United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-004 January 1995

Reregistration Eligibility Decision (RED)

Fosamine ammonium

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 fosamine ammonium. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

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 Frank Rubis at (703) 308-8184. Address any questions on required generic data to the Special Review and Reregistration Division representative Shanaz Bacchus at (703) 308-8065.

Sincerely yours,

Louis P. True, Jr., Acting 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. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); 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 date of this letter (RED issuance date).**

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

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified

limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

Fosamine Ammonium

LIST B

CASE 2355

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

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FOSAMINE AMMONIUM REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

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George Keitt	Biological Analysis Branch
Steve Jarboe	Biological Analysis Branch

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
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

GLOSSARY OF TERMS AND ABBREVIATIONS

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
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
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level

GLOSSARY OF TERMS AND ABBREVIATIONS

OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Agency has conducted risk assessments of the current uses of fosamine ammonium pesticide products and has determined that those uses of fosamine ammonium, as specified in this document, will not cause unreasonable risk to humans or the environment, and are eligible for reregistration.

Fosamine ammonium is a herbicide/plant growth regulator that is used for brush control of nonagricultural rights-of-way (e.g., highways, railroads, and utilities), industrial sites, and fencerows. The pesticide can be applied once from spring to early fall by aircraft, backpack or handwands. It is prohibited from use in irrigation systems. When the pesticide is applied in one year, its brush control effects are achieved by inhibiting bud growth the year following the application. Fosamine ammonium is not registered for application to croplands and soils treated with this herbicide cannot be converted to food/feed croplands within one year of treatment. According to the current label, fosamine ammonium is not registered for sale or use in California and Arizona. A product registered for forest planting sites has been canceled (June 22, 1994), and the current uses on aquatic sites are being voluntarily deleted from the sole product registration.

The health and environmental effects data bases indicate a low level of toxicity of this pesticide. Fosamine ammonium is not very persistent and degrades rapidly in most soils. Data provided to support estimates of acute and chronic exposure and risks to mammalian species, other vertebrates and invertebrates are sufficient for reregistration purposes.

Fosamine ammonium is currently classified as a Toxicity Category II chemical on the basis of acute dermal toxicity studies in mammalian species. Adequate data have been submitted in support of worker exposure. There are no special toxicological concerns for this plant growth regulator which warrant the establishment of minimum or baseline active-ingredient-based personal protective equipment (PPE) for handlers.

The Agency is requiring the submission of additional generic data to confirm its scientific conclusions for fosamine ammonium. These confirmatory data requirements include (i) method validation for a worker exposure study; (ii) certification of limits of the technical grade active ingredient; (iii) a cytogenetics assay; (iv) spray drift characterization; (v) an avian reproduction study in mallards; and (v) data or further information to clarify effects on non-target plants.

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

determined to be eligible for reregistration.

I. INTRODUCTION

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

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

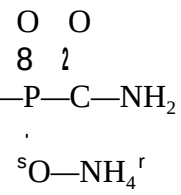
This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of fosamine ammonium. The document consists of six sections. Section I is the introduction. Section II describes fosamine ammonium, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for fosamine ammonium. Section V discusses the reregistration requirements for fosamine ammonium. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** fosamine-ammonium
- **Chemical Name:** ammonium ethyl carbamoylphosphonate
- **Chemical Family:** organophosphonate subclass of organophosphate
- **CAS Registry Number:** 25954-13-6
- **OPP Chemical Code:** 106701
- **Empirical Formula:** $C_3H_{11}O_4N_2P$
- **Structural Formula:**



- **Molecular Weight:** 170.11
- **Basic Manufacturer:** E. I. Du Pont de Nemours and Co., Inc.
- **Trade Name:** Krenite®

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of these uses of fosamine ammonium is in Appendix A.

Type of Pesticide: brush control agent, plant growth regulator.

Use Sites:

Terrestrial nonfood crop

Nonagricultural uncultivated areas (campgrounds; industrial areas, outdoor)

Nonagricultural rights-of-way (highway, railroad, pipeline, utility)

Aquatic nonfood industrial

ditch banks, areas adjacent to and surrounding domestic water supply, reservoirs, supply streams, lakes and ponds

All data in support of these aquatic nonfood industrial sites are analyzed in this RED document, and all outstanding data to support the continued registration of these sites are listed in this RED document. The Agency is processing the registrant's request to amend the label to delete these use sites. If, in the future, the registrant wishes to register aquatic sites, the registrant will have to resubmit all data to support those uses.

Target Pests: control of undesirable brush/herbaceous plant species, which include american elder, basswood, bigleaf maple, birch, blackberry, black cherry, blackgum, black locust, bracken, chinese tallow, chokecherry, eastern cottonwood, eastern pine, elm, field bindweed, hawthorn, hickory, leafy spurge, loblolly pine, multiflora rose, persimmon, pin cherry, quaking aspen, red alder, red maple, red oak, salmonberry, slippery elm, sassafras, sourwood, sumac, sweetgum, sycamore, thimbleberry, tree-of-heaven, tuliptree, vine maple, virginia pine, water oak, white ash, white oak, wild grape, wild plum, winged elm, and willow.

Formulation Types Registered: Water-soluble liquid

Method and Rates of Application:

Equipment - open pour, mix/load, high pressure handwand, backpack, aerial, ultra low-volume equipment.

Method and Rate - Open pour, mix/load; 6 lb ai/A to 24 lb ai/A

Timing - Applied during period from full leaf in spring to first fall coloration.

Use Practice Limitations: Do not apply directly to water, or areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Do not use on food crops. If areas previously treated with fosamine ammonium are converted to cropland, do not plant food crops or graze livestock within 1 (one) year of treatment. However, nonfood/feed plants such as wild flowers and native grasses, may be planted at any time after treatment on the sites listed above.

Do not apply through irrigation system.

Do not cut treated brush until stems are dead, or sprouting may occur.

Not registered for sale or use in California and Arizona on the current registered label.

C. Data Requirements

Data required in the Data Call-In (DCI) Notice (9/30/91) for fosamine ammonium included studies on ecological effects, environmental fate, product chemistry, toxicology and occupational and residential exposure. These data were required to support the registered uses. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

D. Regulatory History

Fosamine ammonium was first registered on July 7, 1975, under EPA Registration No. 352-376 (Du Pont Krenite® Brush Control Agent). It was registered for non-cropland (non-food) use areas such as railroads, pipeline, utility and highway right-of-ways, reforestation areas, drainage ditch banks, storage areas, industrial plants sites, and other similar sites. However, the registrant requested voluntary cancellation of this product which was effective on June 22, 1994.

A second product, (EPA Reg. No. 352-395), was registered on May 2, 1980. Currently, this product is registered under two trade names, Du Pont Krenite® S Brush

Control Agent and Du Pont Krenite® UT Brush Control Agent. This formulated product also contains 41.5% active ingredient, ammonium salts of fosamine. The uses, except for forest planting sites, are the same as for the original product.

On August 23, 1994, Du Pont filed an Application for Amended Registration, requesting voluntary cancellation of direct applications to water, ditchbanks, and to other sites which are adjacent to and surrounding domestic water, supply reservoirs, supply streams, lakes and ponds. The Agency is processing this request, which includes publishing a Notice of Intent to delete these uses in the Federal Register. There will be a ninety (90) day comment period. Because there are no other current registrants and there are outstanding environmental data requirements to support continued registration of these uses, the Agency does not anticipate Du Pont or any other party choosing to retain these uses. Therefore, the Agency presumes that these sites will be deleted from the current label by late 1994.

For this reason and the fact that there are outstanding data requirements for these sites, the Agency has excluded the risk assessment of aquatic sites in its decision to reregister fosamine ammonium. Consideration of the aquatic uses for future registration must include all applicable data requirements.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Fosamine ammonium is a monoammonium salt of phosphonic acid containing an aminocarbonyl group and a monoethyl ester. It is formulated as a soluble concentrate liquid end-use product (EP) containing 41.5% of the active ingredient (a.i.). Technical fosamine ammonium exhibits the following characteristics:

Color	white
Physical State	crystalline solid
Odor	alcoholic
Melting Point	173-175°C (decomposition)
Density, Bulk density or specific gravity	1.24 g/ml at 25°C

Solubility	completely miscible in water; less than 1 ppm in methylene chloride, ether, hexane, toluene 1 ppm in acetone 2 ppm in acetonitrile. 17 g/100 ml in methanol.
Vapor pressure	4×10^{-6} mm Hg at 25°C
Octanol/water partition coefficient	$K_{ow} = 0.0012$
pH	5.79 for 1% solution (w/v) at 25°C
Stability	stable at 25°C and 55°C, stable in the presence of metal (iron) and metal ions (ferric chloride) and to sunlight for at least two weeks.

B. Human Health Assessment

Below is a summary of the toxicology and occupational and residential exposure data bases reviewed by the Agency for the purpose of determining the reregistration eligibility of fosamine ammonium. Data bases for chronic feeding studies, carcinogenic, metabolic and reproductive toxicological endpoints are conditionally required for the current use pattern of the pesticide, under conditions specified in 40 CFR §158.340.

1. Toxicology Assessment

a. Acute Toxicity

Acute studies for oral, dermal, and inhalation endpoints, which were based on a 42% technical grade active ingredient (TGAI), demonstrated low potential toxicity for fosamine ammonium. For the RED, oral, dermal and inhalation exposures were evaluated on the basis of the Toxicity Categories IV, II and IV, respectively, as shown in Table I. Similarly, studies with the 42% formulation indicated low potential for

primary dermal irritation and primary eye irritation. Fosamine ammonium does not appear to be a dermal sensitizer. All data requirements for acute oral, dermal, inhalation, dermal irritation and eye irritation toxicological endpoints are satisfied.

There were no clinical signs of acute delayed neurotoxicity observed in hens at doses of 2000 mg/kg/day. However, there were some perineural lymphoid proliferations of the tibial nerve in both the positive control and treated group, but not in the vehicle control group. Although these proliferations may be unrelated to the degenerative changes observed in the positive control group, their presence in both treated and control groups indicates equivocal results (MRID 42934801).

In an acute mammalian neurotoxicity study, rats were dosed by gavage with 0, 500, 1000 or 2000 mg/kg/day of fosamine ammonium. The systemic NOEL from this study was considered to be 500 mg/kg, while the LEL, based on diarrhea, was 1000 mg/kg. Possible neurotoxic effects were observed, but not statistically significant at 1000 and 2000 mg/kg. These were slight palpebral closure, irregular respiration, both observed in the open arena. Ample positive control data were provided on amphetamine, acrylamide, carbaryl and DDT.

Table 1: Acute Toxicity

TEST	MRID	RESULTS	CATEGORY
Acute Oral	00075735 00026825	LD_{50} (rat): 24,400 mg/kg	IV
Acute Dermal	00075733	LD_{50} (rabbit): >1682 mg/kg (HDT)	II
Acute Inhalation	00030774 00075734 00078990	LC_{50} (rat): >56.6 mg/L air (male), >42.0 mg/L air (female)	IV
Primary Eye Irritation	00075738	Low potential (rabbit)	-
Primary Dermal Irritation	00075733 00026826	Low potential (rabbit)	-
Dermal Sensitization	00075737	Not a sensitizer under conditions of study	-
Acute delayed neurotoxicity	42934801	Perineural lymphoid proliferations. Results equivocal until resolved.	-
Acute mammalian neurotoxicity	42946501	NOEL: 500 mg/kg; LEL 1000 mg/kg. Increases in palpebral closure (non-statistical), irregular respiration.	-

b. Subchronic Toxicity

Subchronic oral studies

Subchronic feeding data are only conditionally required for the fosamine ammonium use pattern if the intended use is expected to result in human exposure to the product via the oral route and if the expected exposure is over a limited portion of the human lifespan, yet is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure. Due to concern for potential drinking water contamination from the use of fosamine ammonium around reservoirs, subchronic feeding data in two species were required. Both subchronic feeding studies in rodents (MRID 00075736) and nonrodents (MRID 42867001) deviate somewhat from the guidelines. However, the combined data from the two studies are sufficient to fulfill the regulatory requirement for subchronic feeding data.

