*ND Not determined.

The existing data show statistically significant effects by parent amitraz on avian reproduction at dietary levels of 40 - 50.5 ppm (i.e. reduction in number of viable embryos per eggs set; increase in eggshell cracking; reduction in number of three-week embryos that survived to become normal hatchlings; reduction in number of 14-day old survivors produced per week) (MRID 42336001).

The existing data show statistically significant effects by BTS-27271 on avian reproduction at dietary levels of 25 ppm for the mallard duck (i.e. increase in the total number of eggs cracked) and 100 ppm for the bobwhite quail (i.e. reduction in number of hatchlings as a percentage of eggs set; reduction in number of 14-day survivors as a percentage of eggs set and eggs laid) (MRIDs 42797801, 42797802).

There were no studies with the amitraz degradate BTS-27919 submitted or required based upon the test results of the avian acute and subacute studies.

Mammal Studies: 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, a rat acute oral LD_{50} is used as a small mammal surrogate to estimate toxicity to mammals. This LD_{50} is reported below.

Mammalian Acute Oral Toxicity Findings					
Species	**% A.I.**	**LD_{50} (mg/kg)**	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Rat (small mammal surrogate)	90	515	00041539	slightly toxic	Yes

The available mammalian data indicate that amitraz is slightly toxic to small mammals on an acute oral basis (MRID 00041539).

(2) Aquatic Data

Effects on Freshwater Fish: For the pear, cotton and cattle/swine uses, the minimum data required for establishing the acute toxicity of amitraz to freshwater fish are the results from two 96-hour studies with the technical product. One study should use a coldwater species (preferably the rainbow trout) and the other should use a warmwater species (preferably the bluegill sunfish). The dog use requires only one 96-hour study with a coldwater fish.

Acute Aquatic Toxicity Studies - Technical, Formulated Product, and Primary Degradates: The studies with technical amitraz indicate that parent amitraz is highly toxic to freshwater fish. Formulated product testing on fish is required when the chemical is applied directly to water. While amitraz does not have such a use pattern, formulated product testing was required since several studies suggested that amitraz may be more toxic in a 20% EC formulation than by itself. A possible explanation is that this probably was the result of an inert ingredient making the active ingredient more available to the fish. Studies reviewed indicated that a 20% EC formulation of amitraz ranged from moderately to very highly toxic to freshwater fish.

Studies were also required on the two major amitraz metabolites (BTS-27271, BTS-27919) because of their potential increased toxicity when compared to the parent compound. BTS-27271 and BTS-27919 can be characterized as slightly toxic to practically nontoxic, respectively, to freshwater fish.

Gdln. No.	MRID No.	Species	% A.I.	96-hr LC_{50}	Fulfills Gdln
TECHNICAL					
72-1(a)	40798001	Bluegill Sunfish	98.08	0.34 ppm	Yes
72-1(b)	00030444	Carp	Technical	1.17 ppm **	Partial
72-1(b)	00030447	Bluegill Sunfish	Technical	1.34 ppm	Partial
72-1(b)	00030448	Harlequin Fish	Technical	3.2 - 4.3 ppm	Partial
72-1(c)	00030445	Rainbow Trout	Technical	2.7 - 4.0 ppm*	Partial
72-1(c)	00030446	Rainbow Trout	Technical	0.74 ppm	Yes
FORMULATED PRODUCT					
72-1(a) and (b)	00030448	Harlequin Fish	20% EC	8.74 ppm ai	Partial
72-1(b)	00030444	Carp	20% EC	0.56 ppm**	Partial
72-1(b)	00030447	Bluegill Sunfish	20% EC	3.14 ppm ai	Partial
72-1(d)	00039445	Rainbow Trout	20% EC	0.2 - 0.4 ppm ai**	Partial
72-1(d)	40780505	Rainbow Trout	20% EC	2.20 ppm ai	Yes
DEGRADATES					
72-1(b)	41827202	Bluegill Sunfish	Technical BTS-27271	29.3 ppm	Yes
72-1(d)	41827203	Rainbow Trout	Technical BTS-27271	28.4 ppm	Yes
72-1(b)	41827206	Rainbow Trout	Technical BTS-27919	66.2 ppm	Yes
72-1(d)	41827205	Bluegill Sunfish	Technical BTS-27919	>100 ppm	Yes

* 48-hour test.
** 120-hour test.

Fish Early Life Stage Studies: A fish early life stage test is required when a product is applied directly to water or is expected to be transported to aquatic sites and 1) exposure of aquatic organisms will be continual or recurrent; or 2) the lowest LC_{50} is 1 mg/L or less; or 3) the EEC in water is equal to or greater than 0.01 of any LC_{50}; or 4) if the EEC is less than any LC_{50} and the product has reproductive effects on, or cumulative effects in, aquatic organisms or has a half-life in water greater than 4 days.

Fish early life-stage testing was required because amitraz is highly toxic to freshwater fish and may be applied repeatedly during the season. Furthermore, an estimate of the initial environmental concentration suggested that residues could be greater than 0.01 of the fish LC50. An early life stage test with a freshwater fish species is required for the pear and cotton uses. No chronic aquatic studies are required for the cattle/swine, and dog uses.

Gldn. No.	MRID No.	%A.I.	Species	Results	Fulfill Gdln.
72-4(a)	40798002	98.8%	Fathead Minnow (embryo-larvae)	NOEC & MATC < 3.53 ppb based on weight (most sensitive parameter)	Partial
72-4(a)	41288702	98.8%	Fathead Minnow (embryo-larvae)	MATC > 1.48 < 2.71 ppb based on length	Yes

An early life-stage study performed with the fathead minnow shows that body length is impaired at environmental concentrations of $\geq$2.71 ppb. The MATC (Maximum Allowable Toxic Concentration) is > 1.48 < 2.71 ppb.

Effects on Freshwater Invertebrates: The minimum data requirements for establishing the acute toxicity of amitraz to aquatic invertebrates depend upon the results from one 48-hour acute toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. This study is required for all amitraz use patterns.

Acute Aquatic Invertebrate Toxicity Studies - Technical, Formulated Product, and Primary Degradates: Parent amitraz can be characterized as very highly toxic to aquatic invertebrates.

Gldn. No.	MRID No.	Species	%A.I.	EC_{50}	Fulfills Gdln.
TECHNICAL					
72-2(a)	RIOAMI01	Daphnia magna	Technical	35 ppb	Yes
FORMULATED PRODUCT					
72-2(b)	40780506	Daphnia magna	20% EC	3.4 ppm	Yes
DEGRADATES					
72-2(b)	41827204	Daphnia magna	BTS-27271 Technical	2.59 ppm	Yes
72-2(b)	41827207	Daphnia magna	BTS-27919 Technical	>100 ppm	Yes

Testing with the formulated product was required since several fish studies suggested that amitraz may be more toxic when in a 20% EC formulation than by itself. The review of the study characterizes the 20% EC formulation of amitraz as moderately toxic to aquatic invertebrates.

Studies on the two major degradates of amitraz (BTS-27271 and BTS-27919) were also required because of their potential increased toxicity when compared to the parent compound. BTS-27271 and BTS-27919 can be characterized as moderately toxic and practically nontoxic, respectively, to *Daphnia magna*.

Aquatic Invertebrate Life-Cycle Study - Technical: A freshwater invertebrate life-cycle test is required when a product is applied directly to water or is expected to be transported to aquatic sites and 1) exposure of aquatic organisms will be continual or recurrent; or 2) the lowest LC_{50} is 1 mg/L or less; or 3) the EEC in water is equal to or greater than 0.01 of any LC_{50}; or 4) if the EEC is less than any LC_{50} and the product has reproductive effects on, or cumulative effects in, aquatic organisms or has a half-life in water greater than 4 days.

Aquatic invertebrate life cycle testing was required because parent amitraz is highly toxic and may be applied repeatedly during the season. Furthermore, an estimate of the initial environmental concentration suggested that residues (i.e., parent plus degradates) could be greater than 0.01 of the aquatic invertebrate LC_{50}. A freshwater invertebrate life-cycle test is required for the pear and cotton uses.

The aquatic invertebrate life-cycle test performed with *Daphnia magna* shows a significant reduction in growth and fecundity at $\geq$ 2.21 ppb. The MATC (Maximum Allowable Toxic Concentration) is > 1.10 < 2.21 ppb. (MRIDs 40780511, 41288701)

Effects on Marine and Estuarine Organisms: 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 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 testing is required for the pear and cotton uses only.

Acute Estuarine and Marine Toxicity Studies - Technical, Formulated Product, and Primary Degradates: There is sufficient information to characterize parent amitraz as highly toxic to oysters, moderately toxic to the sheepshead minnow and slightly toxic to grass shrimp. While the sheepshead minnow study was of supplemental status, this study combined with other estuarine fish tests can be used to satisfy guideline requirements.

Formulated product testing with estuarine/marine species was required since several fish studies suggested that technical amitraz may be more toxic when in a 20% EC formulation than by itself. These studies were originally required for a proposed citrus use and are also applicable to the cotton use pattern. Based on the reviewed data, the 20% EC formulation of amitraz is very highly toxic to the eastern oyster, highly toxic to the mysid shrimp and slightly toxic to the sheepshead minnow.

Studies were also required on the two major amitraz metabolites (BTS-27271 and BTS-27919) because of their potential increased toxicity when compared to the parent compound. BTS-27271 can be characterized as slightly toxic to the sheepshead minnow and eastern oyster and moderately toxic to the mysid shrimp. BTS-27919 can be characterized as practically nontoxic to the sheepshead minnow and eastern oyster and moderately toxic to the mysid shrimp. The Agency has determined that the existing database is sufficient to characterize the toxicity of amitraz degradates to estuarine/marine organisms.

Gdln. No.	MRID No.	Species	% A.I.	LC_{50}	Fulfills Gdln.
TECHNICAL					
72-3(a)	40780507	Sheepshead Minnow	98%	96-hr LC_{50} = 2.4 ppm	Partial
72-3(b)	RIOAMI02	Atlantic Oyster	95%	48-hr TL_{50} = 0.85 ppm	Yes
72-3(c)	00030450	Grass Shrimp	Technical	96-hr EC_{50} = 65.1 ppm	Yes
72-3(c)	00030450	Fiddler Crab	Technical	> 1000 ppm	Partial
FORMULATED PRODUCT					
72-3(d)	40780508	Sheepshead Minnow	20% EC	96-hr LC_{50} > 7.9 ppm	Yes
72-3(e)	40780509	Eastern Oyster	20% EC	96-hr EC_{50} = 85 ppb	Yes
72-3(f)	40780510	Mysid Shrimp	20% EC	96-hr EC_{50} = 0.48 ppm	Yes
DEGRADATES					
72-3(d)	42124608	Sheepshead Minnow	BTS-27271 99.6%	96-hr LC_{50} = 11.5 ppm	Yes
72-3(d)	42134609	Sheepshead Minnow	BTS-27919 99.8%	96-hr LC_{50} =>102 ppm	Yes
72-3(e)	42124610	Eastern Oyster	BTS-27271 99.6%	96-hr EC_{50} = 13.1 ppm	Partial
72-3(e)	42124611	Eastern Oyster	BTS-27919 99.8%	96-hr EC_{50} =>128 ppm	No
72-3(f)	42124612	Mysid Shrimp	BTS-27271 100%	96-hr EC_{50} = 5.81 ppm	Yes
72-3(f)	42124613	Mysid Shrimp	BTS-27919 99.8%	96-hr EC_{50} = 8.2 ppm	Partial

(3) Non-Target Insects Data

The minimum data required to establish the acute toxicity of parent amitraz to honey bees is an acute contact LD_{50} study with the technical material. This study is required for the pear and cotton uses only. There is sufficient information to characterize amitraz as practically nontoxic to bees.

Gdln. No.	MRID No.	Species	% A.I.	LD_{50}	Fulfills Gdln.
141-1	00030455	Apis mellifera	20% EC	no death or repellency in field test	Yes
141-1	00074486	Apis mellifera	Tech.	> 100ug/bee	Yes
141-1	00052490	Stethorus punctum	20% EC	low toxicity at 6 oz ai/ 100 gal.	Yes
141-1	00059461	Stethorus punctum	20% EC	low toxicity at 0.375 lb ai/100 gal	Yes

(4) Non-Target Plants Data

No studies were submitted under this topic and none are required.

b. Ecological Effects Risk Assessment

(1) Terrestrial Food/Nonfood Crops: Cotton and Pears

(a) Terrestrial Organisms

Amitraz is applied to pears in two types of formulations, a 50% a.i. WP and a 19.8% EC. Both labels specify a maximum use rate of 1.5 lbs a.i./A not to exceed 3 lbs. per season. Pears are grown in New England and the far west (California, Washington and Oregon). Pear orchards are normally used as a food source (buds, fruit, seeds and blossoms) by grouse, finch, orioles and sparrows. A variety of mammals (including squirrels, rabbits, muskrat, fox and coyote) utilize the fruit and bark of pear trees.

Amitraz is also applied to cotton in a 19.8% EC formulation with a maximum use rate of 1.0 lb. a.i./A/season. Cotton is grown throughout the southern United States. A variety of avian and mammalian organisms use cotton fields for feeding, cover and brooding. These organisms include both nongame and game species: bobwhite quail, wild turkey, ring-necked pheasant, mourning dove, ducks, geese, sandhill crane, songbirds, prairie chicken, deer, rabbit, raccoon, opossum and antelope.

To characterize the possible effects posed by amitraz use, the following possible scenarios are presented below: acute and chronic risk analyses to terrestrial and aquatic organisms.

Acute Risk to Terrestrial Organisms

Parent Amitraz: For both the cotton and the pear use, parent amitraz does not appear to pose an acute risk to either endangered or non-endangered terrestrial organisms.

Amitraz Degradate BTS-27271: BTS-27271 may be a potential acute hazard to avian species since it is more acutely toxic and is more persistent in the environment (aerobic soil metabolism $t_{1/2}$ = 75 days) than the parent.

In the following table, the number of single dose oral LD_{50} per bird per day for several species of birds exposed to BTS-27271 were calculated for both the cotton and the pear use patterns using three different scenarios: the maximum and typical residue levels from Kenaga (1973) and the values derived from a foliar field dissipation study on cotton. While the foliar dissipation study contains limited information on the dissipation of amitraz and its degradates, it was included in the risk assessment in order to have amitraz specific data with which to compare to Kenaga's general values. It should be noted, however, that one can place only limited confidence in these numbers due to lack of sample replication at each test site and sampling time. In addition, amitraz residues were measured on cotton foliage only; other avian food items (i.e. seeds, grass, insects) were not sampled.

As the foliar dissipation study provided residue levels on cotton foliage only (after a single 1.0 lb. ai/A application and after four 0.25 lb. ai/A applications), the residue levels for other substrates (i.e. short grass, seeds, etc.) were extrapolated using the proportions found in Kenaga's table. For example, if Kenaga determined that the maximum residues on short grass exceed those on foliage by a factor of 1.92, then the foliage residue level from the dissipation study was multiplied by this factor in order to calculate an appropriate value for short grass.

LD_{50}s per Bird per Day for Several Avian Species Exposed to BTS-27271: Cotton and Pear Use Patterns

Avian Species	COTTON (1.0 lb. a.i./A)			PEAR (1.5 lb. a.i./A)	
	Maximum Kenaga	Typical Kenega	Foliar Field Dissipation	Maximum Kenaga	Typical Kenaga
Carolina Wren	0.15**	0.09**	0.07	0.23*	0.13**
Mallard Duck	0.06	0.03	0.03	0.10**	0.05

* Restricted use classification LOC (0.2 LD_{50} per day) is exceeded.
** Endangered species LOC (0.1 LD_{50} per day) is equaled or exceeded.

The use of amitraz on cotton may pose an acute risk to endangered birds feeding on insects. The endangered species LOC (0.10 LD_{50}/day) is exceeded for the Carolina wren (an insect eater) in the maximum Kenaga scenarios. The endangered species LOC is not exceeded for insect eating birds in the field dissipation scenario.

The use of amitraz on pears may also pose an acute risk to endangered birds feeding on insects and on short grass. The endangered species LOC (0.10 LD_{50}/day) is exceeded for the Carolina wren in the typical and maximum Kenaga scenarios. Additionally, this use may pose an acute risk for endangered birds feeding on grass. The endangered species LOC is equaled for the mallard (a grass eater) in the maximum Kenaga scenario.

While the restricted use classification LOC (0.2 LD_{50}/day) is exceeded for the Carolina wren in the maximum Kenaga scenario, the high LOC (0.5 LD_{50}/day), however, has not been surpassed.

Due to the persistent nature of BTS-27271, a second 1.5 lbs ai/A application of amitraz to pears at a 10-day interval would essentially double residue values in the above table for pears thereby increasing risk to nontarget birds.

Chronic Risk to Terrestrial Organisms

Chronic risk to terrestrial organisms are presented in the following tables for both the cotton and pear uses for parent amitraz and the degradate BTS-27271. The diet composition of five avian species was factored into the calculations of total residue (ppm) values. For example, it was assumed that the mourning dove consumes 100% seeds while the Carolina wren eats 99% insects and 1% seeds. These species were used because they are representative of large groups of birds that have similar feeding habits. Maximum and typical residue levels from Kenaga (1973) and the values derived from the registrant's foliar field dissipation study on cotton were used for this risk assessment (MRID 42124619).

Amitraz use on Cotton; Parent Amitraz: Estimated environmental concentrations (EEC's) were calculated for a 1.0 lb. ai/A (maximum application rate) and four 0.25 lb. ai/A applications (typical use pattern indicated by registrant) using both the maximum and typical residue levels for parent amitraz from Kenaga (1973) and the values derived from the registrant's foliar field dissipation study on cotton (MRID 42124619).

Parent Amitraz Chronic Risk; 1 lb. ai/A Application
LOC > NOEL (25 ppm); Shaded blocks represent LOC exceedance.

SPECIES	TOTAL RESIDUE (ppm)					
	Max.[1] Kenaga	RQ[2]	Typ.[3] Kenaga	RQ	Field Study[4]	RQ
Bobwhite Quail[5]	24.5	1.0	11.1	0.4	12.2	0.5
Mourning Dove[6]	12.0	0.5	3.0	0.1	6.0	0.2
Field Sparrow[7]	35.5	1.4	18.3	0.7	17.7	0.7
Carolina Wren[8]	57.5	2.3	32.7	1.3	28.8	1.1
Mallard Duck[9]	240.0	9.6	125.0	5.0	120.0	4.8

1. Maximum residues expected from food items (Kenaga, 1973).
2. RQ = risk quotient (EEC/NOEL), LOC = 1.0.
3. Typical residues to expected food items (Kenaga, 1973).
4. Foliar field dissipation study on cotton (Nor-Am, 1991). Residue values for appropriate diet substrates are extrapolated from the maximum total residue level of 62.2 ppm measured after a single 1 lb. application (see Attachment B).
5. Assumption: bobwhite quail consumes 27% forage (e.g. alfalfa, small insects) and 73% seeds.
6. Assumption: mourning dove consumes 100% seeds.
7. Assumption: field sparrow consumes 51% forage (insects) and 49% seeds.
8. Assumption: Carolina wren consumes 99% forage (insects) and 1% seeds.
9. Assumption: mallard consumes 100% short grass.

Similar LOC exceedances are indicated for the typical use rate of four 0.25 ai parent amitraz/A applications (risk quotients ranging from 1.0 to 7.0).