Fosamine ammonium was tested in a 90-day feeding study in rats at 0, 200, 1000 or 5000/10000 ppm in the diet (0, 10, 50, 250 or 500 mg/kg/day). At the highest dose level, the animals received 5000 ppm for 8 weeks and then 10000 ppm for weeks 9 through 13. The NOEL is 200 ppm. The LOEL is 1000 ppm based on: (a) swollen deep proximal convoluted tubules of the kidney in males at 1000 ppm and above, and (b) on vacuolated and degeneratively affected deep proximal convoluted tubules of the kidney, epithelial hyperplasia of the urinary bladder and slight decreases in body weight, body weight gain and food consumption in males at 5000/10000 ppm. The biological meaning of the kidney effects is unknown. Although this study was accepted, it was considered incomplete because of (i) the lack of data on dietary analyses; (ii) lack of individual animal data for clinical signs, body weight, food consumption and organ weights; (iii) the small number of tissues microscopically examined; and (iv) the lack of adequate examination of the low- and mid-dose animals (MRID 00075736).

In another subchronic feeding study, fosamine ammonium was fed to dogs for 6 months at 0, 200, 1000 or 5000/7500/10000 ppm (0, 5, 25 and 125 or 187.5 or 250 mg/kg/day). At the highest dose level, the dogs received 5000 ppm for the first week and 7500 ppm for the second and third weeks. Beginning at the fourth week, the dogs received 10000 ppm in the diet. Four males and four females were tested at each dose level. There was a statistically significant increase in serum glucose in high-dose female dogs when compared to controls at 2 and 6 months. This increase was attributed to the values from one dog in the group. No other treatment-related effects were observed. The NOEL is 5000/7500/10000 ppm (HDT). Although this study was accepted, it is considered somewhat incomplete because the dogs were 14-16 months old at the start of the study, rather than 4-9 months old, and therefore, the effects on young animals could not be evaluated in the study (MRID42867001). Nevertheless, results from these two studies are sufficient to characterize the potential subchronic toxicity from mammalian oral exposure to the pesticide.

Subchronic Dermal

An acceptable 21-day dermal study is available. In this study, fosamine ammonium was tested in male and female rabbits at 0, 50, 500 or 1500 mg/kg/day. The test material was applied as a paste in deionized water for 6 hours/day for 21 or 22 consecutive days. Intermittent minimal dermal irritation was observed in all groups in both male and female rabbits. Although mild erythema was observed more often in the test

groups than in the controls, it was not clearly related to exposure to the test material. The NOEL is therefore considered to be 1500 mg/kg/day (HDT) (MRID 41998101).

Subchronic mammalian neurotoxicity

In a subchronic mammalian neurotoxicity study in rats, fosamine ammonium was tested at 0, 5000, 10000 or 20000 ppm in the diet for 96-98 days (calculated to be 299, 604 or 1193 mg/kg/day for males and 398, 779 or 1567 mg/kg/day for females). The NOEL for systemic effects is below 299 mg/kg/day. The LEL is 299 mg/kg/day, based on diarrhea in males at all dose levels and in females at 1567 mg/kg/day in females. There were no neurotoxic effects at any dose level. Ample positive control data were provided on amphetamine, acrylamide, carbaryl and DDT. These data were considered acceptable (MRID 42946502).

c. Developmental Toxicity

Fosamine ammonium was tested in Crl:CD®BR rats at the following dose levels: 0, 50, 350, 1000 or 3000 mg/kg/day. The test material was administered by gavage on days 7-17 of gestation. The maternal NOEL is 1000 mg/kg/day and the maternal LEL is 3000 mg/kg/day based on clinical signs of toxicity (diarrhea) and on decreases in body weight gain and food consumption during the dosing period. The developmental NOEL is 3000 mg/kg/day (HDT) (MRID 42320901).

d. Mutagenicity

Mutagenicity studies include: (1) gene mutation assay in S. typhimurium (MRID 41891601); (2) CHO/HGPRT assay for gene mutation (MRID 00148267); (3) in vivo bone marrow cytogenetic assay in rats (MRID 00147636); (4) in vitro assay for chromosome aberrations in Chinese hamster ovary (CHO) cells (MRID 00147635); and (5) unscheduled DNA synthesis/rat hepatocytes in vitro (MRID 00147634).

All of the studies were classified as acceptable except for the unscheduled DNA synthesis study (UDS) in rat hepatocytes, which was not tested at high enough dose levels. The in vitro assay for chromosome aberrations in CHO cells was strongly positive, whereas all the other four assays were negative. Although the UDS study was classified as unacceptable, according to the new mutagenicity testing requirements, the basic regulatory requirement for a mutagenicity battery is satisfied by the

studies that were conducted. The new battery consists of the following studies: a gene mutation assay in S. typhimurium, an in vivo bone marrow cytogenetic assay, and a mouse lymphoma assay or a CHO/HGPRT assay for gene mutation in conjunction with an in vitro assay for chromosomal aberrations in Chinese hamster ovary (CHO) cells. These studies have already been conducted. The basic mutagenicity study battery requirements are fulfilled. However, clastogenic (chromosome breakage) effects in the Tier I studies trigger the need for additional confirmatory data. Based on the strong clastogenic effect in the cultured CHO cells, the Agency requires additional testing with germ cells as a follow-up, confirmatory study. This testing requirement can be satisfied with such assays as an in vivo cytogenetics assay in spermatogonia/spermatocytes or a micronucleus assay with spermatids.

(i) Gene mutation assay in S. typhimurium

Fosamine ammonium was tested for the potential to induce reverse mutations in Salmonella typhimurium strains TA97, TA98, TA100 or TA1535 using the plate incorporation assay, both with and without metabolic activation. The dose levels selected ranged from 10 to 5000 µg/plate. The results were negative.

(ii) CHO/HGPRT assay for gene mutation

Krenite (41.5% formulation) was tested for the potential to induce forward mutations in Chinese hamster ovary cells (CHO/HGPRT assay) up to levels of cytotoxicity, both with and without metabolic activation. Krenite was not mutagenic in this assay.

(iii) Cytogenetic assay

Single oral doses of Krenite (0, 1, 3 or 10 grams/kg) were administered by gavage in rats in an in vivo bone marrow study. Krenite did not induce an increase in the frequency of chromosomal aberrations at any dose level.

Chromosome aberrations in Chinese hamster ovary (CHO) cells

In an in vitro assay for chromosome aberrations in Chinese hamster ovary (CHO) cells, Krenite was tested at levels up to cytotoxicity. Statistically significant, dose-related increases in structural chromosome

aberrations were observed at 16.7 and 33.3 µL/ml Krenite in nonactivated cultures, as well as at 15, 30 or 33.3 µL/ml in S-9 supplemented cultures. Under the conditions of the assay, Krenite was clastogenic both with and without metabolic activation. Chromosome breakage was observed at final concentrations (v/v, in medium) of Krenite equivalent to:

1.4%, 2.8%, or 5.7% (with metabolic activation);
1.6% or 3.2% (without metabolic activation)

Unscheduled DNA synthesis/rat hepatocytes in vitro.

To determine unscheduled DNA synthesis, the EP was tested in an in vitro assay in rat hepatocytes at 8 halflog concentrations ranging from 1×10^{-5} mM to 10 mM. There was no positive response in two separate trials for induction of unscheduled DNA (repair) synthesis as judged by a net increase of 5 silver grains or more per nucleus. In these assays, the EP tested negatively for UDS induction in rat hepatocytes. However, 10 mM (the highest dose tested) is equivalent to 1.7 mg product/ml or 0.88 mg a.i./ml. The limit dose for this assay is 5 mg ai/ml. Therefore, the study was not conducted at a sufficiently high dose level for an adequate negative result.

e. Reference Dose

There is no food use pattern for fosamine ammonium. For potential future food use, the Reference Dose (RfD) is 0.01 mg/kg/day, based on the NOEL of 10 mg/kg/day from the rat subchronic study with an uncertainty factor of 1000.

2. Exposure Assessment

a. Dietary Exposure

Since there are no registered food uses for fosamine ammonium, no dietary exposure is expected. Dietary exposure data are not required.

b. Occupational and Residential

There is a potential for handler exposure to the herbicide during open/pour mixing and loading, and applications by air, backpack and high pressure/volume hand wands. Fosamine ammonium is a Toxicity Category II chemical for acute dermal exposure (LD_{50} > 1682 mg/kg). The other

toxicological endpoint which was used in this assessment is Toxicity Category IV for acute inhalation toxicity (see Table 1).

Mixer/Loader/Applicator (Handler) Exposure:

Chemical specific mixer/loader/applicator data have been submitted to EPA. Estimates of the units of daily dermal and inhalation handler exposure were obtained from MRID No. 42598101 and the Pesticide Handlers Exposure Database (PHED ver. 1.01). Exposure scenarios are presented in Table 2 along with the corresponding exposure assessment. M/L/A exposure estimates are based on the use of the fosamine ammonium end-use-products (EP) at the maximum label rates.

The daily maximum acreages treated are assumed to be: 2 acres by backpack, 10 acres by high pressure handwand, and 350 acres by air. Worker exposure estimates are based on the assumption that workers wear long pants, long sleeve shirt, shoes, and socks, and no gloves, except for workers using backpacks (Scenario V) who are assumed to wear chemical resistant gloves.

The major route of worker exposure is dermal which is estimated to range from 0.3 mg/kg to 9.0 mg/kg during an eight hour work day. Inhalation exposure for the same time frame is estimated to be negligible.

Table 2. Worker Exposure Values for Fosamine Ammonium

Exposure Scenario (Scen. #)	Dermal Exposure[a] (mg/lb a.i.)	Inhalation Exposure[b] (Fg/lb a.i.)	Maximum Label Application Rate (lb a.i./Acre)	Daily Dermal Exposure[c] (mg/kg/day)	Daily Inhalation Exposure (mg/kg/day)
Mixer/Loader Exposure					
Open Mixing Liquids, High Pressure Handwand Application (I-a)	0.15	0.4	24	0.5	0.001
Open Mixing Liquids, Fixed-Wing Aerial (I-b)	0.15	0.4	12	9.0	0.02
Applicator Exposure					
High Pressure Handwand Application[d] (II)	0.8 (avg.)	6.2 (avg)	24	2.7	0.02
Fixed-Wing Aerial[e] (III)	0.005	0.2	12	0.3	0.01
Backpack[f] (IV)	1.3	30	12	0.4	0.01

[a] Dermal unit exposures are reported as the best fit mean, unless noted. The best fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types.

[b] Inhalation exposure values are reported as geometric means (lognormal distributions).