Parent Amitraz Chronic Risk
0.25 lb. ai/A Application (4 applications separated by 7-day intervals)
LOC > NOEL (25 ppm); Shaded blocks represent LOC exceedance

SPECIES	TOTAL RESIDUE (ppm)					
	Max.[1] Kenaga	RQ[2]	Typ.[3] Kenaga	RQ	Field Study[4]	RQ
Bobwhite Quail[5]	17.7	0.7	7.8	0.3	8.8	0.3
Mourning Dove[6]	8.7	0.3	2.0	0.1	4.3	0.2
Field Sparrow[7]	25.9	1.0	13.1	0.5	12.8	0.5
Carolina Wren[8]	41.6	1.7	23.6	0.9	20.8	0.8
Mallard Duck[9]	174.6	7.0	90.8	3.6	86.0	3.4

1. Maximum residue levels were calculated for 4 x 0.25 lb. ai/A with an application interval of 7 days. The residue value determined after a single 0.25 lb. ai/A application (Kenaga) was run through an EFED fate model using a maximum half-life of 36.9 days for total amitraz residues (derived from Nor-Am's field dissipation study).
2. RQ = risk quotient.
3. Typical residues were calculated by the same method described in footnote 1.
4. Foliar field dissipation study on cotton (Nor-Am, 1991). Residue values for appropriate diet substrates are extrapolated from the maximum total residue level of 44.6 ppm measured after four 0.25 lb. ai/A applications separated by 7 day interval (see Attachment 2).
5. Assumption: bobwhite quail consumes 27% forage (e.g. alfalfa, small insects) and 73% seeds.
6. Assumption: mourning dove consumes 100% seeds.
7. Assumption: field sparrow consumes 51% forage (insects) and 49% seeds.
8. Assumption: Carolina wren consumes 99% forage (insects) and 1% seeds.
9. Assumption: mallard consumes 100% short grass.

Avian reproduction studies with parent amitraz indicate that the no observable effect level (NOEL) is 25 ppm. Use of amitraz on cotton may adversely affect avian reproduction. The LOC is exceeded in all three scenarios for a 1.0 lb. ai parent amitraz/A application (foliar field dissipation study and maximum and typical Kenaga) for insect and grass eating birds (risk quotients ranging from 1.1 to 9.6). The LOC is also equaled or exceeded for bird species which eat both seeds and insects (risk quotients ranging from 1.0 to 1.4).

In the core bobwhite quail study, a statistically significant reduction (12%) as compared to the control, was observed at the 50.5 ppm test level in the number of viable embryos per egg set. A 13% reduction in the number of 14-day survivors per egg set and an 11% reduction in the number of hatchlings per egg set were also observed at the 50.5 ppm test level, although these effects were not found to be significantly different from the controls (MRID 42336001).

A supplemental bobwhite reproduction study with parent amitraz demonstrated an increase in eggshell cracking and a reduction in the percentage of viable embryos that survived to become normal hatchlings at 40 ppm; a NOEL was not determined in this study as reproductive effects were seen at the lowest level tested. A supplemental mallard reproduction study with parent amitraz demonstrated a significant reduction at 40 ppm, in comparison to the control, in the number of 14-day old survivors produced per week; again, a

NOEL was not determined in this study since reproductive effects were seen at the lowest level tested (MRIDs 00072411, 00072412).

Amitraz Use on Cotton; Amitraz Degradate BTS-27271: When birds consume amitraz their stomachs rapidly metabolize the residues to the major degradates (BTS-27271 and BTS-27919). Thus, a chronic avian risk assessment was also conducted on the major degradate, BTS-27271. EEC's were calculated after a 1.0 lb. ai amitraz/A equals 0.55 lb. ai BTS-27271/A application using both the maximum and typical residue levels from Kenaga (1973) and residues from the foliar field dissipation study.

BTS-27271
1.0 lb. ai amitraz/A Application
(yielding 0.55 lb. ai BTS-27271/A) LOC > NOEL (25 ppm);
Sshaded blocks represent LOC exceedance

SPECIES	Total Residue (ppm)					
	Max.[1] Kenaga	RQ[2]	Typ.[3] Kenaga	RQ	Field Study[4]	RQ
Bobwhite Quail[5]	13.5	0.5	6.1	0.2	6.7	0.3
Mourning Dove[6]	6.6	0.3	1.7	0.1	3.3	0.1
Field Sparrow[7]	19.5	0.8	10.1	0.4	9.7	0.4
Carolina Wren[8]	31.6	1.3	18.0	0.7	15.8	0.6
Mallard Duck[9]	132.0	5.3	68.8	2.7	66.0	2.6

1. Maximum residue levels were calculated for 4 x 0.25 lb. ai/A with an application interval of 7 days. The residue value determined after a single 0.25 lb. ai/A application (Kenaga) was run through an EFED fate program using a maximum half-life of 36.9 days for total amitraz residues (derived from Nor-Am's field dissipation study).
2. RQ = risk quotient (EEC/NOEL); LOC = 1.0.
3. Typical residues were calculated by the same method described in footnote 1.
4. Foliar field dissipation study on cotton (Nor-Am, 1991). Residue values for appropriate diet substrates are extrapolated from the maximum total residue level of 44.6 ppm measured after four 0.25 lb. ai/A applications separated by 7 day interval (see Attachment 2).
5. Assumption: bobwhite quail consumes 27% forage (e.g. alfalfa, small insects) and 73% seeds.
6. Assumption: mourning dove consumes 100% seeds.
7. Assumption: field sparrow consumes 51% forage (insects) and 49% seeds.
8. Assumption: Carolina wren consumes 99% forage (insects) and 1% seeds.
9. Assumption: mallard consumes 100% short grass.

In determining LOC exceedance, the NOEL from the BTS-27271 study with the bobwhite quail was used. The bobwhite reproduction study indicated a NOEL of 25 ppm and a LOEL of 100 ppm based on statistically significant reductions, as compared to the control, in the number of hatchlings as a percentage of eggs set (16% reduction) and the number of two-week survivors as a percentage of eggs set (18% reduction).

A lower NOEL of 5 ppm exists for BTS-27271 (found in the mallard study). However, the confidence that can be placed on these results is questionable since the lab which conducted the study has historically encountered problems with eggs cracking in their avian reproduction studies; the statistically significant parameter in the mallard study was a 49% increase, as compared to the control, in the number of eggs cracked.

The risk assessment for BTS-27271 strengthens the conclusions that use of amitraz on cotton may adversely affect avian reproduction as comparable LOC exceedances are indicated (risk quotients of 1.3 to 5.3).

Amitraz Use on Pears; Parent Amitraz: Maximum residues (EEC's) were calculated for parent amitraz for a 1.5 lb. ai/A applications using both the maximum and typical residue levels from Kenaga (1973).

Use of amitraz on pears may adversely affect avian reproduction. The LOC is exceeded in both the typical and maximum Kenaga scenarios with a single 1.5 lb. ai/A parent amitraz application for insect, grass and seed/insect eating birds (risk quotients ranging from 1.0 to 14.0).

Parent Amitraz 1.5 lb. ai/A Application LOC > NOEL (25 ppm); shaded blocks represent LOC exceedance				
SPECIES	Total Residue (ppm)			
	Max. Kenaga[1]	RQ[2]	Typ. Kenaga[3]	RQ
Bobwhite Quail[4]	36.6	1.5	16.6	0.7
Mourning Dove[5]	18.0	0.7	4.5	0.2
Field Sparrow[6]	53.2	2.1	27.4	1.0
Carolina Wren[7]	36.3	3.4	49.0	2.0
Mallard Duck[8]	360.0	14.0	187.5	7.5

1. Maximum residues to expected food items (Kenaga, 1973).
2. RQ = risk quotient (EEC/NOEL); LOC = 1.0.
3. Typical residues to expected food items (Kenaga, 1973).
4. Assumption: bobwhite quail consumes 27% forage (e.g. alfalfa, small insects) and 73% seeds.
5. Assumption: mourning dove consumes 100% seeds.
6. Assumption: field sparrow consumes 51% forage (insects) and 49% seeds.
7. Assumption: Carolina wren consumes 99% forage (insects) and 1% seeds.
8. Assumption: mallard consumes 100% short grass.

Amitraz Use on Pears; Amitraz Degradate BTS-27271: Maximum residues (EEC's) for BTS-27271 were calculated after a 1.5 lb. ai/A amitraz (equals 0.83 lb. ai BTS-27271/A) application using both the maximum and typical residue levels from Kenaga (1973). As in the preceding tables, the diet composition of five different avian species was factored into the calculations of total residue (ppm) values.

A second 1.5 lb. ai/A application of amitraz at a 10-day interval would essentially double residue values in the above tables due to the persistent nature of BTS-27271 (aerobic soil metabolism $t_{1/2}$ = 75 days). In any case, it has been concluded that pesticide effects on avian reproduction can occur within a matter of days (e.g., 8 days or less) after treatment (Bennett and Ganio, 1991). Thus, reproductive effects are not merely a function of chronic exposure to a pesticide.

BTS-27271; 1.5 lb. ai amitraz/A Application (yielding 0.83 lb. ai BTS-27271/A); LOC > NOEL (25 ppm); shaded blocks represent LOC exceedance				
SPECIES	**BTS 27271 Residues (ppm)**			
	Max. Kenaga[1]	**RQ[2]**	**Typ. Kenaga[3]**	**RQ**
Bobwhite Quail[4]	20.3	0.8	9.1	0.4
Mourning Dove[5]	10.0	0.4	2.5	0.1
Field Sparrow[6]	29.4	1.2	18.9	0.7
Carolina Wren[7]	48.6	1.9	27.3	1.1
Mallard Duck[8]	199.2	8.0	103.7	4.1

1. Maximum residues to expected food items (Kenaga, 1973).
2. RQ = risk quotient (EEC/NOEL); LOC = 1.0.
3. Typical residues to expected food items (Kenaga, 1973).
4. Assumption: bobwhite quail consumes 27% forage (e.g. alfalfa, small insects) and 73% seeds.
5. Assumption: mourning dove consumes 100% seeds.
6. Assumption: field sparrow consumes 51% forage (insects) and 49% seeds.
7. Assumption: Carolina wren consumes 99% forage (insects) and 1% seeds.
8. Assumption: mallard consumes 100% short grass.

The risk assessment for a major degradate (BTS 27271) indicates that use of amitraz on pears may adversely affect avian reproduction as comparable LOC exceedances are indicated (risk quotients of 1.1 to 8.0).

For the pear use, a second application of amitraz at 1.5 lb. ai/A would essentially double the risk quotients listed above.

Risks to Small Mammals; Cotton and Pear Use

Small mammal exposure is addressed using acute oral LD_{50} values converted to estimate a LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food cons. per day (g)}}$$

Small Mammal Food Consumption in ppm (Based on an LD_{50} = 515 mg/kg)				
Small Mammal	**Body Weight in Grams**	**% of Weight Eaten Per Day**	**Food Consumed Per Day in Grams**	**Estimated LC_{50} Per Day (ppm)**
Meadow vole	46	61	28.1	843
Adult field mouse	13	16	2.1	3188
Least shrew	5	110	5.5	566

The above table is based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

Acute Risks to Mammals: The estimated LC_{50} is then compared to the residues listed above to calculate a risk quotient (EEC/LC_{50}). The table below indicates the risk quotients for application of amitraz at the highest application rate of 1.5 lb. a.i./A on pears.

Mammalian Dietary Risk Quotients on Pears (based on Dietary RQ = EEC/LC_{50})

Mammal Type	Food Item	Residues (ppm)	Risk Quotient
Meadow vole consuming range grasses	long grasses	165	0.19
Adult field mouse consuming seeds	seeds	18	0.005
Least shrew consuming insects	small insects	87	0.15

The table below indicates the risk quotients for application of amitraz at the application rate of 1.0 lb. a.i./A on cotton.

Mammalian Dietary Risk Quotients on Vegetables and Cotton (based on Dietary RQ = EEC/LC_{50})

Mammal Type	Food Item	Residues (ppm)	Risk Quotient
Meadow vole consuming range grasses	long grasses	110	0.13
Adult field mouse consuming seeds	seeds	12	0.003
Least shrew consuming insects	small insects	58	0.1

The LOC for high acute risk (0.5) and restricted use (0.2) to mammals have not been exceeded. However, endangered small mammals exposed to areas treated with amitraz may be affected (RQ for endangered species LOC of 0.1).

Chronic Risks to Mammals: The following table indicates the Chronic risk quotients for application of amitraz at various application rates. For purposes of establishing chronic risk, a three-generation reproduction study on rats was used, with a NOEL of 15 ppm/day. The LOEL for this study was 50 ppm/day, resulting in decrease in litter size.

Mammalian Chronic Risk Quotients (based on Dietary RQ = EEC/15 ppm NOEL)

Use Rate lb. a.i./A(Crop)	Food Item	Maximum Residues (ppm)	Maximum Risk Quotient	Typical Residues (ppm)	Typical Risk Quotient	LOC
1.5 (pears)	long grass	165	11	13.8	9.2	1
1.5 (pears)	insects	87	5.8	49	3.2	1
1.0 (cotton)	insects	58	3.8	33	2.2	1
0.25 (cotton	insects	15	1	8	0.5	1

Small mammals are a vital link in the food chain; a reduction in their numbers may dramatically impact top carnivores (hawks, owls, foxes, etc...).

Using maximum and typical residues on representative food items for mammals, the risk quotients exceed the chronic LOC. However, the factors, as outlined below, all lend to the uncertainty in the conclusion of high chronic (sublethal or reproductive) risk.

Other factors should be considered when assessing the extent of risk and the certainty that chronic effects will occur. Uncertainty stems both from using laboratory toxicity test results, and from limitations in estimating actual exposure.

1. The study, from which the chronic NOEL was derived was a 3-generation feeding study. It is not known at what point-in-time during the test (at 50 ppm exposure) the observed effects were noted. Parent amitraz has a short half-life (<1 day) aerobic soil metabolism), but the degradates are persistent.

2. It is assumed that other mammals would have different sensitivities than the representative test organism (laboratory rat). It is not known if wild mammals would be more or less sensitive. If they are more sensitive, even the lower residue levels may result in sublethal or reproductive risk.

3. It is not known how long the exposure residues will last on mammalian food items. Residues of parent amitraz will not remain the full time the rat 3-generation study lasted, especially at levels exceeding the LOEL. However, because rather short exposure periods could cause sublethal or reproductive effects, this does not preclude the presumed risk.

4. In pear orchards, where the predominant vegetation type is long grass, risk from consumption of maximum or typical residues exceed the LOC for chronic risk. However, small mammals will graze on the lower portions of the grass and would not ingest the highest residues that would be at the upper portions of the long grass.

5. In cotton, the greater chronic risk may come from repeated applications at 0.25 lb. a.i./A rather than a single application of 1.0 lb. a.i./A.

6. Mammals could move about and feed on a variety of items, not just the food items with the maximum residues.

These factors all lend to the uncertainty in the conclusion of chronic (sublethal or reproductive) risk.

Risk to Aquatic Organisms

Acute Toxicity: For the cotton use, an application rate of 1.0 lb. a.i./A would produce EEC's of 3.05, 16.8 and 31.1 ppb for parent amitraz, BTS-27271 and BTS-27919, respectively. For the pear use, an application rate of 1.5 lb. a.i./A would produce EEC's of 4.5, 17.7 and 32.4 ppb for parent amitraz, BTS-27271 and BTS-27919, respectively.

For the cotton use, amitraz degradates (BTS-27919, BTS-27271) should pose minimal acute risk to aquatic organisms since the EEC's do not exceed the restricted use classification LOC (1/10 LC_{50} = 3.5 ppb for daphnia, parent amitraz; 259 ppb for daphnia, BTS-27271; 820 ppb for mysid shrimp, BTS-27919). The aquatic EEC for parent amitraz (3.05 ppb) falls short of the restricted use LOC (1/10 LC_{50} = 3.5 ppb for daphnia) but surpasses the endangered species LOC (1/20 LC_{50} = 1.75 ppb for daphnia). However, because parent amitraz is short-lived in the environment (hydrolysis = 22.1 hours @ pH 7; aerobic metabolism < 1 day), adverse effects to these organisms is expected to be minimal.

For the pear use, parent amitraz may pose acute risk to aquatic invertebrates as the EEC exceeds the restricted use classification LOC for the daphnia (1/10 EC_{50} = 3.5 ppb). As with the cotton use, these effects are expected to be minimal as parent amitraz rapidly dissipates in the environment.

For the pear use, amitraz degradates (BTS-27919, BTS-27271) should pose minimal acute risk to aquatic organisms since the EEC's do not exceed the restricted use classification LOC (1/10 LC_{50} = 259 ppb for daphnia, BTS-27271; 820 ppb for mysid shrimp, BTS-27919).

Chronic Toxicity: For both the cotton and the pear use patterns, the maximum application rates of 1.0 lb. ai/A and 1.5 lb. ai/A, respectively, would produce EEC's for parent amitraz (3.05 ppb and 4.05, respectively) which exceed the MATC (Maximum Allowable Toxic Concentration) found in the chronic daphnia (MATC > 1.10 < 2.2 ppb) and the fish early-life stage (MATC >1.48 < 2.7 ppb) studies.

However, parent amitraz is short-lived in the environment (hydrolysis = 22.1 hours @ pH 7; aerobic metabolism < 1 day) and the potential for chronic effects to nontarget aquatic organisms is expected to be minimal.

Although amitraz degradates are less acutely toxic than the parent to aquatic organisms, their potential chronic toxicity is of concern because they are more persistent in aquatic environments than the parent (see Environmental Fate section).

The cotton use pattern does not appear to pose a chronic risk to aquatic organisms as the EEC's for BTS-27271 and BTS-27919 (16.8 ppb and 31.1 ppb, respectively) do not exceed 1/100 EC_{50} of the most sensitive species (25.3 ppb for daphnia, BTS-27271; 82 ppb for mysid shrimp, BTS-27919).

The pear use pattern, however, is of concern since it can be applied at a higher application rate. The EEC would be 33.8 ppb which surpasses 1/100 EC_{50} (25.3 ppb) when calculations were made for BTS-27271 using *Daphnia magna,* the most sensitive species. Therefore, chronic adverse effects to aquatic invertebrates may be expected from use of amitraz on pears. Therefore, in order to complete the amitraz aquatic risk assessment, the Agency is requiring that a daphnia life-cycle study be conducted on the degradate, BTS-27271.

Risks from Cattle and Swine Use

There are two amitraz containing products (Taktic EC 12.5% a.i. and Taktic Dairy Collar 10% a.i.) which are used to control ectoparasites on cattle and swine. The Agency is mainly concerned with Taktic EC since this product can be applied directly to cattle/swine as a dip or spray. While swine raised for meat production are mainly restricted to stalls/ farrowing pens, cattle are commonly allowed to range freely. Thus, there is a potential for exposure to aquatic ecosystems when newly sprayed cattle roam into a pond or stream. Considering that amitraz is highly toxic to fish and aquatic invertebrates, the Agency is concerned with any use pattern in which this chemical may be transported to water.

Data available to the Agency indicates that amitraz is used mainly on swine versus cattle: approximately 2-3% of cattle are treated with amitraz, while 10-20% of swine are treated. In addition the use of amitraz on cattle is largely in quarantine situations (i.e. cattle imported into the U.S. from Mexico). Therefore, use of amitraz on cattle and swine is expected to result in minimal exposure to aquatic organisms. No further data are needed to characterize this use pattern.

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 amitraz data required to support reregistration of products containing amitraz 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 amitraz. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of amitraz, 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 amitraz and to determine that provided certain label modifications were implemented, amitraz can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing

amitraz as the active ingredients 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 and the data identified in Appendix B. Although the Agency has found that all uses of amitraz 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 amitraz, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for amitraz, the Agency has sufficient information on the health effects of amitraz and on its potential for causing adverse effects in humans, fish and wildlife, and the environment to make a reregistration eligibility decision. Therefore, the Agency concludes that products containing amitraz for all registered uses are eligible for reregistration, provided certain risk mitigation measures outlined and required in this RED document are implemented.

The Agency has determined that amitraz products, labeled and used as specified in this RED document, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all currently registered uses of amitraz which labels adhere to the mitigation measures outlined in this RED document are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances for residues of amitraz in/on plant and animal commodities are expressed in terms of the combined residues of amitraz and its metabolites BTS-27271 (N-(2,4-dimethyl phenyl)-N-methylmethanimidamide) and BTS-27919 (N-(2,4-dimethylphenyl)) formamide both calculated as the parent compound [40 CFR 180.287]. No food/feed additive tolerances have been established for amitraz residues.

There is an error in the tolerance expression for the BTS-27919 metabolite. The chemical name for the metabolite now reads N-(2,4-dimethylphenyl)-N-methyl formamide. The correct name for the metabolite is N-(2,4-dimethylphenyl) formamide. The tolerances listed in 40 CFR §180.287 have been evaluated in the table and are presented below.

- The 0-ppm tolerance for apples should be revoked since there are no registered uses for this raw agricultural commodity.

- The 3.0-ppm tolerance for pears is supported by adequate residue chemistry data.