[c] Daily Exposure (mg/kg/8 hr day) =

$$\frac{\text{Exposure (mg/lb a.i.) X Max. Appl. Rate (lb a.i./acre) X Max. Treated}}{\text{70 kg}}$$

[d] Rights-of-way, high pressure handwand sprayer at 100 to 300 psi.

[e] All cab types.

[f] Two gallon knapsack

Postapplication Exposure

Postapplication/reentry and residue dissipation data are not required in support of the current fosamine ammonium use patterns.

3. Risk Assessment

a. Dietary

There are no registered food uses for fosamine ammonium. A dietary risk assessment is not required for the current fosamine ammonium use pattern.

b. Occupational and Residential

Fosamine ammonium is considered to be in Toxicity Category IV for acute oral and inhalation toxicity, and Category II for acute dermal toxicity. The dermal effects observed in rabbits and guinea pigs after acute or subchronic dermal exposure at the highest doses tested were either intermittent dermal irritation or at most mild erythema. Currently, there are no toxicity concerns for short term (1 to 7 days) or intermediate term (1 week to several months) occupational exposure. The NOELs identified in the rat acute neurotoxicity study (500 mg/kg), the developmental toxicity study (3000 mg/kg/day) and the 21 day dermal study (1500 mg/kg/day) were very high and thus trigger no risk concern based on expected exposure.

For this use pattern of fosamine ammonium, the estimated exposure of commercial mixer/loader/applicators is likely to reflect the worse case scenario. However, there are no known significant acute or chronic toxicological endpoints that warrant the establishment of risk mitigation measures to any category of handlers of the pesticide. Clothing as described in the exposure assessment will provide adequate protection to handlers.

C. Environmental Assessment

1. Environmental Fate

Available environmental fate data support a qualitative environmental fate assessment of fosamine ammonium. Fosamine ammonium dissipation is predominantly dependent on rapid, microbial mediated degradation. Major degradates of fosamine ammonium are carbamoylphosphonic acid (CPA), carboxylphosphonic acid (ING-3003), and carbon dioxide (CO_2). However, no definitive environmental fate data are available for CPA and ING-3003. Additionally, this environmental fate assessment excludes the aquatic sites, due to

the lack of applicable data, namely aerobic aquatic and aquatic field dissipation studies, and the registrant's desire to remove them from the product label.

a. Environmental Chemistry, Fate and Transport

(1) Hydrolysis

Fosamine ammonium is stable to hydrolysis. Radiolabeled fosamine ammonium, at 9.2 to 10.3 µg/ml, did not hydrolyze in sterile, buffer solutions at pH 5,7, and 9 (MRID 40133701).

(2) Photodegradation in water, soil and air

Radiolabeled fosamine ammonium also did not photodegrade in irradiated pH 9 buffer solution and Keyport silt loam soil. The requirements for photodegradation in water and soil have been satisfied. The data to support the photodegradation in air were waived because fosamine ammonium volatilization from soil does not appear to be a major route of dissipation. Fosamine ammonium also has a low vapor pressure of 4.6×10^{-6} mm Hg as reported in MRIDs 40133702 and 40133703.

(3) Aerobic and anaerobic soil metabolism

Fosamine ammonium dissipation is predominantly dependent on rapid, microbial-mediated degradation. Radiolabeled fosamine ammonium, at 10 µg/g, had a first-order degradation half-life of 0.5 days ($k = 1.441$ days^{-1}) in an aerobic Delaware silt loam soil. Supplemental soil metabolism data indicate fosamine ammonium had a half-life of 1.2 weeks in aerobic silt loam and sandy loam soil. Degradates of fosamine ammonium were CPA (94 percent of applied immediately posttreatment), IN-G3003 (26 percent of applied 1 month posttreatment), and CO_2 (33 percent of applied).

Radiolabeled fosamine ammonium had a half-life of 4 days in anaerobic sediment and pond water from Meyersville, Maryland. Radiolabeled fosamine ammonium was stable in sterile, anaerobic sediment and water samples. Degradates of fosamine ammonium were CPA (59 percent of applied at 14 days posttreatment), ING-3003 (43 percent of applied at 9 months posttreatment), and CO_2 (7.6 percent of applied) (MRIDs 42060601, 42724301, 42060602, 42680701).

(4) Anaerobic aquatic metabolism

Data indicate fosamine ammonium degradation in anaerobic environments is a rapid, microbial-mediated process. Anaerobic aquatic studies provide marginally acceptable data on the metabolism of fosamine ammonium in anaerobic aquatic environments.

As described above in the section on anaerobic soil metabolism, radiolabeled fosamine ammonium, at 10 µg/g, had a half-life of 4 days ($k = 0.156$ $days^{-1}$) in Meyersville, MD sandy loam sediment and pond water. Fosamine ammonium was stable in sterile sediment and pond water. Radiolabeled residues in sediment extracts were parent fosamine ammonium (104 percent of applied immediately posttreatment), carbamoylphosphonic acid (59 percent of applied fosamine ammonium at 14 days posttreatment), and carboxylphosphonic acid (43 percent of applied fosamine ammonium at 9 months posttreatment). Radiolabeled residues in the potassium hydroxide traps were identified as CO_2 (7.6 percent of applied fosamine ammonium at 12 months posttreatment). Radiolabeled residues were also detected (less than 15 percent of applied fosamine ammonium) in nonextractable sediment organic matter. The anaerobic aquatic metabolism data requirement is satisfied (MRIDs 42060602 and 42680701).

(5) Leaching and adsorption/desorption

Based on limited data, fosamine ammonium appears to be very mobile in sandy loam soil. A batch equilibrium study provides acceptable data on the binding affinity of fosamine ammonium in sandy loam soil. The reported data indicate that fosamine ammonium should be very mobile in sandy loam soil, with a Freundlich adsorption coefficient of 0.066 ml/g ($1/n = 0.8603$; $Koc = 8.087$ ml/g). A simple desorption coefficient (K_{des}) was greater than 16 ml/g.

Although the unaged portion of the batch equilibrium/soil column leaching is not fulfilled at this time, the weight of evidence from acceptable and supplemental mobility data indicate that fosamine ammonium has a very low binding affinity to sandy loam and silt loam textured soils. No additional mobility data are needed to assess the mobility of fosamine ammonium (parent) at this time. The aged residues portion of the Guideline 163-1 data requirement, to address mobility of the individual degradates, has not been satisfied (MRIDs 42492401, 42492301).

(6) Field volatility

Fosamine ammonium has a low vapor pressure (4.6×10^{-6} mm Hg). Therefore, the data requirement for a field volatility study (Guideline 163-3) was

waived because fosamine ammonium volatilization from soil does not appear to be a major route of dissipation.

(7) Terrestrial field dissipation

Fosamine ammonium rapidly dissipates in the field. Acceptable field dissipation data indicate fosamine ammonium, at 24 lbs a.i./A in 0-15 cm surface soil, had a half-life of 1 day (Lexington, TN), 1 day (Newark, DE) and 5 days at Fayetteville, NC. Fosamine ammonium was detected (0.4 ppm) immediately posttreatment in 15-30 cm soil samples at the Fayetteville, NC site. These detections were considered to be sample contamination because there was no detection of fosamine ammonium at later sampling periods.

Supplemental field dissipation data from small microplots indicate fosamine ammonium, at 11 kg/ha in 0-2 inch soil depth, had a calculated half-life of 1.1 weeks in a Delaware Keyport silt loam soil, 0.79 weeks in an Illinois Flanagan silt loam, 0.55 weeks in a Florida Leon Immokalee fine sandy loam soil. The degradate CPA was detected at 26.7 percent of recovered radioactivity in the Delaware silt loam (6 weeks), 40 percent of the recovered radioactivity in the Illinois silt loam (6 weeks), and 83 percent of the recovered radioactivity in Florida sandy loam (2 weeks). Radiolabeled residues were detected (0.6 to 5.1 percent of applied radioactivity) to a depth of 15 inches soil samples after 3 to 12 months post fosamine ammonium application. The majority of radiolabeled residues were not identified as fosamine ammonium and CPA (less than 1 percent of recovered radioactivity at depths greater than 2 inches). Cumulative rainfall for the studies was 64.95 inches (12 months) at the Delaware site, 26.85 inches at the Illinois site (6 months), and 15.91 inches at the Florida site (6 months). Soil samples were not taken deeper than 15 inches.

Radiolabeled fosamine ammonium, at 12 lbs a.i/A applied to microplots planted with fescue, grass, red clover, and pin oak, was not detected (less than 0.05 ppm) in underlaying 0-3 inch soil samples between 1 to 12 months posttreatment. Radiolabeled residues in soil were CPA (1.3 to 8.6 ppm at 1 month to 0.5 to 1.1 ppm at 7 months) and unextractable residues (ratio of CPA: unextractable residues (1:1)). Radiolabeled fosamine ammonium was detected (381-481 ppm immediately posttreatment to 0.05 ppm at 3 months posttreatment) on plant foliage. The degradate CPA and carboxyphosphonic acid also were detected on plant foliage.

Field dissipation studies indicate that fosamine ammonium degrades rapidly ($t_{1/2}$ less than 5 days) in soil under typical use conditions. Although fosamine ammonium is a mobile compound, there is little evidence to indicate leaching is a major route of dissipation. In addition, supplemental studies indicate that CPA dissipation does not appear to be dependent on leaching. However, unidentified residues were detected at a depth of 15 inches (MRID 40955701).

(8) Fish bioaccumulation

Marginally acceptable accumulation in fish data indicate fosamine ammonium at 1 ppm did not bioaccumulate in bluegill sunfish tissues. Bioconcentration factors for fosamine ammonium could not be estimated because of analytical limitations. Average concentrations of ^{14}C-fosamine ammonium were 0.334 mg/kg in fillet tissues, 0.337 mg/kg in whole fish, and 0.348 mg/kg in viscera. The K_{ow} of fosamine ammonium also is low (less than 0.0012). These data indicate fosamine ammonium residues should not accumulate in fish tissues. However, a nine percent fish mortality was observed in the accumulation in fish study. Data requirements for Guideline 165-4 are satisfied. (MRID 42587601).

(9) 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 and aerial spray application methods for fosamine ammonium. These data requirements have been imposed on the registrant who has chosen to satisfy them through participation in the industry Spray Drift Task Force. Spray Drift data from the Task Force are due June 30, 1995. If the new data suggest substantially different drift potential for the use patterns of fosamine ammonium, the Agency will reassess its impact on the associated environmental risks.

b. Environmental Fate Assessment

Based on supplemental and acceptable environmental fate data, fosamine ammonium dissipation is predominantly dependent on rapid, microbial-mediated degradation ($t_{1/2}$ 0.5 to 11 days). Fosamine ammonium is also mobile (K_{ad} less than 1 and R_f greater than 0.98) in mineral soils.

Degradates of fosamine ammonium are carbamoylphosphonic acid (CPA), carboxylphosphonic acid (ING-3003), unidentified polar compounds and CO_2. Supplemental soil column leaching studies indicate fosamine ammonium residues are relatively immobile. The mobility and persistence of individual degradates (CPA, ING-3003, and unidentified polar degradates) are unknown at this time. Field dissipation studies confirm laboratory data for fosamine ammonium.

Fosamine ammonium rapidly dissipated, with a half-life of less than 5 days from the surface field soils. Leaching does not appear to be a major route of dissipation for fosamine ammonium and CPA in field studies. However, unidentified, radiolabeled polar residues were detected at a depth of 15 inches in confined field dissipation studies.