- The recently established (58 FR 14314, 3/17/93) tolerances for cottonseed (1.0 ppm), eggs, (0.01 ppm), poultry fat and meat (0.01 ppm), and poultry meat byproducts (0.05 ppm) in connection with PP#9F3730 are supported by adequate residue chemistry data.

- The recently established (57 FR 53566, 11/12/92) tolerances for honey (1.0 ppm) and honeycomb (6.0 ppm) in connection with PP#0F3825 are supported by residue chemistry data.

Tolerance reassessment summary for amitraz [40 CFR §180.287]		
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment**
Apples	0.00	Revoke
Beeswax	6.0	
Cattle, fat	0.1	Adequate
Cattle, mbyp	0.3	
Cattle, meat	0.05	
Cotton, seed	1.0	Adequate
Eggs	0.01	Adequate
Goats, fat	0.00	Revoke. The registrant must propose to raise the tolerance per PP#9F3772 - goats meat, and meat-by-products 0.3(ppm), goats fat 0.5 (ppm)
Goats, mbyp	0.00	
Goats, meat	0.00	
Hogs, fat	0.1	Adequate
Hogs, kidney	0.2	
Hogs, liver	0.2	
Hogs, mbyp	0.3	
Hogs, meat	0.05	

Tolerance reassessment summary for amitraz [40 CFR §180.287]		
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment**
Honey and Comb	1.0	Adequate
Horses, fat	0.00	Revoke
Horses, mbyp	0.00	
Horses, meat	0.00	
Milk	0.03	Adequate
Milk, fat	0.3	
Pears	3.0	2.0 ppm
Poultry, fat	0.01	Adequate
Poultry, mbyp	0.05	
Poultry, meat	0.01	
Sheep, fat	0.00	Revoke. The registrant must propose to raise the tolerance as per PP#9F3772 - sheep meat and meat-by-products 0.3(ppm), sheep fat 0.5 (ppm)
sheep, mbyp	0.00	
sheep, meat	0.00	

2. Codex Harmonization

Several maximum residue limits (MRLs) for amitraz have been established by Codex in various commodities. The Codex MRLs are currently expressed as the sum of amitraz and N-(2,4-dimethylphenyl)-N'-methylformamidine calculated as N-(2,4-dimethylphenyl)-N'-methylformamidine.

The Codex tolerance expression is somewhat different from the U.S. tolerance expression. The Codex expression is the sum of amitraz plus metabolite BTS-27271, calculated as BTS-27271. The U.S. expression is the sum of amitraz and its metabolites BTS-27271 and BTS-27919, both calculated as the parent compound. The enforcement method for amitraz tolerances in the U.S. (Methods I and II of PAM Vol. II) consists of hydrolysis of all metabolites containing the 2,4-DMA moiety to 2,4-DMA, extraction, and determination using gas chromatography with electron capture detection. The enforcement method under the Codex system involves treatment of the RAC with acidic methanol to convert the parent compound to metabolite BTS-27271, followed by extraction, cleanup, and determination of BTS-27271 using gas liquid chromatography with flame ionization detection. Presently, compatibility between the Codex MRL and U.S. tolerance cannot be achieved due to the differences between the tolerance definitions and analytical enforcement methods.

A summary of the established and proposed Codex MRLs is presented in the table below. The U.S. tolerances and Codex MRLs are identical in magnitude for cattle and swine tissues. When comparing tolerances versus MRLs which the U.S. and Codex have in

common, the Codex MRLs are somewhat lower than the U.S. tolerances. There are several Codex MRLs, either established or proposed, that do not have analogous U.S. tolerances.

Codex MRLs and applicable U.S. tolerances		
Commodity	**Codex MRL (mg/kg) [1]**	**U.S. Tolerance (ppm)**
Cattle meat	0.05 [2]	0.05
Cherries	0.5	None established
Cottonseed	0.5	1.0
Cottonseed crude oil	0.05	None established
Cucumber	0.5	None established
Edible offal of cattle, pigs, and sheep	0.2	0.1 (hog fat), 0.2 (hog liver and mbyp), 0.3 (hog mbyp)
Milk	0.01 [3]	0.03 (for milk) 0.3 (for milk, fat)
Oranges, sweet, sour	0.5	None established
Peach	0.5	None established
Pig meat	0.05 [2]	0.05
Pome fruit	0.5	2.0 (for pears)
Sheep meat	0.1 [2]	0.3 ppm (proposed for the meat and mbyp of sheep)
Tomato	0.5	None established

1. All amitraz MRLs are final (CXL) except for tomato which is at Step 8.
2. The MRL accommodates veterinary uses.
3. At or about the limit of detection.

3. Reference Dose

The reference Dose (RfD) for amitraz was determined to be 0.0025 mg/kg/day, based on a NOEL of 0.25 mg/kg/day from the chronic oral toxicity study in dogs (MRID 00044586). An uncertainty factor of 100 (a factor of 10 each for interspecies extrapolation and intraspecies variance) was used. The critical effects were increased blood glucose concentration, hypothermia and CNS depression. An ADI for amitraz was established by WHO (1990) at 0.003 mg/kg/day, based on the same chronic dog study and using the same uncertainty factor.

4. Risk Mitigation Measures

The following risk mitigation measures for post-application workers combined with generic worker protection labeling, should mitigate the unacceptable neurotoxicity and cancer risks to workers exposed to amitraz residues after application is complete:

- for the pear use:
  1) Minimum of 35 days between applications, and
  2) Restricted-entry interval of 28 days
- for the cotton use:
  1) Mechanical harvesting, and
  2) Restricted-entry interval of 48 hours

The following risk mitigation measures for handlers, combined with generic worker protection labeling, should mitigate the unacceptable neurotoxicity risks to handlers:

- for the pear use:
  1) Closed system mixing/loading (e.g, water soluble packaging)
  2) Application from within an enclosed cab, and
  3) Minimal (baseline) personal protective equipment (PPE)
- for the cotton use:
  1) Closed system mixing/loading (e.g., water soluble packaging)
  2) Mechanical flagging, and
  3) Minimal (baseline) PPE
- for the livestock spray/dip use:
  1) Minimal (baseline) PPE

The following risk mitigation measures are being required to reduce exposure to avian species and small mammals:

- for the pear use:
  1) Deletion of pre-bloom use
  2) Limit use to two applications

5. Endangered Species

The Agency has concerns about the exposure of threatened and endangered animal species to amitraz. Based on the conclusions discussed in the preceding sections of this risk assessment, amitraz and its two primary degradates may pose an acute risk to nontarget avian and mammalian species. While the United States Fish and Wildlife Service (USFWS) has developed a biological opinion for pesticide use on cotton (10/12/83), amitraz was not one of the pesticides considered in this consultation. Therefore, this information is of limited use to the Agency with respect to amitraz's exceedance of endangered species criteria for "may affect." To date, consultation with the USFWS concerning pesticide use on pear orchards has not been pursued.

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 modifications or a generic product label statement,

requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

6. Labeling Rationale and Requirements

Compliance with the Worker Protection Standard

In order to remain in compliance with FIFRA, it is the Agency's position that any product whose labeling reasonably permits use in the production of an agricultural plant on any agricultural establishment (farm, forest, nursery, or greenhouse) must comply with the labeling requirements of the Agency's labeling regulations for worker protection statements (40 CFR part 156, subpart K).

These labeling revisions are necessary to implement the 1992 Worker Protection Standard (WPS) for Agricultural Pesticides (40 CFR Part 170) and must be completed in accordance with the deadlines specified in the WPS, unless official the Agency guidance specifies otherwise. The Agency has issued PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard, and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," which contain specific instructions to registrants about how to complete the required WPS labeling changes and offer guidance and deadline-options for making those changes. Unless otherwise specifically directed in this RED, all statements required by the WPS (and reflected in PR Notices 93-7 and 93-11) are to be on the product labeling.

- In order to remain in compliance with FIFRA, after April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, or other Agency guidance, all products within the scope of those notices must bear WPS PR-Notice-complying labeling when they are distributed or sold by the registrant or any supplementally registered distributor, or any repackager under the Agency's Bulk Repackaging Policy.

- In order to remain in compliance with FIFRA, after October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11 or other Agency guidance, all products within the scope of those notices must bear WPS PR-Notice-complying labeling when they are distributed or sold by any person.

Uses Within the Scope of the Worker Protection Standard

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.

Some of the registered uses of amitraz are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some uses are outside the scope of the WPS. Those that are outside the scope of the WPS include use on livestock or other animals.

Personal Protective Equipment (PPE) and Engineering Controls for Handlers (Mixer/Loader/Applicators)

Occupational-Use Products (WPS and NonWPS Uses)

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

1. If the Agency has no special concerns about the acute 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 will be established using the process described in PR Notice 93-7 or more recent Agency guidelines.

2. If the Agency has special concerns about an active ingredient due to 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 occupational 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 each 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.

There are special toxicological concerns about some uses of amitraz that warrant the establishment of active-ingredient-based minimum PPE and engineering control requirements for handlers. Amitraz is classified as a Group C carcinogen and has low Margins of Exposure for handlers based on acute neurotoxic effects. Therefore, active-ingredient-based minimum PPE requirements will be established for the following handlers.

- Handlers associated with amitraz applications to pears,
- Handlers associated with amitraz applications to cotton who are exposed to amitraz in concentrated form (such as for spill clean-up if the closed-system fails),
- Handlers associated with amitraz applications to cotton who are exposed to amitraz in diluted form (such as repairing, cleaning, or adjusting application equipments)
- Occupational handlers associated with placing amitraz-impregnated collars on livestock
- Handlers associated with amitraz spray or dip applications to livestock.

Handler PPE for Homeowner-Use Products: One product containing amitraz (impregnated collars for dogs) is intended primarily for homeowner use. No minimum (baseline) PPE is being established on this product, since the expected exposure to homeowners placing an amitraz-impregnated collar on a dog is expected to result in negligible exposure.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

- **Entry Restrictions for Occupational-Use Products (WPS Uses)**

Restricted Entry Interval: Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an

organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

For occupational end-use products containing amitraz as an active ingredient, the Agency is establishing a 28-day restricted-entry interval for each use of the product on pears and a 48-hour restricted-entry interval for each use of the product on cotton. The basis for this recommendation is that amitraz is categorized as a "Group C" possible human carcinogen and the Agency is concerned about acute neurotoxicity.

The WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. The Agency believes that these existing WPS protections are sufficient to mitigate post-application exposures of workers who contact surfaces treated with amitraz.

The WPS REI in effect until now was 24 hours. The Agency found no reason to retain the 24-hour interim REI placed on amitraz products by PR Notice 93-7. The 24-hour interim WPS REI was established because amitraz is in toxicity category II for acute dermal toxicity, but did not take into account the acute neurotoxicity concerns or amitraz's classification as a Category C carcinogen.

Early-Entry PPE: The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If the Agency has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

There are special concerns about amitraz based on the toxicological endpoint for short-term exposures, the carcinogenic concern for long-term exposures, and the low MOEs for certain handlers. Therefore, for early entry following applications of amitraz, the Agency is

establishing PPE for dermal protection that is more stringent than the PPE that would otherwise be established based on the acute toxicity of the active ingredient. Since amitraz is classified as category IV for eye irritation potential, protective eyewear is not required.

- **Entry Restrictions for Occupational-Use Products (Non WPS Uses)**

The Agency is establishing no entry restrictions at this time for nonWPS occupational uses of amitraz end-use products.

- **Entry Restrictions for Homeowner-Use Products**

The Agency is establishing no entry restrictions at this time for amitraz end-use products that are intended primarily for homeowner use.

Additional Labeling Requirements

The Agency is requiring labeling statements to be located on all end-use products containing amitraz that are intended primarily for occupational use. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED BY 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 amitraz for the eligible uses has been reviewed and determined to be substantially complete. However, the following confirmatory studies listed below are needed:

- Life-Cycle Aquatic Invertebrate (Guideline 72-4(b)) is required for the degradate BTS-27271 for the pear use.

- Concurrent Dislodgeable Foliar Residue (Guideline 132-1(a)) and Dermal Exposure (Guideline 133-3) data.

- Batch equilibrium (Guideline 163-1) be conducted for BTS-27271 and BTS-27919.

- Droplet size spectrum (Guideline 201-1) and field drift (Guideline 202-1). The registrant may elect to satisfy both data requirements through the Spray Drift Task Force.

- Dermal Exposure Data (Guideline 231) and Inhalation Exposure Data (Guideline 232) to support the reregistration of amitraz spray/dip treatment of livestock.

An additional confirmatory study, not part of the target database for amitraz, is required to support the continued registration of amitraz. This requirement is:

- A combined developmental/neurological/reproduction toxicity study in rats. The reason for requiring this confirmatory study is that both the developmental and reproductive toxicity studies in rats were supplementary and neither could be considered as a reliable assessment of the potential developmental or reproductive toxicity for amitraz. Furthermore, there exists "...some evidence that amitraz was associated with maternal/reproductive/ developmental toxicity at relatively low dose levels," and the fact that neurotoxicity was observed in both rodents and non-rodents. Prior to initiation, the registrant should consult with the Agency on the protocols for this study.

2. Labeling Requirements for Manufacturing-Use Products

The Agency has determined that the current label precautions are still applicable and are required for product reregistration. Refer to the October 1987 Amitraz Registration Standard). Further, to remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current Agency regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

> "Only for formulation into an _____ [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s): _____ [fill blank only with those uses that are being supported by MP registrant]."

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 the support of such use(s)."

(b) "This product may b 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 the 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 Attachment 3 of Appendix D in the Combined Generic and 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

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10.

a. Occupational/Residential Labeling

Personal Protective Equipment Requirements for Pesticide Handlers (Mixers, Loaders, Applicators, Etc)

Sole-active-ingredient end-use products that contain amitraz must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain amitraz must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

- **Handler PPE for Occupational-Use Products** (products NOT intended primarily for home use -- (see text in PR Notice 93-7 and 93-11):

Minimum (Baseline) Personal Protective Equipment Requirements: The minimum (baseline) PPE requirements are:

For Pear Uses:

Applicators and other handlers must wear:
- coveralls over long-sleeve shirt and long pants,
- chemical-resistant footwear plus socks,
- chemical-resistant gloves*,
- chemical-resistant headgear for overhead exposure,
- chemical-resistant apron when cleaning equipment, mixing, or loading

For Cotton Uses:

Mixers, loaders, and others exposed to the concentrate must wear:
- coveralls over long-sleeve shirt and long pants,
- chemical-resistant footwear plus socks,
- chemical-resistant gloves*,
- chemical-resistant headgear for overhead exposure,
- chemical-resistant apron

Applicators and other handlers exposed to the dilute must wear:
- long-sleeve shirt and long pants
- chemical-resistant gloves*
- shoes plus socks

For Livestock Spray or Dip Uses:

Applicators and other handlers must wear:
- coveralls over long-sleeve shirt and long pants,
- chemical-resistant footwear plus socks,
- chemical-resistant gloves*,
- chemical-resistant headgear for overhead exposure,
- chemical-resistant apron when cleaning equipment, mixing, or loading**

For Livestock Impregnated Collar Uses:

Applicators and other handlers must wear:
- long-sleeve shirt and long pants
- chemical-resistant gloves*
- shoes plus socks

* The glove statement for amitraz is the statement established through the instructions in Supplement Three of PR Notice 93-7.
** The words "mixing, or loading" may be removed if the product is formulated as "ready-to-use."

Actual End-Use Product Personal Protective Equipment Requirements: The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) personal protective equipment, if any, 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 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.

- **Products Intended Primarily For Homeowner Use**

Personal Protective Equipment Requirements for Homeowners: The Agency is not establishing minimum (baseline) handler PPE for amitraz end-use products that are intended primarily for homeowner use. Personal protective equipment, if appropriate, will be established based on the acute toxicity of the end-use product.

Placement in Labeling: The personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

Entry Restrictions; Labeling

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

Multiple-active-ingredient end-use products that contain amitraz must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

- **Occupational-Use Products (Products NOT Intended Primarily For Home Use):**

Uses Within the Scope of the WPS:

Restricted-Entry Interval: A restricted entry interval (REI) is specified for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products (see tests in PR Notices 93-7 and 93-11). This REI must be inserted onto the revised labeling as required by Supplement Three of PR Notice 93-7.

For Pear Uses: The restricted-entry interval is 28 days.

For Cotton Uses: The restricted-entry interval requirement must state:

"Do not enter or allow workers entry into the treated area during the restricted-entry interval of 48 hours. Note: mechanical harvesting may be performed during the restricted-entry interval ONLY if the harvesters will have no dermal or inhalation contact with treated surfaces, including both the treated foliage and the residues in airborne dusts generated by the mechanical harvesting." Crop advisor may enter if they are wearing full early entry Personal Protective Equipment (PPE) described below.

Early-Entry Personal Protective Equipment (PPE):

For Pear and Cotton Uses:

The PPE required for early entry is:

- coveralls over long-sleeve shirt and long pants,
- chemical-resistant gloves,
- chemical-resistant footwear plus socks,
- chemical-resistant headgear for overhead exposures.

Placement in Labeling: The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early entry PPE statement required by Supplement Three of PR Notice 93-7.

Uses Not Within the Scope of the WPS:

No entry restrictions are being established for nonWPS uses.

Products Primarily Intended for Home Use:

No entry restrictions are being established for products intended primarily for home use.

b. Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing amitraz 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."

"For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas."

"For pear applications, allow a minimum of 35 days between applications."

"Do not rotate to root and leafy vegetables for 44 days or to small grains and other crops for 60 days following application."

Engineering Controls

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

"No human flaggers allowed. Mechanical flaggers are required."

"Cotton must be harvested mechanically. No hand harvesting is allowed."

"For pear uses, this product must be mixed and loaded using a closed system (water-soluble bags are considered a closed mixing/loading system) and the applicator must be inside an enclosed cab during application. The closed mixing/loading system and enclosed cab must meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-5)]. When these engineering controls are used correctly, the handler PPE requirements may be reduced or modified as specified in the WPS."

"For cotton uses, this product must be mixed and loaded using a closed system (water-soluble bags are considered a closed mixing/loading system). The closed mixing/loading system must meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-5)]. When these engineering controls are used correctly, the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist 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."

Notification Requirement for WPS Uses

"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."

Labeling for Fish and Wildlife Hazard

In order to remain in compliance with FIFRA, labels must bear the following in the **Precautionary Statements** section under the subheading **Environmental Hazards**:

- **End Use - Emulsifiable Concentrate and Wettable Powder Formulations**

"This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate."

- **MITAC WP label**

Additionally, for the MITAC WP label, revise the Directions for use to control pear psylla statement to include the following restrictions:

> PEAR PSYLLA: Apply a maximum of 1 1/2 pounds of amitraz per acre. Do not exceed 3 lbs of amitraz per acre per season. Do not make more than two applications of amitraz per season.

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. 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 amitraz products bearing old labels/labeling, i.e., labels absent the modifications specified in this RED document, except as noted below, for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED 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

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. Dose	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
The uses in Appdix 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 in this document.												
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
BEEF/RANGE/FEEDER CATTLE (MEAT)				Use Group: INDOOR FOOD								
Animal treatment (spray)., When needed., Sprayer.	EC	NA	.00753 lb. animal	*	NS	NS	NS	NS	10	NS		S09(0)
Animal treatment (spray-dip), When needed., Spray-dip machine.	EC	NA	.00753 lb. animal	*	NS	NS	NS	NS	7	NS		S09(0)
COTTON (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP								
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	.9994 lb. A	*	NS	NS	1 lb.	NS	NS	NS		C46, C47, GG3
Low volume spray (concentrate)., Foliar., Aircraft.	EC	NA	.9994 lb. A	*	NS	NS	1 lb.	NS	NS	NS		C46, C47, GG3
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	.9994 lb. A	*	NS	NS	1 lb.	NS	NS	NS		C46, C47, GG3
Ultra low volume., Foliar., Aircraft.	EC	NA	UC	*	NS	NS	1 lb.	NS	NS	NS		C46, C47, GG3
Ultra low volume., Foliar., Low volume ground.	EC	NA	UC	*	NS	NS	1 lb.	NS	NS	NS		C46, C47, GG3
DAIRY CATTLE (LACTATING OR UNSPECIFIED)				Use Group: INDOOR FOOD								
Animal treatment (spray)., When needed., Sprayer.	EC	NA	.00753 lb. animal	*	NS	NS	NS	NS	10	NS		F01(0), S09(0)
Animal treatment (spray-dip), When needed., Spray-dip machine.	EC	NA	.00753 lb. animal	*	NS	NS	NS	NS	7	NS		F01(0), S09(0)
Animal treatment (spray)., When needed., Sprayer.	EC	NA	UC	*	NS	4/1 yr	NS	NS	7	NS		C27, S09(3) H01(14)

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 /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
HOG/PIG/SWINE (MEAT)				Use Group: INDOOR FOOD									
Dip treatment., When needed., Not on label.	EC	NA	UC	*	NS	4/1 yr	NS	NS	NS	NS			C27, S09(3)
Enclosed premise treatment., When needed., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	7	NS			C27, S09(3)
PEAR				Use Group: TERRESTRIAL FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1.5 lb. A	*	NS	NS	3 lb.	NS	14	NS			C46, C47, C92, CAL, GC1, H01(14)
	WP	NA	1.5 lb. A	*	NS	NS	3 lb.	NS	14	NS			C46, C47, C92, GC1,
Low volume spray (concentrate)., Foliar., Aircraft.	EC	NA	1.5 lb. A	*	NS	NS	3 lb.	NS	14	NS			C46, C47, C92, CAL, GC1, H01(14)
	WP	NA	1.5 lb. A	*	NS	NS	3 lb.	NS	14	NS			C46, C47, C92, GC1, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1.5 lb. A	*	NS	NS	3 lb.	NS	14	NS			C46, C47, C92, CAL, GC1, H01(14)
	WP	NA	1.5 lb. A	*	NS	NS	3 lb.	NS	14	NS			C46, C47, C92, GC1, H01(14)
NON-FOOD/NON-FEED													
DOGS/CANINES (ADULTS/PUPPIES)				Use Group: INDOOR RESIDENTIAL									
Animal treatment (collar)., When needed., By hand.	IC/T	NA	.005456 lb. animal	*	NS	NS	NS	NS	NS	NS			

LEGEND

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)
Restr. Entry Interv (days)	: Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

EC	: EMULSIFIABLE CONCENTRATE
IC/T	: IMPREGNATED COLLAR/TAG
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
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C27 : Remove feed and water prior to treatment.
C46 : Do not apply through any type of irrigation system.
C47 : Do not enter treated areas without protective clothing until 24 hours after application.

LEGEND

444444

USE LIMITATIONS CODES (Con't)

C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.

CAL : Do not contaminate water, food or feed.

F01 : __ day(s) prefreshening interval.

GC1 : Do not graze treated areas.

GG3 : Do not feed treated vegetation to livestock.

H01 : __ day(s) preharvest interval.

S09 : __ day(s) preslaughter interval.

* 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 0234 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0234 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 Amitraz

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	00030051, 40650703
61-2A	**Start. Mat. & Mnfg. Process**	All	40650701
61-2B	**Formation of Impurities**	All	40650701
62-1	**Preliminary Analysis**	All	40650702
62-2	**Certification of limits**	All	40650703
62-3	**Analytical Method**	All	40650704, 40650705, 40650706
63-2	**Color**	All	40650707
63-3	**Physical State**	All	40650707
63-4	**Odor**	All	40650707
63-5	**Melting Point**	All	40650707
63-6	**Boiling Point**		Guideline waived
63-7	**Density**	All	40650707
63-8	**Solubility**	All	40650707, 41068401, 41068402
63-9	**Vapor Pressure**	All	40650707
63-10	**Dissociation Constant**	All	41068404
63-11	**Octanol/Water Partition**	All	40650707
63-12	**pH**	All	Not Applicable
63-13	**Stability**	All	41068403
63-14	**Oxidizing/Reducing Action**	All	42496001

Data Supporting Guideline Requirements for the Reregistration of Amitraz

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**	All	42496001
63-16	**Explodability**	All	42496001
63-17	**Storage stability**	All	41068403
63-18	**Viscosity**		Guideline Waived
63-19	**Miscibility**		Guideline Waived
63-20	**Corrosion characteristics**	All	42496001

ECOLOGICAL EFFECTS

Ecological Effects Footnotes

- Study citations without a letter preceding the study number identifies studies submitted for parent amitraz.
- The studies noted with a ("*") may be upgraded to core and will fulfill guideline requirements upon acceptable review of chemical analyses.
- Citations noted with a "(a)" after the study number, were submitted for amitraz degradate BTS 27271.
- Citations noted with a "(b)" after the study number, were submitted for amitraz degradate BTS 27919.
- (c) - This study for amitraz degradate BTS 27271 is reserved pending the results of the daphnia life-cycle study.
- (d) - This study is required as the EEC is greater than 0.01 of the EC_{50} for BTS 27271.

71-1A	**Acute Avian Oral - Quail/Duck**	A,B,C,H,L,O	00030451
71-1B	**Acute Avian Oral - Quail/Duck TEP**	A,B,C	42124602(a), 42124603(b)
71-2A	**Avian Dietary - Quail**	A,B,C,H,L,O	00030452, 00030453, 40780502 42124604(a) 42124605(b)
71-2B	**Avian Dietary - Duck**	A,B,C,H	00030453, 42124606(a) 42124607(c)
71-4A	**Avian Reproduction - Quail**	A,B,C	00072412,40840301, 42336001, 42797801(a)* 42797802(a)*
71-4B	**Avian Reproduction - Duck**	A,B,C	00072411, 42336002
72-1A	**Fish Toxicity Bluegill**	A,B,C	00030447, 00030448, 00030444 40798001

Data Supporting Guideline Requirements for the Reregistration of Amitraz

REQUIREMENT		USE PATTERN	CITATION(S)
72-1B	**Fish Toxicity Bluegill - TEP**	A,B,C	00030447, 00030448, 00030444 41827202(a) 41827205(b)
72-1C	**Fish Toxicity Rainbow Trout**	A,B,C,H,L,O	00030446, 00030445
72-1D	**Fish Toxicity Rainbow Trout- TEP**	A,B,C	00030445, 40780505, 41827203(a) 41827206(b)
72-2A	**Invertebrate Toxicity**	A,B,C,H,L,O	GS00234021
72-2B	**Invertebrate Toxicity - TEP**	A,B,C	40780506, 41827204(a) 41827207(b)
72-3A	**Estuarine/Marine Toxicity - Fish**	A,B,C	40780507, 40780508
72-3B	**Estuarine/Marine Toxicity - Mollusk**	A,B,C	GS00234022
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A,B,C	00030450
72-3D	**Estuarine/Marine Toxicity Fish - TEP**	A,B,C	40780508, 42124608(a) 42124609(b)
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	A,B,C	40780509, 42124610(a), 42124611(b)
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	A,B,C	40780510 42124612(a),42124613(b)
72-4A	**Early Life Stage Fish**	A,B,C	40798002, 41288702, footnote (c)
72-5	**Life Cycle Fish**	A,B,C	Guideline Waived for parent amitraz. Guideline Reserved for the two degradates of concern.
72-6	**Aquatic Org. Accumulation**	A,B,C	Guideline Waived for parent amitraz and the two degradates of concern.

REQUIREMENT		USE PATTERN	CITATION(S)
72-4B	**Life Cycle Invertebrate**	A,B,C	40780511, 41288701, footnote (d)
141-1	**Honey Bee Acute Contact**	A,B,C	00074486
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A	00041539
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A	00040862
81-3	**Acute Inhalation Toxicity - Rat**	A	00029963
81-4	**Primary Eye Irritation - Rabbit**	A	00040861
81-5	**Primary Dermal Irritation - Rabbit**	A	00040862
81-6	**Dermal Sensitization - Guinea Pig**	A	00029965
N/A	**Cholinesterase study in housefly**	A	00040324
82-1A	**90-Day Feeding - Rodent**	A	00028715
82-1B	**90-Day Feeding - Non-rodent (dog)**	A	00040345, 00028716
82-2	**21-Day Dermal - Rabbit**	A	00029972
83-1A	**Chronic Feeding Toxicity - Rodent**	A	00044585
83-1B	**Chronic Feeding Toxicity - Non-Rodent (dog)**	A	00044586
83-2A	**Oncogenicity - Rat**	A	00044585
83-2B	**Oncogenicity - Mouse**	A	00139552, 00111886
83-3A	**Developmental Toxicity - Rat**	A	00029959, 00029960
83-3B	**Developmental Toxicity - Rabbit**	A	00029961

Data Supporting Guideline Requirements for the Reregistration of Amitraz

REQUIREMENT		USE PATTERN	CITATION(S)
83-4	**2-Generation Reproduction - Rat**	A	00029962
84-2A	**Gene Mutation - Ames**	A	Acc.#s 161008, 161009, 161012, 253131
84-2B	**Structural Chromosomal Aberration**	A	41795101
84-4	**Other Genotoxic Effects**	A	Acc.#s 161010, 161011
85-1	**General Metabolism**	A	Acc.# 160964
85-2	**Dermal Absorption Study in Rats**	A	42133501, 43396801
86-1	**Domestic Animal Safety**	A	00041513, 00044591
----	**Special Studies**	A	Acc.# 160964
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	A	42496002
231	**Estimation of Dermal Exposure at Outdoor Sites**	A	42496003
232	**Estimation of Inhalation Exposure at Outdoor Sites**	A	42496002
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A	40780512, 42124616, 42124617
161-2	**Photodegradation - Water**	A	40780513, 41206703
161-3	**Photodegradation - Soil**	A	40780514, 41444204
162-1	**Aerobic Soil Metabolism**	A	40798003, 42124620
162-2	**Anaerobic Soil Metabolism**	A	40798003
162-3	**Anaerobic Aquatic Metabolism**	A	42124618, 42124622, 41444205