The environmental fate data indicate fosamine ammonium should be very mobile in mineral soils. However, fosamine ammonium should not pose a threat to groundwater or surface waters because it rapidly degrades in aerobic and anaerobic environments. The mobility of CPA, ING-3003 and individual polar degradates has not been adequately quantified at this time.

Ground water. Fosamine ammonium (parent) has a low probability to impact ground-water quality. Although the chemical is highly soluble in water and mobile in various soils, fosamine ammonium (parent) is not persistent in soil under aerobic or anaerobic conditions. The rapid degradation of fosamine ammonium reduces the likelihood that the chemical will move through the aerobic soil layer without any degradation. There are inadequate data to assess the environmental fate and transport of the degradates of fosamine ammonium, namely carbamoylphosphonic acid (CPA) and carboxylphosphonic acid (ING-3003). However, due to the lack of toxicological concern for these compounds, the Agency is not requiring further definitive fate and transport data for them.

Surface water. Fosamine ammonium could move to surface water through spray drift and to a lesser extent in surface water runoff. There is a low probability that fosamine ammonium will be found in most runoff waters because it degrades rapidly in aerobic and anaerobic environments ($t_{1/2}$ less than 4 days) through microbial-mediated processes. However, fosamine ammonium may be found in surface waters with low microbiological activities or long hydrological residence times. The Agency has no data on the concentrations of fosamine ammonium in surface waters. The available data on major degradates of fosamine ammonium are insufficient to assess their runoff potential or persistence in surface waters. However, available data indicate that fosamine ammonium will not significantly impact the quality of surface waters.

Drinking Water. No MCLs or drinking water health advisories have been established for fosamine ammonium or its degradates. Consequently, the Agency is not recommending at this time any mandated monitoring of drinking water derived from surface water sources for fosamine ammonium or its degradates.

2. Ecological Effects

The ecotoxicological data base is sufficient to characterize the toxicity of fosamine ammonium to nontarget terrestrial and aquatic organisms when used on noncropland for control of undesirable brush/herbaceous plant species.

a. Ecological Effects Data

(1) Terrestrial Data

(a) Avian Acute Toxicity

The minimum data required to evaluate the acute toxicity of fosamine ammonium to birds is an avian single-dose oral LD_{50} test with technical material utilizing either a waterfowl or upland game-bird species. The minimum data required to evaluate fosamine ammonium's subacute toxicity are two avian dietary LC_{50} tests with technical material, utilizing a waterfowl and upland game-bird species. The minimum data required to evaluate chronic toxicity are two avian reproduction studies with technical material, utilizing a waterfowl and an upland game-bird species.

Data from the avian single-dose studies indicate that technical fosamine ammonium is practically nontoxic to avian species on the basis of acute oral toxicity. LD_{50}s for a 99.4% TGAI fosamine ammonium in both the mallard duck and the bobwhite quail are greater than 5000 mg/kg which was the highest dose tested (MRIDs 00093715 and 00130225).

(b) Avian Subacute Dietary Toxicity

Data in support of avian subacute dietary toxicity indicate that technical fosamine ammonium is practically nontoxic to avian species (mallard, bobwhite quail). The LC_{50}s (> 10000 and 5620 ppm, see Table 3) are estimated to be greater than the highest dose tested (MRIDs 00093716, 41891602, and 41891603).

Table 3. Avian Subacute Dietary Studies Using Fosamine Ammonium

Species	% ai	LC_{50} (ppm)	Conclusions
Mallard	99.4	>10000	practically non-toxic
	97.7	>5620	practically non-toxic
Bobwhite quail	97.7	>5620	practically non-toxic

(c) Avian Reproduction/Chronic Effects

Suggestive evidence for reproductive effects to avian species was demonstrated in a laboratory study sponsored by the U.S. Fish and Wildlife Service. This study examined the embryotoxic and teratogenic effects of various solutions of the end-use product (EP: equivalent to 1.5 percent, 6.5 percent and 30 percent a.i.) on mallard and bobwhite quail eggs following a 10 second dipping. An embryotoxic response was seen in eggs treated with the 6.5 percent and 30 percent EP solutions. The solutions were more embryotoxic to the mallard than to the bobwhite quail. While this study is not a guideline study and is classified as supplemental, it reflects a more representative exposure associated with direct spray application to eggs.

In an avian reproduction study utilizing bobwhite quail, no reproductive effects were noted at any of the dose levels tested (250, 1000, or 4000 ppm). As shown in Table 8 below, the estimated environmental concentrations (EEC) of fosamine ammonium on different avian and mammalian food items range from 18 ppm to 5760 ppm at the typical and maximum application rates. Because the highest dose level tested, 4000 ppm, is below the maximum EEC of 5760 ppm on short-grass, this study is classified as supplemental, but is adequate to perform a risk assessment on avian species (MRID 42948301).

Table 4. Avian Reproduction/Chronic Effects

Species	% ai Fosamine ammonium	Effect Level	Conclusions
Bobwhite Quail	97.7	no effects noted at highest dose level tested (4000 ppm)	not tested at maximum EEC
Mallard	97.7	scientifically unsound study, ambiguous results	Not applicable
Bobwhite Quail and Mallard	41	embryotoxic response seen at 6.5% and 30% a.i. solution application to eggs	not guideline study

There is some indication of potential chronic avian reproduction effects in another study utilizing mallard species fed 99.7% fosamine ammonium in the diet. However, this study deviated from the protocol and was not considered scientifically sound. While there was a statistically significant decrease in numbers of eggs laid at the lowest concentration, 250 ppm (Williams test), no statistically significant effects were noted at the highest dose level, 4000 ppm (MRID 42948302). These results were considered ambiguous and were not used to assess the risk to avian species.

Given the ambiguous nature of the data from these studies, the Agency is requiring a new mallard duck reproduction study for confirmatory purposes. There appears to be no indication of reproductive effects in bobwhite quail based on the concentrations (up to 4000 ppm) tested, therefore the Agency is not requiring any additional data for the bobwhite quail.

(d) Toxicity to Nontarget Mammals

An LD_{50} value was derived from acceptable rat acute oral toxicity tests submitted to EPA. The rat LD_{50} of formulated fosamine ammonium (43 percent) is 24400 mg/kg. This value characterizes the acute toxicity to mammals as practically nontoxic (MRIDs 00075735, 00026835).

(2) Aquatic Data

(a) Freshwater Fish Toxicity

Two 96-hour LC_{50} fish toxicity tests utilizing the technical material are the minimum data required to evaluate the acute toxicity of fosamine ammonium to freshwater fish. One test is for warmwater fish, preferably bluegill sunfish, and the other is for coldwater fish, preferably rainbow trout. The minimum data required to evaluate the acute toxicity to estuarine/marine species are a fish 96-

hour LC_{50} test using either a marine or estuarine species, a mollusc 96-hour EC_{50} shell deposition study or 48-hour EC_{50} on oyster embryolarvae, and a shrimp 96-hour LC_{50} test using either a marine or estuarine species. The minimum data required to evaluate chronic toxicity are from a fish early life stage study.

Table 5. Freshwater Fish LC_{50} Studies

Species	% ai fosamine ammonium	LC_{50} (ppm)	Conclusions
Rainbow trout	98.6	377	practically non-toxic
Bluegill	98.6	590	
Coho Salmon	unknown	>200	

Data from fish acute toxicity studies indicate that fosamine ammonium is practically nontoxic to coldwater and warmwater fish (MRIDs 41607103, 41607102 and 00129075).

(b) Freshwater Invertebrate Toxicity

The minimum data required to establish the acute toxicity of fosamine ammonium to freshwater invertebrates is a 48-hour LC_{50} test utilizing the technical material. At a minimum chronic toxicity to aquatic invertebrates is evaluated by an early life stage study. These data indicate that technical fosamine ammonium (99% ai) is practically nontoxic to freshwater invertebrates, such as Daphnia (LC_{50} 1524 ppm) (MRIDs 00143492 and 92086005). No further data are required.

(c) Estuarine/Marine Toxicity

Fosamine ammonium (41.5% a.i.) is practically nontoxic to estuarine species as suggested by the results from the following studies (MRIDs 42715101, 42715103, and 42715102). No further data are required.

Table 6. Estuarine/Marine LC50/EC50 Studies

Species	% ai	LC_{50}/EC_{50} (ppm)	Conclusions
Sheepshead Minnow	97.7	>128	practically nontoxic
Mysid Shrimp	97.7	>136	
Eastern Oyster	97.7	>122	

For the current use patterns of fosamine ammonium, a fish early life stage and an invertebrate life cycle study could have been triggered under certain conditions:

(i) if actual or estimated environmental concentrations in water resulting from the use is less than 0.01 of any EC_{50} or LC_{50} value determined in required testing; and

(ii) the pesticide is persistent in water (e.g., half-life in water greater than 4 days).

The Agency's assessment of fosamine ammonium for this RED document indicates a half-life of less than 4 days in soil based on acceptable aerobic and anaerobic soil metabolism studies. Supplemental data show somewhat higher half-life values (up to 1.2 weeks). The half-life reported in the anaerobic aquatic metabolism study ($t_{1/2}$ = 4) is a combined half-life in sediment and soil. Because fosamine ammonium has a low binding affinity to sediment/soil, a similar half-life in water is expected. Based on these acceptable fate studies, showing a half-life of less than 4 days in soil and a similar expected half-life in water, neither a fish-early life stage study nor an invertebrate life cycle study is required for fosamine ammonium.

(3) Non-Target Insects Data

A 48-hour LD_{50} test utilizing the technical material is the minimum requirement to establish the acute toxicity of fosamine ammonium to nontarget insects. The test organism is the honey bee (Apis mellifera). In such a study technical fosamine ammonium (95% a.i.) was shown to be practically nontoxic to the honey bee. The estimated LD_{50} is considered to be greater than 200 µg/bee (MRID 41215802).

(4) Non-Target Plants Data

(a) Terrestrial, Semi-Aquatic, Aquatic Plant Data

The minimum data required to establish the phytotoxicity of fosamine ammonium are seed germination/seedling emergence testing for terrestrial plants and aquatic plant testing. For the aquatic plant testing, the following species were required to be tested for fosamine ammonium: Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, and a freshwater diatom. Eight aquatic plant studies were submitted and found acceptable.

Table 7: Nontarget Aquatic Plant Testing Data

Species	% ai	Results (mg/l)
Selenastrum capricornutum	64	NOEC >1000 (the highest level tested)
Selenastrum capricornutum	98.3	EC_{50} > 18 NOEC = 18
Anabaena flos-aquae	98.3	EC_{50} > 17 NOEC = 17
Skeletonema costatum	98.3	EC_{50} > 15 NOEC = 15
Navicula pelliculosa	98.3	EC_{50} > 19 NOEC = 19
Lemna gibba	97.7	NOEC < 21

The terrestrial plant studies which were submitted (MRID 42647601) are classified as supplemental. Data for four of the ten species tested (corn, sugar beet, pea and cucumber) were determined to be inadequate, because the seeds had been pretreated with a fungicide and/or insecticide. These studies need to be repeated using seeds that have not been pretreated with a fungicide and/or insecticide. Alternatively, these studies may be accepted if the registrant can successfully demonstrate that the pretreatment pesticide was surface active and non-systemic, and not antagonistic to, or synergistic with fosamine ammonium. These studies may be upgraded when acceptable Tier I seed germination, complete Tier II seedling emergence and complete Tier II vegetative vigor studies are submitted (MRIDs 41215804, 42902901, 42902902, 42902904, 42902903, and 42587602).

b. Ecological Effects Risk Assessment

(1) Risk to Avian and Mammalian Species

Characterizing risk to avian and mammalian species is a function of ecotoxicological hazard and environmental exposure. The Agency characterizes risk in part by calculating risk quotients, and compares them to levels of concern (LOCs). A risk quotient is derived by dividing exposure (EEC) by an appropriate toxicity endpoint (e.g. generally the LC_{50} or LD_{50} of the most sensitive species). The risk quotient is compared to the LOCs. LOCs for birds and mammalian species are: 0.5 for acute High Risk (HR); 0.2 for acute Restricted Use (RU); 0.1 for acute Endangered Species (ES); and 1.0 for chronic risk. When the risk quotient exceeds the LOC for a particular category, then risk to that category is presumed to exist.

The Agency obtained estimates of expected environmental concentrations (EECs) on various food items consumed by birds and mammalian species by using the monograph of Hoerger and Kenaga (1972). These estimates were used in assessing risk, because actual field study residue data were lacking. Hoerger and Kenaga describe both "maximum" and "typical" EECs. Maximum EECs are those values representing the most extreme, and, probably infrequent, residue scenarios. Typical EECs are those values representing environmental conditions which are likely to occur. For purposes of the fosamine ammonium risk assessment both "typical" and "maximum" EEC values are used. Expected "typical" and "maximum" EECs resulting from application of fosamine ammonium at the typical and highest application rates are listed below. Application rates on the labels of currently registered products range from 6 lb a.i./A to 24 lb a.i./A.

Table 8. Maximum and Typical EECs After Application of Fosamine Ammonium on Different Avian/Mammalian Food Items

Substrate	Typical/Maximum Residues (ppm) 12 lb a.i./A	Typical/Maximum Residues (ppm) 24 lb a.i./A
Short Grass	1500/2880	3000/5760
Long Grass	1104/1320	2208/2640
Leaves and Leafy Crops	420/1500	840/3000
Forage, (alfalfa) Insects	396/696	1188/1392
Pods Containing Seeds	36/144	72/288
Fruit	18/84	36/168

(2) Avian Acute Oral and Chronic Risks

The Agency's Guidelines for Avian Dietary LC_{50} Testing specify that a study may demonstrate that the actual LC_{50} is greater than 5000 ppm in lieu of demonstrating an actual LC_{50}. Both bobwhite quail and mallard studies included tests up to the maximum 5000 ppm level and no indications of toxicity were noted in either species. Therefore, the Agency has determined it is reasonable to assume that the levels of concern for acute effects will not be exceeded if fosamine ammonium is used as labeled.

The avian reproductive effects via chronic ingestion of fosamine ammonium are not as clearly defined as the avian acute oral effects. While some data suggest potential sensitivity to mallards, no effects were observed in bobwhite quail at the highest dose tested (4000 ppm). The data which are indicative of avian reproductive effects, however, are either ambiguous or do not meet guideline requirements.

Additional non-guideline data were provided by the U.S. Fish and Wildlife Service. These studies indicated that 6.5 percent and 30 percent end-use product solutions containing fosamine ammonium produced a statistically greater embryotoxic response in mallard ducks than bobwhite quail eggs.

Because of the ambiguity associated with the mallard duck reproduction study, the Agency is relying on the bobwhite guideline reproduction study and the U.S. Fish and Wildlife Service data for the risk assessment. A conservative quantitative estimation of risk using the maximum application rate of 24 lb a.i./A was performed for this risk assessment using only bobwhite quail reproductive data. The risk quotient for chronic effects using the bobwhite quail data (5760

ppm/4000 ppm) is 1.4 which exceeds the Agency's level of concern for avian chronic risk (LOC = 1). Therefore based on a conservative estimation of risk, the use of fosamine ammonium may present a potential for chronic risk to avian species.

However, in order to determine whether there are actual reproductive effects associated with chronic exposure to fosamine ammonium, the Agency is requiring the registrant to conduct a new confirmatory mallard duck reproduction study. The Agency has determined that the bobwhite quail study is adequate for purposes of this risk assessment. In addition, the registrant has provided to the Agency some initial risk mitigation measures which may help reduce the avian exposure to fosamine ammonium and thereby reduce the potential reproductive risk. The risk mitigation measures are discussed in Sections IV and V below.

(3) Mammalian Acute Oral and Chronic Risks

Using the rat as a small mammal surrogate, fosamine ammonium is expected to be practically non-toxic to small mammalian species. The rat LD_{50} of formulated fosamine ammonium (43%) is 24,400 mg/kg. Acute oral and subacute dietary risks to non-endangered and endangered non-target mammals are not expected to result from present label uses of fosamine ammonium.

The results of an acceptable developmental toxicity study, in which sexually mature rats were gavaged for an eleven day period with fosamine ammonium at levels up to 3000 mg/kg/day, showed no mortality (3000 mg/kg/day equates to about 30000 ppm). No mortality was seen at the highest dose tested, 20000 ppm, in an acceptable 90-day neurotoxicity study. Given that the highest exposure case EEC for fosamine ammonium is 5760 ppm, and comparing this value to actual mammalian data showing no acute/longer term effects at levels up to 30000 ppm, there would be no expected acute or chronic mammalian effects to occur.

(4) Risks to Aquatic Animals

Exposure to nontarget aquatic organisms can result from spray drift and runoff from treated areas. Characterizing risk to aquatic species is a function of ecotoxicological hazard and environmental exposure. It is performed in a manner similar to that for birds and small mammals. The exception is that the EECs are calculated differently. The Agency calculates risk quotients (EEC/LC_{50} or LD_{50} of the most sensitive species), and then compares these to levels of concern (LOCs). LOCs for aquatic species are: 0.5 for acute High Risk (HR); 0.1 for acute Restricted Use (RU); 0.05 for acute Endangered Species (ES); and 1.0 for chronic risk. When the risk quotient exceeds the LOC for a particular category, then risk to that category is presumed to exist.

Estimated Environmental Concentrations (EECs) were calculated using the Agency's Hazard Evaluation Division's Standard Evaluation Procedure for Ecological Risk Assessment (EPA-540/9-85-001). These estimates were used in assessing risk, because actual field study residue data were lacking. The Agency generally employs the highest application rate permitted on the label and calculates the EEC resulting from direct application, from spray drift, and from runoff of the pesticide into a 6-foot deep 1-acre pond, and the EEC resulting from runoff of the pesticide into a 6-inch deep 1-acre pond. For purposes of this risk assessment, the typical (12 lb a.i./A) and highest (24 lb a.i./A) application rates were employed.

The EECs resulting from direct application, spray drift, and runoff of fosamine ammonium applied at 12 and 24 lb a.i./A application rates into 6 inch and 6 foot deep one acre ponds are listed in 4 below. This table also provides a comparison of acute risk quotients to the Agency's levels of concern (LOCs). The LC_{50} for rainbow trout (96-hr LC_{50} of 377), the most sensitive freshwater aquatic organism tested, was used in risk quotient calculations.

Table 9. Risk Quotients and LOCs for Pond Scenarios (Rainbow Trout LC_{50} = 377 ppm)

Use Site	Application Rate	EEC (ppm)	Risk Quotient (EEC/LC_{50})	Level of Concern (LOC)
Rights of Way, Non-cropland, Industrial Sites	12 lbs ai	Runoff (6') = 0.366 Drift (6') = 0.256 Direct (6')= 0.73	0.001 0.002	High Risk 0.5 Restricted Use 0.1 Endangered Species 0.05
		Runoff (6")= 4.4 Drift (6") = 3.08 Direct (6")= 8.8	0.012 0.008 0.023	
Rights of Way, Non-cropland, Industrial Sites	24 lbs ai	Runoff (6') = 0.732 Drift (6') = 0.512 Direct (6')= 1.46	0.002 0.001 0.004	High Risk 0.5 Restricted Use 0.1 Endangered Species 0.05
		Runoff (6") = 8.8 Drift (6") = 6.16 Direct (6") = 17.6	0.023 0.016 0.047	

The acute risk quotients do not exceed any level of concern. Therefore, the Agency concludes that acute effects to freshwater fish and aquatic invertebrates are not expected as a result of the normal use of fosamine ammonium.

In the absence of an actual LC_{50} or EC_{50}, the Agency did not estimate an acute risk quotient for estuarine species. However, the highest dose levels tested in each of the three estuarine species tested resulted in no mortalities (sheepshead minnow 96-hr LC_{50} > 128 ppm; mysid shrimp 96-hr LC_{50} > 136 ppm; and eastern oyster 96-hr EC_{50} > 122 ppm). Therefore, the Agency assumes that acute hazards

to estuarine species are not expected as a result of the use of fosamine ammonium as labeled.

Additional information which supports this conclusion are: (i) there is only one seasonal application of fosamine ammonium; (ii) acute toxicity values are greater than 1 ppm, (iii) EECs in water are less than 0.01 of individual acute toxicity values; and (iv) environmental fate data (anaerobic aquatic metabolism) indicate a half life of 4 days under certain conditions. The Agency also believes that it is reasonable to assume that there are no chronic risks to aquatic organisms.

(5) Risks to Aquatic Plants

Exposure to nontarget aquatic plants can result from spray drift from treated areas, surface runoff, or wind blown soil particles. Estimated Environmental Concentrations (EECs) were calculated using the Agency's Hazard Evaluation Division Standard Evaluation Procedure for Ecological Risk Assessment (see under Risks to Aquatic Organisms). The Agency's LOC for aquatic plants is 1. There are no separate LOCs for restricted use, endangered species, or chronic risks. If the EEC $>$ EC_{25}, the Agency presumes a high risk and endangered plants may be affected. The risk quotient is derived using the most conservative EC_{25} value for aquatic plants, greater than 15 mg/l (the highest level tested for Skeletonema costatum).

Table 10. Nontarget Aquatic Plant Risk Quotients and LOC of Fosamine Ammonium based on EC_{25} greater than 15

Use Site	Application Rate	EEC (water depth)	Risk Quotient (EEC/LC_{50})	LOC
Rights of Way, Non-cropland, Industrial Sites	12 lbs ai	0.366 ppm (6')	<0.02	1
		4.4 ppm (6")	<0.29	
Rights of Way, Non-cropland, Industrial Sites	24 lbs ai	0.732 ppm (6')	<0.05	1
		8.8 ppm (6")	<0.59	

None of the acute risk quotients exceed the LOC. Therefore, the Agency concludes that no acute effects to aquatic plants are expected as a result of the use of the registered uses of fosamine ammonium. A chronic risk assessment to aquatic plants cannot be performed because data are not available. However, the registrant is not supporting any aquatic sites. Data in support of chronic risks to aquatic plants will be required if, in the future, the registrant wishes to register such sites.

(6) Risk to Terrestrial Plants

A terrestrial nontarget plant risk assessment cannot be conducted until all Tier I and II data requirements have been fulfilled. Data are outstanding for corn, sugar beet, pea and cucumber. Because results of the most sensitive terrestrial plant species tested are needed in order to conduct an acute risk assessment, a risk assessment cannot be performed. Any movement of this herbicide from the treatment site via spray drift, surface runoff, or wind blown soil particles has the potential to adversely affect nontarget and endangered/threatened plants. Direct applications to rights-of-way are a special concern, because of the large numbers of endangered plants growing in rights-of-way areas.

Applications of fosamine ammonium at the registered rates may pose a significant risk to endangered plant species inhabiting treated rights-of-way. EPA has been working with the U.S. Fish and Wildlife Service and other federal and state agencies to develop a program to avoid jeopardizing the continued existence of listed endangered species from the use of pesticides. The Endangered Species Protection Program is expected to become final in 1995. Limitations on the use of fosamine ammonium may be required to protect endangered and threatened species, but these limitations have not yet been defined, and they may be formulation-specific. The Agency anticipates that consultation with the U.S. Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of the consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing fosamine ammonium as the active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing fosamine ammonium for certain sites as specified in this document. The registrant has voluntarily requested cancellation of the aquatic sites as discussed previously. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of fosamine ammonium, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B for fosamine ammonium were sufficient to allow the Agency to assess its registered uses, except for aquatic sites. The Agency has determined that fosamine ammonium can be used for registered sites, except the aquatic sites, as specified in this document, without resulting in unreasonable adverse effects to humans or the environment. The Agency is requiring risk mitigation measures for non-target animal species. The reregistration requirements of fosamine ammonium products are addressed in this Section and in Section V below.

The Agency made its reregistration eligibility determination based upon the target database required for reregistration, the current guidelines for conducting acceptable studies to generate such data, the registrant's request for voluntary cancellation of aquatic sites and the data identified in Appendix B. The Agency has found that certain uses of fosamine ammonium, as discussed in this document, are eligible for reregistration, under the conditions specified herein. However, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the reregistration of products containing fosamine ammonium, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all currently registered uses of fosamine ammonium, except for aquatic sites, as described in this document, are eligible for reregistration. The registrant has voluntarily requested cancellation of those aquatic sites. The Agency is not including those sites in its eligibility decision, because of the inadequate environmental data for those sites and the impending deletion of those uses from all current registrations.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances are not currently established for the herbicide fosamine ammonium since there is no registered food or feed use.

2. Labeling Rationale/Risk Mitigation Measures

a. Personal Protection Equipment (PPE) Requirements

The current registered uses of fosamine ammonium do not include uses associated with the production of an agricultural plant on/in any farm, forest, nursery, or greenhouse. Sites on which this herbicide/plant growth regulator is used are limited to utility rights-of-way, outdoor industrial areas, campgrounds, storage areas and noncropland. These uses and the single registered product do not fall under the scope of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7". The Agency's labeling regulations for worker protection statements (40 CFR 156, subpart K) are not applicable to fosamine end-use products at this time.

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

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be established 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 EPA guidelines.

2. If EPA 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, the following conditions apply:

    - In the RED for that active ingredient, EPA 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 no special toxicological concerns about fosamine ammonium that warrant the establishment of baseline or minimum active-ingredient based PPE for handlers (mixer/loader/applicators). Therefore, the PPE for pesticide handlers will be established based on the acute toxicity of the end-use product.

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

For liquid applications:
"Do not enter or allow others to enter the treated area until sprays have dried."

Other Labeling Requirements

The Agency is requiring labeling statements concerning application restrictions and user safety recommendations to be located on all end-use products containing fosamine ammonium that are intended primarily for occupational use. See Chapter V for the actual statements.

b. Spray-Drift Label Advisory

In order to inform the user of best management practices that would minimize spray drift from the target site, the Agency is currently preparing spray drift statements. This future labelling may be required for all fosamine products that may be applied aerially.

c. Avian Risk Mitigation

The Agency has determined that there is a potential for adverse effects on avian reproduction with the use of fosamine ammonium. The data indicative of such effects are not conclusive as discussed earlier (Section III). Briefly, the U.S. Fish and Wildlife data suggest that reproduction in avian species may be adversely affected when eggs are directly exposed to sprays of the end-use product (EP). By way of contrast, the data from the bobwhite quail reproduction study shows no effects at any dose levels. The Agency, therefore, thought it prudent to regulate fosamine ammonium based on the weight of evidence supporting the reregistration of fosamine, the low toxicity profile of the herbicide and the following considerations.

Information provided by Agency use experts suggests that fosamine ammonium is not typically applied at the permitted maximum application rate of 24 lb a.i./A. Rather, users and the registrant suggest that as much as 80 percent of the use of fosamine ammonium is at the rate of 12 lb a.i. to 16 lb a.i. per acre. Based on these more typical use rates, the estimated EECs for avian species would be approximately 33 percent to 50 percent lower than for the 24 lb a.i. rate. In addition, less than one percent of the sites are treated with fosamine ammonium, and application is limited to once per year. Furthermore, the sites treated are narrow strips of land, rather than vast acreages of cropland. These factors further decrease the potential for exposure to nesting birds.

The registrant has voluntarily submitted label amendments to allow applications during the period after spring growth has hardened to the development of fall coloration on deciduous species, and to restructure maximum rates of application. These label amendments reduce the maximum application rate to 16 lb a.i./A for low shrubs/brush (floor work), which constitute 80 percent of the use of the herbicide. Applications to a maximum of 24 lb a.i./A are proposed only for tall dense wood species with very heavy foliage (side trim work). Prior to this modification, all applications were permitted up to the 24 lb a.i./A.

Additionally, submission of a new mallard duck reproduction study should resolve any question of the potential for fosamine ammonium to cause reproductive effects in this avian species. The Agency may require further risk mitigation measures depending on the results of the required study.

3. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered avian species to fosamine ammonium as discussed above in the Section IIIC.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use 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.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in 1995 and have enforceable county-specific bulletins available. 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.

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

While there is currently no registered manufacturing-use product, the generic data base supporting the reregistration of fosamine ammonium for the above eligible uses has been reviewed and determined to be substantially complete except for the following confirmatory data requirements:

- Guideline 62-2: Certification of limits. The registrant must provide information to certify that the limits are within the standards required by 40 CFR §158.120.

- Guideline 71-4b: Avian reproduction (mallards). Data are required to confirm that the chronic avian reproductive risk does not exceed the Level of Concern at the Estimated Environmental Concentration.

- Guideline 84-2a: An in-vivo cytogenetics assay on spermatogonia/spermatocytes to satisfy Guideline 84-2a requirements for toxicology mutagenicity.

- Guideline 201-1, Guideline 202-1: Droplet size spectrum, and field drift data are needed to evaluate off-target movement of spray applied fosamine ammonium. These data requirements are being fulfilled by the registrant through their participation in the Spray Drift Task Force. These data are scheduled for submission by June 30, 1995.

- Guidelines 231, 232: Method validation data for worker exposure study, MRID 42598101.

- Guidelines 122-1 and 123-1: Terrestrial plant testing data requirements. Four of the ten terrestrial plant testing studies for corn, sugarbeet, pea, and cucumber, need to be repeated. Alternatively, the registrant can provide documentation to demonstrate that the compounds used for pretreatment of seeds do not interfere with the fosamine ammonium results in these studies. The other studies may be upgraded when acceptable Tier I seed germination, complete Tier II emergence and complete Tier II vegetative vigor studies are submitted.

- Guidelines 164-2 and 162-4. Aerobic aquatic metabolism and aquatic field dissipation data would be required to support future use patterns of an aquatic site. Assuming that the aquatic sites will be deleted from the current registration, the Agency does not expect to receive these data. In the future, if the registrant wishes to register any aquatic uses, these and all data in support of those sites must be resubmitted.

2. Labeling Requirements for Manufacturing-Use Products

Effluent Discharge Labeling Statements

While there is no currently registered manufacturing-use product, these requirements are appropriate for future registrations of fosamine ammonium.

All manufacturing-use or end-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the following revised effluent discharge labeling statement.

Within Environmental Hazards section of the Precautionary Statement of the label:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All affected products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October 1, 1995. All products distributed or sold by persons other than registrants or supplemental registrants after October 1, 1997 must bear the correct labeling. Refer to PR Notice 93-10 or 40 CFR 152.46(a)(1) for additional information.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) 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 and other applicable notices.

(a) Within Environmental Hazards section of the Precautionary Statement of the label:

> "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate."

(b) To reduce environmental loading and potential exposure to non-target species, the product label must include language to limit use as outlined below:

> (i) the end-use product can be applied only once annually during the period after spring growth has hardened to the development of fall coloration in deciduous species, and
> (ii) the maximum application rate for low shrubs/brush is 16 lb a.i./A, and for tall dense woody species with very heavy foliage can be 24 lb a.i./A.

(c) The end-use product labels cannot include directions for applications to aquatic sites. The current, sole registrant has submitted an application for amended registration to delete these uses from its product registration. Future submissions of appropriate data to support registration for these uses will be considered by the Agency.

(d) The Agency is requiring the following labelling statements to be located on all end-use products containing fosamine ammonium:

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 applications."

Entry restrictions

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

For liquid applications:
"Do not enter or allow others to enter the treated area until sprays have dried."

Other Labelling Requirements

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 clothing immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

These statements must be included on the labels, as they are appropriate, after PPE requirements are set by the Agency.

C. Spray Drift Label Advisory

In order to inform the user of best management practices that would minimize spray drift from the target site, the Agency is currently preparing spray drift labelling statements. This future labelling may be required for all fosamine ammonium products that may be applied aerially.

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

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /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												
NON-FOOD/NON-FEED												
DRAINAGE SYSTEMS					Use Group: AQUATIC NON-FOOD INDUSTRIAL							
High volume spray (dilute)., When needed., High volume ground.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Airblast.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Backpack mist blower.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Spray., When needed., Aircraft.	SC/L	NA	12 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
INDUSTRIAL AREAS (OUTDOOR)					Use Group: TERRESTRIAL NON-FOOD CROP							
High volume spray (dilute)., When needed., High volume ground.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Airblast.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Backpack mist blower.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Spray., When needed., Aircraft.	SC/L	NA	12 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS					Use Group: TERRESTRIAL NON-FOOD CROP							
High volume spray (dilute)., When needed., High volume ground.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Airblast.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Backpack mist blower.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Spray., When needed., Aircraft.	SC/L	NA	12 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS					Use Group: TERRESTRIAL NON-FOOD CROP							
High volume spray (dilute)., When needed., High volume ground.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Airblast.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Backpack mist blower.	SC/L	NA	24 lb A	*	NS NS	NS	NS	NS	NS	AZ, CA		C46, C93

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps Max. Rate @ Max. Dose /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													
NON-FOOD/NON-FEED (con't)													
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
Spray., When needed., Aircraft.	SC/L	NA	12 lb A	*	NS	NS	NS	NS	NS	NS	AZ, CA		C46, C93
RECREATIONAL AREAS				Use Group: TERRESTRIAL NON-FOOD CROP									
High volume spray (dilute)., When needed., High volume ground.	SC/L	NA	24 lb A	*	NS	NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Airblast.	SC/L	NA	24 lb A	*	NS	NS	NS	NS	NS	NS	AZ, CA		C46, C93
Low volume spray (concentrate)., When needed., Backpack mist blower.	SC/L	NA	24 lb A	*	NS	NS	NS	NS	NS	NS	AZ, CA		C46, C93
Spray., When needed., Aircraft.	SC/L	NA	12 lb A	*	NS	NS	NS	NS	NS	NS	AZ, CA		C46, C93

LEGEND
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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
SC/L : SOLUBLE CONCENTRATE/LIQUID

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
C46 : Do not apply through any type of irrigation system.
C93 : Do not apply directly to water.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AZ : Arizona
CA : California

APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 2355 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 2355 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 Fosamine Ammonium

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	41607104
61-2A	**Start. Mat. & Mnfg. Process**	All	41607104
61-2B	**Formation of Impurities**	All	41607104
62-1	**Preliminary Analysis**	All	41607105
62-2	**Certification of limits**	All	required
62-3	**Analytical Method**	All	41607105
63-2	**Color**	All	41607106
63-3	**Physical State**	All	41607106
63-4	**Odor**	All	41607106
63-5	**Melting Point**	All	41607106
63-7	**Density**	All	41607106
63-8	**Solubility**	All	41607106
63-9	**Vapor Pressure**	All	41215803
63-10	**Dissociation Constant**	All	41607106
63-11	**Octanol/Water Partition Coefficient**	All	00164989
63-12	**pH**	All	41607106
63-13	**Stability**	All	41607106
63-15	**Flammability**	All	41687501

Data Supporting Guideline Requirements for the Reregistration of Fosamine Ammonium

REQUIREMENT		USE PATTERN	CITATION(S)
63-16	**Explodability**	All	41687501
63-17	**Storage Stability**	All	00094669
63-18	**Viscosity**	All	41687501
63-20	**Corrosion characteristics**	All	41687501
63-21	**Dielectric Breakdown Voltage**	All	Waived
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	CF	00093715 00130225
71-2A	**Avian Dietary - Quail**	CF	41891603, 00093716
71-2B	**Acute Avian Diet- Duck**	CF	41891602
72-1C	**Fish Toxicity Rainbow Trout**	CF	41607103
72-2A	**Invertebrate Toxicity**	CF	00143492
72-3A	**Estu/Marine Tox. Fish**	CF	42715101
72-3B	**Estu/Marine Tox. Mollusk**	CF	42715102
72-3C	**Etsu/Marine Tox. Shrimp**	CF	42715103
122-2	**Aquatic Plant Growth**	CF	42902901,42902902, 42902903, 42902904, 41215804
141-1	**Honey Bee Acute Contact**	CF	41215802

Data Supporting Guideline Requirements for the Reregistration of Fosamine Ammonium

REQUIREMENT		USE PATTERN	CITATION(S)
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	CF	00026825, 00075735
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	CF	00075733
81-3	**Acute Inhalation Toxicity - Rat**	CF	000789990, 00075734, 00000774
81-4	**Primary Eye Irritation - Rabbit**	CF	00075738
81-5	**Primary Dermal Irritation - Rabbit**	CF	00026826, 00015733
81-6	**Dermal Sensitization - Guinea Pig**	CF	00075737, 00097289
81-7	**Acute Delayed Neurotoxicity Screen**	CF	42934801
81-8ss	**Acute Neurotoxicity**	CF	42946501
82-1A	**90- Day Feeding-rodent**	CF	00075736
82-1B	**90-day Feeding nonrodent**	CF	42867001
82-2	**21-day Dermal Rabbit**	CF	41998101
82-7ss	**90 day Neurotoxicity Screen**	CF	42946502
83-3A	**Teratogenicity-Rat**	CF	42320901
84-2A	**Gene Mutation (Ames Test)**	CF	41891601, 00148267
84-2B	**Structural Chromosomal Aberration**	CF	00147636, 00147635
84-4	**Other Genotoxic Effects**	CF	147634

Data Supporting Guideline Requirements for the Reregistration of Fosamine Ammonium

REQUIREMENT		USE PATTERN	CITATION(S)
86-1	**Domestic Animal Safety**	CF	92086999
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	CF	40133701
161-2	**Photodegradation in Water**	CF	40133702
161-3	**Photodegradation in Soil**	CF	40133703
161-4	**Photodegradation in Air**	CF	Waived
162-1	**Aerobic Soil Metabolism**	CF	42060601, 42724301
162-2	**Anaerobic Soil Metabolism**	CF	42060602, 42680701, 257323
162-3	**Aerobic Aquatic Metabolism**	CF	42060602, 42680701
162-4	**Aerobic Aquatic Metabolism**	F	00257323, 42492401
163-1	**Leaching/Adsorption/Desorption**	CF	42492401, 40133704, 00257323
163-2	**Lab Volatility**	F	42492401, 42492301
163-3	**Field Volatility**	CF	42492401
164-1	**Terrestrial Field Dissipation**	CF	40955701, 00257323
164-2	**Aquatic Field Dissipation**	CF	Required
164-3	**Forest Field Disipation**	F	Waived
165-1	**Confined Roatational Crops**	CF	Waived
165-4	**Bioaccumulation in Fish**	CF	42587601
201-1	**Droplet Size Spectrum**	CF	Required
202-1	**Drift Field Evaluation**	CF	Required

REQUIREMENT		USE PATTERN	CITATION(S)
OCCUPATIONAL AND RESIDENTIAL EXPOSURE			
231	**Estimation of Dermal Exposure at outdoor sites**	CF	42598101
232	**Estimation of Inhalation Exposure at outdoor sites**	CF	42598101

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of 2355

GUIDE TO APPENDIX C

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

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

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

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

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

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

as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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42946501	Christoph, G. (1993) Acute Neurotoxicity of DPX-R1108-100 (Fosamine Ammonium) in Rats: Lab Project Number: 431-93: 9326-001: HLR 431-93. Unpublished study prepared by Du Pont's Haskell Lab for Toxicology and Industrial Medicine. 496 p.
42946502	Christoph, G. (1993) Subchronic Neurotoxicity of DPX-R1108-100 (Fosamine Ammonium) in Rats: Lab Project Number: 438-93: 9327-001: HLR 438-93. Unpublished study prepared by Du Pont's Haskell Lab for Toxicology and

BIBLIOGRAPHY

MRID	CITATION
	Industrial Medicine. 534 p.
42948301	Fletcher, D.; DuCharme, D. (1993) H-18642 (DPX-R1108-100; Fosamine Ammonium): Toxicity and Reproduction Study in Bobwhite Quail: Lab Project Number: 124-004-07: 9324: HLO 527-93. Unpublished study prepared by Bio-Life Associates, Ltd.; Haskell Lab for Toxicology and Industrial Medicine. 409 p.
42948302	Fletcher, D.; DuCharme, D. (1993) H-18642 (DPX-R1108-100; Fosamine Ammonium): Toxicity and Reproduction Study in Mallard Ducks: Lab Project Number: 124-005-08: 9324: HLO 526-93. Unpublished study prepared by Bio-Life Associates, Ltd.; Haskell Lab for Toxicology and Industrial Medicine. 472 p.

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APPENDIX D. List of Available Related Documents

The following is a list of available documents related to fosamine ammonium. 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 fosamine ammonium 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. Fosamine ammonium 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

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,…. of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the com-plete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, …250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in mul-tiple volumes is permissible so long as the entire study is pag-inated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely

broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with pet-itions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d) (1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been

excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous corres-pondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a tran-smittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____ Name
Signature

Company Name _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

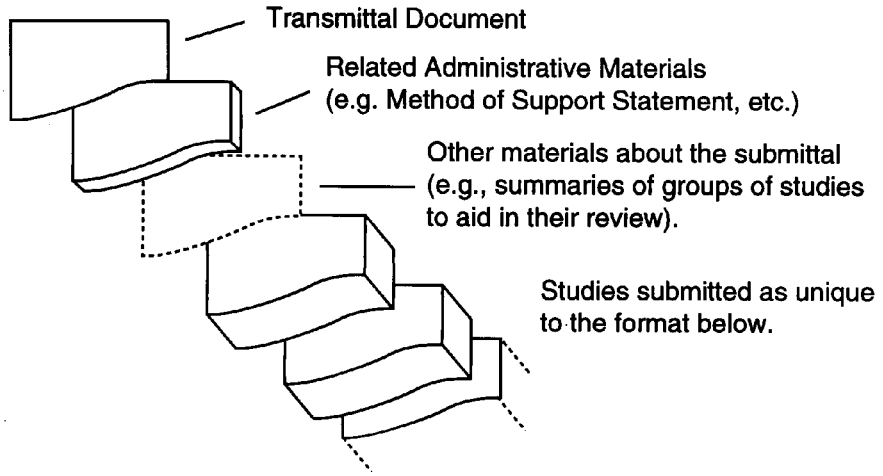
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

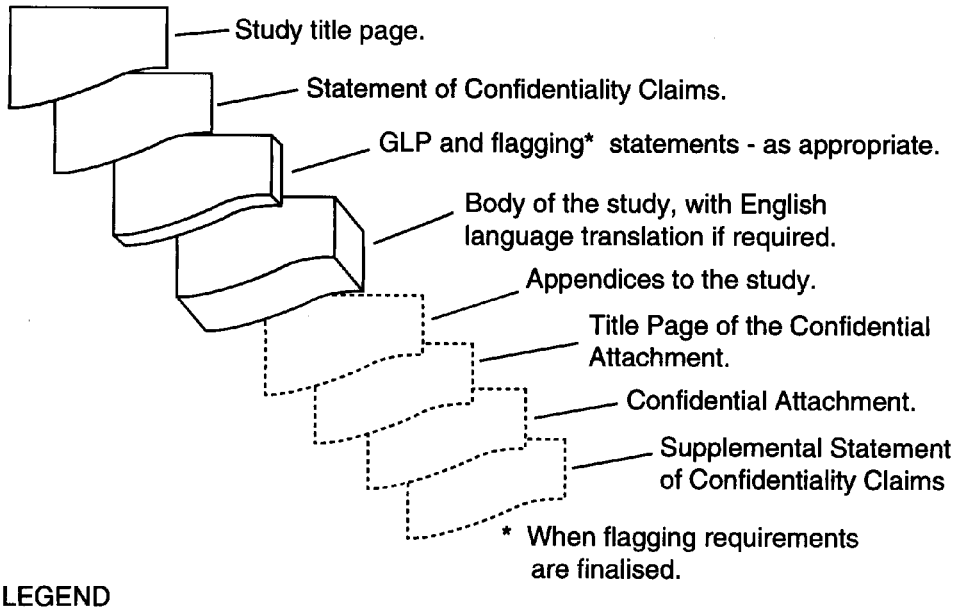
Submitter_____

ATTACHMENT 7.

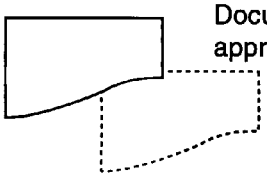
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Generic Data Call-In

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You Are Receiving This Notice
Section II	-	Data Required By This Notice
Section III	-	Compliance With Requirements Of This Notice
Section IV	-	Consequences Of Failure To Comply With This Notice
Section V	-	Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries And Responses To This Notice

The Attachments to this Notice are:

Attachment 1 - Data Call-In Chemical Status Sheet
Attachment 2 - Data Call-In Response Form
Attachment 3 - Requirements Status And Registrant's Response Form
Attachment 4 - List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Attachment 2) and the Requirements Status and Registrant's Response Form (Attachment 3). The Data Call-In Response Form must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

   If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

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

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

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are

discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and 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. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data --

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the

Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and 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 should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

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

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

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

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form; or,

   b. fulfill the commitment to develop and submit the data as required by this Notice; or,

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and 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.

C. EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Federal Insecticide, Fungicide, and Rodenticide Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell,

distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Attachment 2) and a completed Requirements Status and Registrant's Response Form (Attachment 3) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Louis P. True, Jr., Acting Director
Special Review
and Reregistration Division

Attachment 1. Chemical Status Sheet

2355 DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing 2355.

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 2355. 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) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this 2355 Generic Data CallIn (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for 2355 are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on 2355 are needed. These data are needed to fully complete the reregistration of all eligible 2355 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 Shanaz Bacchus at (703) 308-8065.

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

Shanaz Bacchus, Chemical Review Manager
Accelerated Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: 2355

Attachment 2. Generic DCI Response Forms Inserts (Form A) plus Instructions

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and

incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

Attachment 3. Requirements Status and Registrants' Response Forms Inserts (Form B) plus Instructions

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be

submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities

DEGR Degradates

*See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially 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.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

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

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

Attachment 4. List of Registrant(s) sent this DCI (Insert)

APPENDIX G. Product Specific Data Call-In

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

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 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the

laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and 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 should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the

Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted
without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

    a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

    b. fulfill the commitment to develop and submit the data as required by this Notice; or

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and 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 would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular

risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Louis P. True, Jr., Acting Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration

5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

Attachment 1. Chemical Status Sheet

2355 DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 2355.

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 2355. 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) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this 2355 Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for 2355 are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 2355 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 2355 products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of 2355, please contact Shanaz Bacchus at (703) 308-8065.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008.
(703) 308-8184.

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

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

RE: **2355**

Attachment 2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed

"**Certification of Offer to Cost Share in the Development Data**" **form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data

requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3. Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use patters (s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/ or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. lt is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter Only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the require data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be require 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 chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

NOTE:You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

THERE IS NO BATCHING FOR THIS CASE

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $<$ 0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4. *___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*_____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*_____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C (+2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

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

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.

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

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, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

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

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

APPENDIX H. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-005 January 1995

R.E.D. FACTS

Fosamine ammonium

Pesticide Reregistration

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

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2355, fosamine ammonium.

Use Profile

Fosamine ammonium is an herbicide/plant growth regulator used to control brush and herbaceous plants on noncropland. It is applied to nonagricultural rights-of-way (e.g. highways, railroads, and utilities), industrial sites, and fencerows.

Fosamine ammonium is formulated in end use products as a water soluble liquid. It is applied once per year from Spring to early Fall, by aircraft, backpack and handwands. After application, the brush control effects of the pesticide are achieved by inhibiting bud growth the following year.

Use practice limitations prohibit fosamine ammonium from being used on croplands or in irrigation systems. It may not be applied directly to water, or areas where surface water is present, including intertidal areas. Soils treated with this herbicide cannot be converted to food/feed croplands within one year of treatment.

Fosamine ammonium is not registered for use in California and Arizona.

Regulatory

Fosamine ammonium was first registered as a pesticide in the U.S. in

History

1975. It was registered for non-cropland (non-food use) areas such as railroads, pipelines, utility and highway rights-of way, reforestation areas, drainage ditch banks, storage areas, industrial plants, and other similar sites. However, this product was voluntarily cancelled on June 22, 1994.

A second product was registered in 1980 with the same uses as the original product except for reforestation uses. This product currently is marketed under two trade names. The registrant requested to voluntarily cancel direct applications to water, ditch banks, and to other sites which are adjacent to and surrounding domestic water supply reservoirs, supply streams, lakes and ponds. The Agency is processing this request, which involves publishing a Notice of Intent to delete these uses in the Federal Register. Because there are no other current registrants and there are outstanding environmental data requirements to support continued registration of these uses, the Agency expects that these sites will be deleted from the label by early 1995.

Human Health Assessment

Toxicity

Fosamine ammonium is classified as Toxicity Category II for acute dermal studies in mammalian species. This classification represents the second most severe level of acute toxicity for studies using laboratory animals (Toxicity Category I is the highest). Fosamine ammonium is very mildly toxic for acute oral and acute inhalation (Toxicity Category IV), and is not a dermal sensitizer.

In one subchronic oral study, the laboratory animals given the highest dose of fosamine ammonium exhibited some statistically significant effects, including effects to the kidneys, bladder and decreases in body weight. There were no subchronic neurotoxic effects of fosamine ammonium at any dose level.

Fosamine ammonium displayed some mutagenic potential in one in vitro test for chromosome aberrations, while four other tests were negative for mutagenic potential.

Dietary Exposure

Since there are no registered food uses for fosamine ammonium, no dietary exposure is expected.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to fosamine ammonium during and after application of the pesticide. Worker exposure estimates are based on the assumption that workers wear long pants, long sleeved shirt, shoes, and no gloves, except for workers using backpacks (who are assumed to wear chemical resistant gloves). The primary route of exposure to fosamine ammonium is expected to be dermal. Another potential route of exposure is through inhalation. However, based on the exposure assumptions, the potential for inhalation exposure is negligible.

Human Risk Assessment

Since no food uses are registered, fosamine ammonium poses no human dietary risks. Regarding acute toxicity, fosamine ammonium falls in Toxicity Category II for acute dermal exposure. However, the mild skin effects observed with this chemical do not trigger any significant toxicological concerns. The herbicide/plant growth regulator is of low toxicity by the oral and inhalation routes. Based on the mixed results of studies suggesting mutagenetic potential, the Agency is requiring additional testing with germ cells as a confirmatory study.

Based on the current use pattern of fosamine ammonium, the estimated exposure to workers, which is likely to reflect a worse-case scenario, does not pose a serious threat to workers. However, there are no known significant acute or chronic toxicological endpoints that warrant the establishment of risk mitigation measures or minimum personal protective equipment (PPE) requirements to protect handlers of the pesticide. Clothing as described in the exposure assessment will provide adequate protection to handlers. In addition, EPA is requiring application restrictions and user safety recommendations on end-use product labeling.

Environmental Assessment

Environmental Fate

Fosamine ammonium is not very persistent under aerobic or anaerobic conditions and degrades rapidly in most soils. Dissipation of fosamine ammonium is dependent on rapid, microbial mediated degradation. Thus, in field studies fosamine ammonium was found to be highly soluble in water and is mobile in various soils. However, in the sterile conditions of the laboratory, fosamine ammonium is stable to hydrolysis. Although fosamine ammonium is a mobile compound, there is little evidence that leaching is a major route of dissipation. Data on the residues of fosamine ammonium indicate they are also relatively mobile.

Fosamine ammonium may be found in surface waters with low microbiological activities or long hydrological residence times.

Exposure of fosamine ammonium to non-target aquatic plants can result from spray drift from treated areas, surface runoff, or wind blown soil particles. However, no acute risk quotients exceed the level of concern, so no acute effects to aquatic plants are expected from the normal use of fosamine ammonium.

The risk to terrestrial non-target plants cannot be determined until Tier I and Tier II data requirements have been fulfilled. Results of the most sensitive terrestrial plant species tested are needed in order to conduct an acute risk assessment.

Any movement of fosamine ammonium from the treatment site via spray drift, surface runoff, or wind blown soil particles can adversely affect non-target and endangered/threatened plants. Direct application of rights-of-way are a special concern, because large numbers of endangered plants grow in rights-of-way areas. Thus applications of fosamine ammonium at

the registered rates may pose a significant risk to endangered plant species inhabiting treated rights-of-way.

EPA has been working with the U.S. Fish and Wildlife Service and other federal and state agencies to develop a program to avoid jeopardizing endangered species. The Endangered Species Program is expected to be final soon. Further limitations on the use of fosamine ammonium may be imposed at that time.

Further droplet size spectrum and field drift studies are due to the Agency at the end of June 1995 as part of the spray drift data requirements to be submitted by the Spray Drift Task Force. If the new data suggest substantially different drift potential, the Agency will reassess its impact on the associated environmental risks at that time.

Ecological Effects

Exposure to non-target aquatic organisms can result from spray drift and runoff from treated areas. However, acute effects to freshwater fish and aquatic invertebrates are not expected from the normal use of fosamine ammonium. Fosamine ammonium is practically nontoxic to coldwater and warmwater fish, and does not appear to bioaccumulate in fish. However, a nine percent fish mortality was observed in the accumulation in fish study. Fosamine ammonium is practically nontoxic to freshwater invertebrates and to estuarine species.

Fosamine ammonium is practically nontoxic to honey bees, which are used to assess the effects on non-target insects.

Fosamine ammonium is practically nontoxic to avian species on an acute oral and a subacute dietary basis. Mixed results were found in the avian reproductive studies. In one mallard duck study, there was some indication of chronic reproductive effects. However, in another avian reproductive study, using the bob white quail as the test organism, there were no reproductive effects at any dose level.

Fosamine ammonium is practically nontoxic to small mammalian species. Acute oral and subacute dietary risks to non-endangered and endangered non-target mammals are not expected to result from current label uses.

Ecological Effects Risk Assessment

Based on the data, fosamine ammonium dissipation is predominantly dependent on rapid microbial-mediated degradation. It is also mobile in mineral soils. However, fosamine ammonium should not pose a threat to groundwater or surface waters because it rapidly degrades in aerobic and anaerobic environments. There are no Maximum Concentration Levels

(MCLs) or drinking water health advisories for fosamine ammonium or its degradates.

The health and environmental data on fosamine ammonium indicate a low level of toxicity of this pesticide. However, the inconclusive results in the avian reproductive studies have led the Agency to require a new mallard duck reproduction study on a confirmatory basis. In addition, risk mitigation measures are required to reduce the potential for avian reproductive effects.

Additional Data Required

EPA is requiring the following additional generic data for fosamine ammonium to confirm its regulatory assessments and conclusions: Certification of limits (62-2), Avian reproduction, mallards (71-4b), In-vivo cytogenetics (84-2a), Droplet size spectrum and field drift data (201-1, 202-1), Method validation for worker exposure (231, 232), Terrestrial plant (122-1, 123-1), and Aerobic aquatic (164-2, 162-4) if aquatic sites are not deleted.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs) and revised labeling for reregistration.

Product Labeling Changes Required

All fosamine ammonium end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

a) Within the Environmental Hazards section of the Precautionary Statement of the label:

> "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate."

b) To reduce environmental loading and potential exposure to non-target species, the product label must include language to limit use as outlined below:

> i) the end-use product can be applied only once annually during the period after spring growth has hardened to the development of fall coloration in deciduous species, and
>
> ii) the maximum application rate for low shrubs/brush is 16 lb a.i./A, and for tall dense woody species with very heavy foliage can be 24 lb a.i./A.

c) The end-use product labels cannot include directions for applications to aquatic sites. The current, sole registrant has submitted an application for amended registration to delete these uses from its product registration. Future submissions of appropriate data to support registration for these uses will be considered by the Agency.

d) The Agency is requiring the following labelling statements to be located on all end-use products containing fosamine ammonium:

> 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 applications."

Entry Restrictions

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

For liquid applications:

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

Other Labelling Requirements:

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 clothing immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

These statements must be included on the labels, as they are appropriate, after product-specific PPE requirements are set by the Agency. Although it is not required under the current labeling, it is assumed that the workers wear long pants, long sleeved shirts, shoes, and socks.

Regulatory Conclusion

The use of currently registered products containing fosamine ammonium in accordance with approved labeling, except use in aquatic sites, will not pose unreasonable risks or adverse effects to humans or the environment. The registrant has voluntarily requested cancellation of the aquatic uses. The Agency is not including the aquatic uses in its eligibility decision, because of the inadequate environmental data and the impending deletion of those uses from all current registrations. Therefore, all uses of fosamine ammonium products, other than application to aquatic sites, are considered eligible for reregistration.

Fosamine ammonium products will be reregistered once the required, product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for fosamine ammonium during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of

Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV,* or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the fosamine ammonium RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

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

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.