Data Supporting Guideline Requirements for the Reregistration of Amitraz

REQUIREMENT		USE PATTERN	CITATION(S)
163-1	**Leaching/Adsorption/Desorption**	A	Acc.# 248318, 00114299, 41206704 40780515, 40931501, 42124614, 42124615 42124620, 40780516
163-2	**Volatility - Lab**	A	40780518
164-1	**Terrestrial Field Dissipation**	A	40798004, 41637301
165-1	**Confined Rotational Crop**	A	42673901
165-2	**Field Rotational Crop**	A	40999509, 41637302
165-4	**Bioaccumulation in Fish**	A	00072503, 41444206, 42124623 40780519
201-1	**Droplet Size Spectrum**	A	Task Force Participant
202-1	**Drift Field Evaluation**	A	Task Force Participant
164-A-SS	**Glove Permeability Special Study**	A	Reserved
RESIDUE CHEMISTRY			
171-2	**Chemical Identity**	TGAI	GS00234015, GS00234016
171-3	**Directions for Use**	---	GS0023406, GS 0023415, GS0023416
171-4A	**Nature of Residue - Plants**	PAIRA and plant metabolites	00028664, 00028666, 00055718, 00161022 00161023, 40590601, 40590801, 40999502 41206701
171-4B	**Nature of Residue - Livestock**	PAIRA and plant metabolites	40811305, 40999503, 43287101
171-4C	**Residue Analytical Method - Plants**	TGAI and metabolites	00046030, 00051929, 00051930, 40811310 40811311, 40811312
171-4D	**Residue Analytical Method - Animal**	TGAI and metabolites	Same study numbers as listed above

Data Supporting Guideline Requirements for the Reregistration of Amitraz

REQUIREMENT		USE PATTERN	CITATION(S)
171-4E	**Storage Stability**	TGAI and metabolites	00046029, GS00234014, 40811308, 40811309 40999508
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Eggs**	TGAI or plant metabolites	
	Cattle		40811306, 40811307
	Poultry		40999504, 40999505
	Honey & Beeswax		41295501, 41295502, 41295503
171-4K	**Crop Field Trials**	TEP	00046029, 00051717, 43370301
	Pome Fruits Group- **Pears**		
	Misc. Commodities- **Cottonseed**		41444201, 41444202, 41444203
171-4L	**Processed Food**	TEP	
	Cottonseed		41478901, 414444202

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.

BIBLIOGRAPHY

MRID	CITATION
00028664	Lewis, D.K. (1970) RD 27 419, Plant Biochemistry Report No. 1: FM 70 158. (Unpublished study received Apr 9, 1980 under 43142-EX1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099371-A)
00028666	Somerville, L.; Spiers, M.J. (19??) BTS 27 419: Metabolism in Apple Leaves: AX 72 002. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099371-C)
00028712	Sutton, M.M.; Williams, G.A.H. (1973) BTS 27 419: 90-Day Toxicity Study in Rats: P71548; C44. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099365-A)
00028715	Shaw, J.W.; Williams, G.A.H. (1972?) BTS 27 419: 90-Day Chronic Toxicity Study in Mice: TX 74 016; C47. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099365-D)
00028716	Patton, D.S.G.; Williams, G.A.H. (19??) BTS 27 419: 90-Day Toxicity Study in Dogs: P71547; C48. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099365-E)
00029959	Sutton, M.M. (19??) BTS 27 419: Teratogenicity in the Rat: Report No. TX 73028. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099368-I)
00029960	Sutton, M.M. (19??) BTS 27 419: Effect on Pregnancy, Parturition and Care of the Young in Rats: Report No. TX 73031. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL: 099368-J)
00029961	Sutton, M.M. (19??) BTS 27 419: Teratogenicity in the Rabbit: Report No. TX 73029. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099368-K)
00029962	Sutton, M.M. (19??) BTS 27 419: Multigeneration Feeding Test in Rats: Report No. TX 73036. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099368-L)

BIBLIOGRAPHY

MRID	CITATION
00029963	Berczy, Z.S.; Binns, R.; Newman, A.J. (1972) Acute Inhalation Toxicity to the Rat of BTS 27419: Report No. 4971/72/406. (Unpublished study received Apr 9, 1980 under 43142-EX-1; prepared by Huntingdon Research Centre, submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099368-M)
00029965	Sutton, M.M. (1971) BTS 27 419: Contact Sensitisation sic in the Guinea Pig. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099368-O)
00029972	Sutton, M.M. (1977) BTS 27 419: Three Week Dermal Toxicity to Rabbits: Report No. TX 73026. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099368-V)
00030051	Boots Hercules Agrochemicals Company (19??) Chemical Information on Amitraz. (Unpublished study received Apr 9, 1980 under 43142-EX-1; CDL:099362-A)
00030444	Nissan Chemical Industries, Limited (1972) JA-119 (BTS-27419): Test on Fish Toxicity. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099369-B)
00030445	Fraser, W.D.; Jenkins, G. (1972) The Acute Toxicities of BTS 27419 (Tech) and BTS 27419 (20% E/C) to Rainbow Trout under Continuous Flow Conditions: 4880/72/315. (Unpublished study received Apr 9, 1980 under 43142-EX-1; prepared by Huntingdon Research Centre, submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099369-D)
00030446	Bentley, R.E. (1975) Acute Toxicity of Technical Amitraz to Rainbow Trout (Salmo gairdneri). (Unpublished study received Apr 9, 1980 under 43142-EX-1; prepared by Bionomics, EG&G, submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL: 099369-E)
00030447	Fraser, W.D.; Jenkins, G. (1973) The Acute Toxicities of Technical and Formulated BTS 27419 to Blue Gill (Lepomis macrochirus): BTS/73116. (Appendix 4; unpublished study received Apr 9, 1980 under 43142-EX-1; prepared by Huntingdon Research Centre, submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099369-F)

BIBLIOGRAPHY

MRID	CITATION
00030448	Fraser, W.D.; Jenkins, G. (1973) The Acute Toxicities of Technical and Formulated BTS 27419 to Harlequin Fish (Rasbora heteromorpha) under Continuous Flow Conditions: BTS/73117. (Appendix 5; unpublished study received Apr 9, 1980 under 43142EX-1; prepared by Huntingdon Research Centre, submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099369-G)
00030450	Bentley, R.E. (1973) Acute Toxicity of BTS-27419 Technical to Grass Shrimp (Palaeomonetes vulgaris) and Fiddler Crab (Uca pugilator). (Appendix 7; unpublished study received Apr 9, 1980 under 43142-EX-1; prepared by Bionomics, Inc., submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL: 099369-I)
00030451	Fink, R. (1976) Final Report: Acute Oral LD50--Bobwhite Quail: Project No. 137-105. (Unpublished study including unofficial analytical report, received Apr 9, 1980 under 43142-EX-1; prepared by Truslow Farms, Inc., submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099369-J)
00030452	Ross, D.B.; Roberts, N.L. (1973) The Acute Toxicity (LC50) of BTS 27 419 to Mallard Duck: BTS/73497. (Appendix 9; unpublished study received Apr 9, 1980 under 43142-EX-1; prepared by Huntingdon Research Centre, submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099369-K)
00030453	Ross, D.B.; Roberts, N.L. (1973) The Acute Toxicity (LC50) of BTS 27 419 to Japanese Quail: BTS/73498. (Appendix 8; unpublished study received Apr 9, 1980 under 43142-EX-1; prepared by Huntingdon Research Centre, submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099369-L)
00030455	Palmer-Jones, T.; Clinch, P.G. (1973) Effect on honey bees of BTS 27419 applied as a spray to apple trees. New Zealand Journal of Experimental Agriculture 1(?):195-196. (Also~In~unpublished submission received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL: 099369-N)
00040323	Merryman, D.C.; Sutton, M.M. (1972) BTS 27 419 Effects on the Oestrus Cycle of the Rat: PM72003. (Unpublished study received Oct 7, 1974 under 5G1558; submitted by Upjohn Co., Kalamazoo, Mich.; CDL:094252-R)
00040324	Lewis, D.K. (1970) Anticholinesterase Activity of RD 27,419, a Promising Acaricide, and Some Derivatives. (Unpublished study received Oct 7, 1974 under 5G1558; prepared by Boots Pure Drug Co., Ltd., submitted by Upjohn Co., Kalamazoo, Mich.; CDL: 094252-S)

BIBLIOGRAPHY

MRID	CITATION
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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 Registrant:

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 Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. 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 and 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 Registrant'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 Registrant'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 Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and 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 Registrant'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:

1a - Product Specific Data Call-In Chemical Status Sheet
1b - Generic 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 (with Instructions), and Cost Share and Data Compensation Forms

1a. PRODUCT SPECIFIC DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 0234. 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 (7) the Cost Share and Data Compensation Forms in replying to this 0234 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 amitraz are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on amitraz 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 amitraz products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of amitraz, please contact Mario F. Fiol at (703) 308-8049.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact CP Moran at (703) 308-8590.

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

CP Moran, Chemical Review Manager
Product Reregistration Branch
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: **0234**

1b. GENERIC DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing 0234.

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 0234. 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 4), (5) and (6) the Cost Share and Data Compensation Forms in replying to this 0234 Generic Data CallIn (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for 0234 are contained in the Requirements Status and Registrant's Response, Attachment C.

The Agency has concluded that additional product chemistry data on 0234 are needed. These data are needed to fully complete the reregistration of all eligible 0234 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 (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: 0234

2. 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.

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.**

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.

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3. 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.

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

4. EPA'S BATCHING OF PRODUCTS CONTAINING AMITRAZ AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Amitraz, the Agency has batched products which can be considered similar in terms 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. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statment of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must

select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batch for the active ingredient amitraz.

Table 1.

EPA Reg. No.	Active Ingredient	Formulation Type
54382-4	Amitraz ... 10.0%	collar
54382-5	Amitraz ... 10.0%	collar

Table 2 lists those products the Agency was unable to batch. These products were either considered not to be similar to other products for purposes of acute toxicity or the Agency lacked sufficient information for decision making. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Table 2.

EPA Reg. No.	Active Ingredient	Formulation Type
2382-104	Amitraz ... 9.0%	collar
45639-49	Amitraz ... 19.8%	liquid
45639-51	Amitraz ... ≥97%	solid
45639-61	Amitraz ... 50.0%	solid
45639-146	Amitraz ... 19.8%	liquid
54382-3	Amitraz ... 12.5%	liquid

5. LIST OF 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)

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

LIST OF AVAILABLE RELATED DOCUMENTS

The following is a list of available documents related to 0234. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for 0234 and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. 0234 RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement