United States Environmental Protection Agency
Office of Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-033 February 1996

Reregistration Eligibility Decision (RED)

Prometryn

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 prometryn which includes the active ingredients 2,4-bis (isopropylamino)-6-methylthio-s-triazine. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It 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 Jean Holmes at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Mario F. Fiol at (703) 308-8049.

Sincerely yours,

Lois A. Rossi, Director
Special Review
and Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. 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

PROMETRYN

LIST A

CASE 0467

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

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PROMETRYN REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Background

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide prometryn, 2,4-bis (isopropylamino)-6-methylthio-s-triazine.

Prometryn is a substituted thiomethyl triazine herbicide registered for the control of several annual grasses and broadleaf weeds in the terrestrial food and feed crops cotton, celery, pigeon peas and dill. Prometryn was first registered in 1964 by Ciba Crop Protection. Prometryn is also manufactured by the Verolit Chemical Manufacturer, Ltd. Prometryn's major use sites are cotton and celery.

A Registration Standard for prometryn was issued in March 1987. Since then, two Data Call-Ins (DCI) have been issued. The first DCI, issued in September 1991, required phytotoxicity studies and spray drift data. The second DCI, issued in September 1992, required data concerning hexachlorobenzene (HCB) and pentachlorobenzene (PCB) in technical prometryn. The Agency has now completed its review of the prometryn target data base including data submitted in response to the 1987 Standard and the DCIs.

Reregistration Eligibility

The Agency has determined that all uses of prometryn as currently registered will not cause unreasonable risk to humans or the environment and all uses are eligible for reregistration. However, the Agency is requiring two ecological effects studies, a post-application reentry exposure study for celery, a dermal absorption/penetration study and a limited field rotational crop study as confirmatory data.

Health Effects

Prometryn was classified by the Agency's Office of Pesticide Program's Carcinogenecity Peer Review Committee as a Group E Carcinogen (no evidence of human carcinogenic potential). A RfD has been set at 0.04 mg/kg/day based on a NOEL of 3.75 mg/kg/day from a chronic toxicity study in dogs with an uncertainty factor of 100 to account for inter- and intra-species variability.

An acute dietary analysis was conducted using a NOEL of 12 mg/kg body weight/day from a rabbit developmental toxicity study. The LEL was based on increased resorptions, abortions and significant changes in other reproductive parameters at 72 mg/kg body weight/day. MOE's calculated for both the average and highest exposed individuals are greater than 100, indicating that acute dietary exposure from the use of prometryn on food poses only a minor risk.

The residue chemistry data base for prometryn is adequate. Tolerances are established for residues of prometryn in or on agricultural commodities and are listed under 40 CFR 180.222. Revised or new tolerances are needed for cotton, cotton gin byproducts and for rotational small grains (forage, straw and hay).

Prometryn residues do not concentrate in any cottonseed processed commodities. Therefore, no food/feed additive tolerances are required for cottonseed processing commodities other than grain byproducts.

Occupational Exposure/Risk Assessment

A NOEL of 12 mg/kg/day from a rabbit developmental study together with a 15% dermal absorption factor was used to assess both short and intermediate term occupational exposure. This is the same NOEL used to assess the acute dietary analysis.

The Agency has determined that there is an exposure potential for handlers (mixers, loaders, applicators) using prometryn. Data from the most recent version of the Pesticide Handlers Exposure Database were used to estimate daily exposures to mixers/loaders/ applicators.

The Agency also determined that there is a potential for exposure to prometryn to persons entering treated sites after application is complete. For many uses of prometryn, the potential for post-application exposure exists when the task being performed either disturbs the soil sub-surface or the person comes into contact with the area to which the spray was directed (soil incorporation and lay-by treatments, respectively).

The Worker Protection Standard for Agricultural Pesticides -- 40 CFR Parts 156 and 170 -- established an interim restricted-entry interval (REI) of 12-hours. However, the Agency is establishing a 24-hour REI for uses on celery and a 12-hour REI for all other uses within the scope of the Worker Protection Standard for Agricultural Pesticides. The basis for the 24-hour REI on celery is that prometryn has a toxicological endpoint of concern for systemic toxicity for short-term and intermediate exposures, no post-application exposure data are available, and hand-labor tasks (hand-thinning) are associated with the timing of the celery use. Furthermore, the Agency is also requiring additional labeling statements regarding user safety to be located on all end-use products containing prometryn that are intended primarily for occupational use.

Additionally, in order to alleviate the concerns to handlers, the technical registrant has agreed to formulate wettable powder in water soluble packets. This requirement should adequately mitigate the risks associated with mixing and loading of wettable powder formulations. To mitigate the risks associated with mixing and loading liquid formulations to support aerial applications, the Agency is requiring minimum (baseline) PPE of a chemical-resistant apron and a respirator equipped with a dust/mist filter.

Environmental Fate and Ecological Effects

The Agency has reviewed all of the ecological effects and environmental fate data for prometryn. All of the ecological effects data required to complete a risk assessment for the reregistration of prometryn are fulfilled with the exception of an avian reproduction (upland gamebird) study and a fish early life stage study. These studies are needed to fully assess prometryn's risk assessment to birds and fish and both studies are considered confirmatory. Prometryn poses an acute risk to nonendangered and endangered terrestrial and aquatic plants, a chronic risk to birds, and an acute risk to endangered small mammals. In order to reduce the potential risks, the Agency is requiring products to carry environmental hazard labeling.

All environmental fate data required to complete an environmental fate assessment for the reregistration of prometryn are fulfilled. The laboratory mobility data for prometryn indicate that prometryn has the potential to leach into ground water and will be most mobile in sandy, alkaline soils which contain little organic matter or clay. Prometryn was detected in ground water from an irrigation well in California. However, in California, Arizona and New Mexico, prometryn labels instruct potential users not to apply the product to sand or loamy sand soils. Prometryn was not detected in ground water during a retrospective ground-water monitoring study performed by the registrant in Missouri, at a site which was underlain by sandy loams and loamy sands. In light of the registrant's stewardship and the data in-house, the Agency has determined that ground water and surface water label advisories are not necessary at this time. The use of prometryn is prohibited on sand and sandy loam soils.

Before reregistering the products containing prometryn, 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 prometryn. The document consists of six sections. Section I is the introduction. Section II describes prometryn, 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 prometryn. Section V discusses the reregistration requirements for prometryn. 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.

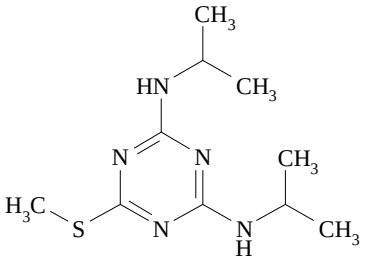
II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Decision:

Common Name: Prometryn

Chemical Name: [2,4-bis (isopropylamino)-6-methylthio-s-triazine]



Empirical Formula:	$C_{10}H_{19}N_5S$
Molecular Weight:	241.37
CAS Registry No.:	7287-19-6
Shaughnessy No.:	080805
Basic Manufacturers:	Ciba Crop Protection and Verolit Chemical Manufacturers, Ltd.

Technical prometryn is a white crystalline solid with a melting point of 118-120°C. Prometryn is soluble at 20°C in water at 33 ppm and is readily soluble (10-30 g/100 mL) in the following organic solvents: acetone, dichloromethane, methanol, octanol, and toluene. The vapor pressure for prometryn is low, 1.0×10^{-6} mm Hg at 20°C.

B. Use Profile

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

Type of Pesticide: a substituted thiomethyl triazine herbicide

Other Names: Prometryne, Caparol, Gesagard, Primatol Q, Prometrex

Mechamism of Action: inhibits electron transport

Use Groups and Sites -

TERRESTRIAL FOOD CROP: celery, dill, pigeon peas

TERRESTRIAL FOOD + FEED CROP: cotton (unspecified), pigeon peas

Target Plants:

broadleaves: black nightshade, cocklebur, coffeeweed, dock, Florida pusley, ground-cherry, henbit, lambsquarters, mallow, morningglory, mustard, pigweed, prairie sunflower, prickly sida, purslane, ragweed, rough blackfoot, smartweed, spurred anoda

grasses: barnyardgrass, crabgrass, foxtail, goosegrass, junglerice, panicum, sandbur, signalgrass, wild oat

Formulation Types Registered:

Single Active Ingredient (AI) Products

Wettable powder -- 80%
Crystalline -- 97%
Flowable concentrate -- 44 to 45.41%
Formulation not identified/solid -- 95%

Multiple Active Ingredient Product

Flowable concentrate -- 8.4% + monosodium methanearsonate (MSMA)

Method and Rates of Application:

Wettable powder

Apply to celery at planting, pre- or postemergence, postplant, posttransplant, or seed bed as broadcast by sprayer at 0.8 to 3.2 lb AI/acre.

Apply to dill at preemergence or postemergence as broadcast with sprayer at 1.6 lb AI/acre.

Apply to pigeon peas at preemergence as broadcast with sprayer at 2.0 to 2.8 lb AI/acre.

Apply to cotton at planting, fall, lay-by, plant bed, postemergence, postplant, preemergence, seedbed, or winter as broadcast with sprayer at .64 to 2.8 lb AI/A; or, at fall as broadcast by airplane at .8 lb AI/A; or, at preplant as soil incorporated treatment by aircraft or sprayer at 2.4 lb AI/acre.

Flowable concentrate

Apply to celery at planting, preemergence, postemergence, postplant, posttransplant, or seed bed as broadcast by sprayer at .8 to 3.2 lb AI/A [4.0 lb AI/A for Hawaii].

Apply to cotton at planting, fall, lay-by, postemergence, postplant, preemergence, seedbed, or winter as broadcast by sprayer at .5 to 2.8 lb AI/A; [3.5 lb AI/A for Sharkey clay (Arkansas only) and for silt and clay loam in Mississippi River Delta in Mississippi] or, apply to cotton at planting, fall, lay-by, postplant, preemergence, seedbed, or winter as broadcast by aircraft at .8 to 2.8 lb AI/A; or apply to cotton at postemergence by low pressure ground equipment, shielded application, or sprayer as directed spray at .5 lb AI/A; or, at postemergence as directed spray by sprayer at .65 lb AI/A; or, at preplant as soil incorporated treatment by aircraft or sprayer at 1.6 to 2.4 lb AI/A.

Apply to pigeon peas at planting, postplant, or preemergence as broadcast by aircraft or sprayer at 2 to 3 lb AI/A.

Use Practice Limitations:

Do not apply through any type of irrigation system. Do not feed treated foliage to livestock or graze treated areas. Please refer to Appendix A for more information.

C. Estimated Usage of Pesticide

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

Percent of Various U.S. Crops Treated with Prometryn, 1990 - 1992

Site/1	Acres Grown/2 (000)	Acres Treated (000)	Percent Crop Treated	Pounds AI Applied
Celery	36	20 - 30	56 - 83	15 - 25
Cotton	13,230	1,800 - 2,800	14 - 21	1,100 - 1,800
Other	N/A	40 - 50	N/A	20 - 25
Total		1,865 - 2,850		1,135 - 1,850

1 - Site identification based on REFS.
2 - 1990 - 1993 average (USDA/NASS).
Note: There is no known usage on pigeon peas and there are no data available for dill.

D. Regulatory History/Data Requirements

Prometryn was registered in the United States in 1964 for use as a herbicide for the control of weeds in cotton, celery, pigeon peas, and dill. A Registration Standard was issued in March 1987 (PB87-184826), and required product and residue chemistry, toxicology, fish and wildlife, plant protection and environmental fate data. The Special Review and Reregistration Division issued two Data Call-Ins, one September 30, 1991, requesting Tier 3 non-target phytotoxicity field studies and Spray Drift information, and the second, September 2, 1992, requesting hexachlorobenzene (HCB) and penta-chlorobenzene (PCB) data in technical prometryn to determine the potential presence of these impurities. Since then, the registrant has submitted adequate information addressing the PCB and HCB deficiencies. Lacking appropriate guidance for conducting Tier III testing and because of our new policy, the Agency has decided to assess risk and make reregistration decisions based on Tier II lab data. Consequently the Agency has placed Tier III study requirements on reserve. This Reregistration Eligibility Decision document reflects the reassessment of the data submitted in response to the Registration Standard and to the Data Call-Ins.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The physical and chemical properties of prometryn are as follows:

o Prometryn Technical

Color: white

Physical State: a crystalline solid

Odor: odorless or very faint

Melting Point: 118-120^{o} C

Specific Gravity: 1 - 16 g/ml @20^{o} C

Solubility: 33 ppm in water at 20^{o} C and is readily soluble (10-30 g/100 ml) in the following organic solvents: acetone, dichloromethane, methanol, octanol and toluene.

Vapor Pressure: 1.0 x 10^{-6} mm Hg at 20^{o} C

pH: 6.7 @ 20^{o} C (saturated solution)

Stability: stable in neutral and slightly acidic or alkaline media; hydrolyzed by alkali and mineral acids at elevated temperatures.

There are two prometryn manufacturing-use products (MPs); the Ciba Crop Protection 97% T (EPA Registration Number 100-542) and the Verolit Chemical Manufacturers, Ltd. 95% T (EPA Registration Number 46386-2).

The product chemistry data base for prometryn is adequate to support the reregistration eligibility decision of prometryn. However, there are several product chemistry requirements not fully satisfied. References for all studies submitted in support of the product chemistry data requirements are listed in Appendix B of this document.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological database for prometryn is adequate and will support reregistration eligibility for current uses. The laboratory animal data consists of the following:

a. Acute and Subchronic Toxicity

Acute Toxicity: The following table summarizes the results of acute toxicity studies on prometryn and the toxicity categories for the different routes of administration. Data pertaining to acute eye and dermal irritation and dermal sensitization are not required to support the reregistration of the technical grade active ingredient (TGAI). These data are presented for informational purposes:

TEST	RESULTS	TOX CATEGORY
Oral LD50 in rat (MRID 00060314)	M: 1802 (1265-2568) mg/kg F: 2076 (1654-2607) mg/kg	III
Dermal LD50 in Rat (MRID 00060647)	LD50 >3170 mg/kg.	III
Four-hr Inhalation LC50 in rat (MRID 42325503) [80% formulation]	LC50 = 4.96 mg/L	III
Eye Irritation in rabbit (MRID 40776601) [95% formulation]	Mild Irritation	III
Dermal Irritation in rabbit (MRID 00060316)	Slight Irritation	IV
Dermal sensitization in Guinea Pig (MRID 40966001) [44.4% formulation]	Not a sensitizer	N/A

b. Subchronic Toxicity

In a 28-day pilot feeding study prometryn technical (purity not reported) was fed to groups of five male and five female Charles River CD-1 mice at levels of 0, 30, 100, 300, 600, 1,000, 3,000, 10,000 or 30,000 ppm (0, 4.5, 15, 45, 90, 150, 450, 1500, or 4500 mg/kg/day) for 28 days. (MRID 40457515)

All the high-dose animals died by the end of week two. Macroscopic and microscopic pathological findings in the high dose animals were limited to the G.I. tract. Clinical signs (i.e., hunched appearance, labored respiration, thinness) and marked decreases in body weights were seen in these animals. Gross findings in the small intestine were observed in some of the mice fed 10,000 ppm (1500 mg/kg/day); however, the gross findings were not accompanied by histological effects. Clinical signs and moderate to marked decreases in body weights were also noted in these animals. There were no effects of toxicological importance in animals receiving less than 10,000 ppm (1500 mg/kg/day). The NOEL (males & females) was 3,000 ppm (450 mg/kg/day), while the LOEL was 10,000 ppm (1500 mg/kg/day) based on decreased body weights.

In a 21-day dermal toxicity study prometryn technical was applied to five male and five female New Zealand White rabbits per dose group at 0, 10, 100, or 1000 mg/kg/day, 5 days/wk for three weeks. No local or systemic toxicity was observed at these dose levels. The systemic NOEL is >1000 mg/kg/day for males & females, and the NOEL is >1000 mg/kg/day. (MRID 40573702)

c. Chronic Toxicity/Carcinogenicity

In a 102-week feeding/oncogenicity mouse study, prometryn technical was fed to groups of 60 male and 60 female Charles River CD-1 mice at dietary levels of 0, 10, 1,000, or

3,000 ppm (0, 1.42, 2, 142, 429 mg/kg/day) for 102 weeks and observed for signs of toxicity including oncogenicity. (MRID 40466201)

Mean body weight gain in the high-dose females was lower than those of controls during the first 48 weeks of the study (statistically significant($p \leq 0.05$)). There was no significant effect of dosing on clinical signs, mortality, gross pathology or histopathology. No effects were observed in males. The NOEL was 1,000 ppm for females. The LOEL was 3,000 ppm for females based on decreased body weight gain.

Although significant toxicity was observed only in females, the RfD committee (July 26, 1994) considered the study adequate since 1) levels were close to one-half the limit dose in mice; 2) no effects were noted in the study to warrant repeating the study at higher dose levels; 3) all tumors noted with other members of the s-triazine class were mainly in rats and not mice. Prometryn was not oncogenic under the conditions of the study.

Prometryn technical was fed to male and female Sprague-Dawley rats for 104 weeks at dietary levels of 0, 10, 100, 750 or 1500 ppm (males: 0, 0.38, 3.90, 29.45 or 60.88 mg/kg/day, respectively; females: 0, 0.49, 4.91, 37.25, or 80.62 mg/kg/day, respectively.) (MRID 41901201)

Decreased body weight and body weight gain were observed in high-dose males and females during the first and second year of treatment. Transient decreases (weeks 1 and 2) in food consumption in both sexes at the high dose and in males at the mid-dose, were attributed to decreased palatability of the diet. An increase in the incidence of renal lesions (mineralized concretions) in high dose males was noted. The LOEL in males and females was 1500 ppm, and the NOEL 750 ppm. Prometryn was not oncogenic under the conditions of the study.

Groups of 3 male and 3 female beagle dogs (4 - 8 months old) were dosed in the diet for 106 weeks with prometryn 80W (80% wettable powder) as active ingredient concentrations of 0, 15, 150, or 1500 ppm (0.0, 0.375, 3.75, or 37.50 mg/kg/day). (MRID 00042794).

No clinical signs or effects on body weight were observed. No changes in clinical pathology or urinalysis parameters were observed. All of the high-dose males showed slight to moderate renal tubular degeneration, including degeneration of the loops of Henle, cortical congestion, thickening of capsular basement membranes, and hypercellularity of the glomeruli. Slight bone marrow atrophy was observed in 2 of 3 high-dose males, and 1 of 3 males had a congested liver. The NOEL was 3.75 mg/kg/day a.i., and the LOEL was 37.5 mg/kg/day based on degenerative hepatic changes, renal tubule degeneration, and bone marrow atrophy.

The Agency's Office of Pesticide Programs RfD Committee classified prometryn as a Group E Carcinogen (no evidence of human carcinogenic potential) on May 19, 1994,

because prometryn did not alter the spontaneous tumor profile for the strains of rats and mice tested.

d. Developmental Toxicity

In a developmental rat toxicity study, prometryn technical was administered by gavage to groups of 26 pregnant Sprague-Dawley rats at levels of 0, 10, 50 or 250 mg/kg/day during gestational days 6 to 15. A compound-related increased incidence of clinical signs was noted at 250 mg/kg, as was decreased body weight, body weight gain and food consumption during the dosing period. Body weight was also significantly decreased ($p \leq 0.05$) at 50 mg/kg/day, but the decrease was minimal, <5%, and therefore not of concern. The maternal NOEL was 50 mg/kg/day, the LOEL was 250 mg/kg/day, based on salivation and decreases in body weight and food consumption. At 250 mg/kg/day, fetal body weight was significantly decreased and incomplete ossification in the sternebrae and metacarpals was observed ($p \leq 0.05$). No significant effects were noted at 50 mg/kg/day. The developmental NOEL was 50 mg/kg/day, the LOEL was 250 mg/kg/day. (MRID 40457517)

In a developmental toxicity study, prometryn technical was administered by gavage to pregnant New Zealand White rabbits at 0, 2, 12, or 72 mg/kg/day during days 6 thru 19. Decreased food consumption (10-36%) was observed in high-dose animals, but a corresponding decrease in body weight parameters was not observed. A slight, not significant increase in abortions was observed. No other toxicity was observed. The maternal NOEL was 12 mg/kg/day, the LOEL was 72 mg/kg/day based on decreased food consumption. The HDT was observed to have a decreased number of live litters and live fetuses due to increased late resorption and abortion. It cannot be determined whether the abortions were a consequence of maternal toxicity. The developmental NOEL was 12 mg/kg/day, the LOEL was 72 mg/kg/day based on increased fetal resorptions. (MRID 00157995)

e. Reproductive Toxicity

In a two-generation reproductive toxicity study, prometryn technical was administered in the diet to groups of 30 male and 30 female Sprague-Dawley rats at levels of 0, 10 ppm (0.6 mg/kg/day in males, 0.7 mg/kg/day in females), 750 ppm (47.8 mg/kg/day in males, 53.6 mg/kg/day in females) or 1500 ppm (96.7 mg/kg/day in males, 105.6 mg/kg/day in females). (MRID 41445101)

Body weight gain in F0 males decreased significantly at 1500 ppm (11-40%) and 750 ppm (11-18%). Body weight gain decreased in F0 females by up to 50% at 1500 ppm and 750 ppm. Similar changes in body weight gain were seen in F1 males. Corresponding decreases in food consumption were also observed. The parental systemic toxicity NOEL was 10 ppm; the LOEL was 750 ppm, based on decreased food consumption, body weight and body weight gain.

Statistically significant decreases in F1 pup body weights were observed at 1500 and 750 ppm (up to 12%) during lactation. A similar, though less marked, profile was seen in F2 generation pups. While actual weight loss was small (5 - 12%), and may be artifactual to maternal weight losses, it is considered of toxicological significance because of its potential negative impact on postnatally developing systems such as the neuro- and immune systems. The reproductive NOEL was 10 ppm (0.65 mg/kg/day); and, based on decreased pup weight, the LOEL was 750 ppm (≈50 mg/kg/day).

f. Mutagenicity

In an Ames salmonella test, prometryn was negative for gene mutation up to cytotoxic solubility limits (1000-2000 µg/plate). (MRID 40457518)

In a chromosomal aberration in vivo Chinese hamster bone marrow test, prometryn was negative for nuclear anomalies (micronuclei) when animals were dosed orally up to 5000 mg/kg. (MRID 40466203)

Prometryn was negative for bacterial DNA repair and gene mutation up to precipitating levels (1000 μg/plate). (MRID 40457519)

In an unscheduled DNA synthesis test, prometryn was negative (measured as UDS) in rat hepatocytes cultured in vitro up to cytotoxic levels 156.25 μg/ml). (MRID 40457522)

g. Metabolism

In a series of general metabolism studies, three groups of Crl:CD BR rats (5 males, 5 females per group) were given a single oral dose of ^{14}C-prometryn. Group 1 received 0.46-0.47 mg/kg. Group 2 received 467 mg/kg (average). Group 3 received 0.5 mg/kg unlabeled prometryn daily for 14 days, followed by 0.46 mg/kg ^{14}C-prometryn on day 15. An additional group, Group 4, was used for metabolite isolation and identification purposes and received 540 mg/kg ^{14}C-prometryn. (MRID 41255901)

Data from these studies indicate that the distribution of prometryn is greatest in the blood, followed by the spleen, and finally in the lungs (the three highest tissues measured). Distribution is not dosage-dependant. It is extensively metabolized with <2% of recovered ^{14}C radioactivity representing the parent compound. Twenty-eight metabolites were identified in the urine, and 28 in the feces. Ten metabolites were identified in both urine and feces. Prometryn is excreted predominantly in the urine and feces, with slightly higher concentrations in the urine. The 7-day recovery of ^{14}C radioactivity averaged 95% for all dosing groups.

h. Additional Toxicicity Endpoints

The RfD has been set at 0.04 mg/kg/day by the Office of Pesticide Programs RfD/Peer Review Committee based on a NOEL of 3.75 mg/kg/day in a chronic toxicity study in dogs. The LEL was 37.5 mg/kg/day based on bone marrow atrophy and degenerative changes in the liver and kidneys. An uncertainty factor of 100 was used to account for inter- and intra-species variability.

An acute dietary analysis has been recommended in the Toxicology Endpoint Selection Document. The endpoint for acute dietary risk assessment is the NOEL of 12 mg/kg body weight/day from a rabbit developmental toxicity study. The LEL was based on increased resorptions, abortion and significant changes in other reproductive parameters at 72 mg/kg body weight/day.

A NOEL of 12 mg/kg/day from a rabbit developmental study was used to assess both short and intermediate term occupational and residential exposure. (MRID 00157995)

i. Dermal Absorption

The Agency has determined that a dermal absorption value of 15% should be used for risk assessment purposes. This value is based on an interpretation of data from two toxicology studies (an oral developmental study and a 21 day dermal study) in which rabbits were used as the test species.

In the developmental toxicity study in rabbits, the maternal and fetal NOEL were determined to be 12 mg/kg/day; the LEL = 72 mg/kg/day. These effects included significantly decreased food consumption, increased resorption (113%), and increased post-implantation loss (130%). There was a corresponding decrease in the number of viable litters (-35%) and live fetuses (-15%). These or other effects were not observed at lower doses. (MRID No. 00157995)

In the 21-day dermal study in rabbits, no signs of systemic or local toxicity were observed. A dermal NOEL was determined to be > 1000 mg/kg/day. (MRID 40573702)

Although no dermal absorption study with prometryn was ever conducted, the Agency has concluded that a 7% absorption factor is a reasonable upper limit for dermal absorption. The 7% is based on a comparison between an oral rabbit developmental study and a 21-day dermal rabbit study. Uncertainties and concerns regarding the use of 7% in conducting the risk assessment exist because the parameters typically measured in a 21-day dermal study are not extensive (i.e., no clinical chemistries) and the effects observed in the developmental study are significant including increased abortion and increased post-implantation loss. Therefore, the Agency is using a more protective absorption rate of 15% with the stipulation that a dermal absorption study be conducted as confirmatory data.

2. Exposure Assessment

a. Dietary Exposure

The residue chemistry data base for prometryn is adequate and will support reregistration as a food use pesticide. Prometryn is registered for food/feed use on celery, cotton, dill, and pigeon peas.

The residue of concern (i.e. that which should be included in the tolerance expression) is prometryn, *per se*. Magnitude of the residue data are available for dill, pigeon peas, cottonseed, and celery. An adequate processing study has been submitted for cottonseed, and demonstrates that residues of prometryn do not concentrate in any cottonseed processed commodities. Acceptable storage stability studies are available to support the established tolerances, provided that storage stability issues are adequately resolved for the celery and cottonseed studies reviewed.

The qualitative nature of the residue in animals is adequately understood; the residue of concern in animals is prometryn, *per se*. Since there are no residues of prometryn *per se* in poultry feed items, no tolerances are required for poultry meat and eggs. Based on the maximum theoretical dietary burden for prometryn *per se* for ruminants and on data from the ruminant metabolism study, the Agency has concluded that residues of prometryn *per se* in meat and milk may be classified under Category 3 of 40 CFR §180.6(a), (i.e., there is no reasonable expectation of detectable residues). Therefore, a ruminant feeding study is not required, and tolerances for residues in meat and milk are not required.

The Agency concludes that a risk assessment for the uses of prometryn can be conducted using tolerance-level residues of prometryn, *per se* in cottonseed, pigeon peas, celery and dill.

Tolerances are established for residues of prometryn in or on the following raw agricultural commodities: celery (0.5 ppm); corn fodder (field, pop, and sweet, 0.25 ppm); corn forage (field, pop, and sweet, 0.25 ppm); fresh corn (sweet K + CWHR, 0.25 ppm); corn grain (0.25 ppm); cotton [forage] (1 ppm); cottonseed (0.25 ppm); and pigeon peas (0.25 ppm). A tolerance with regional registration is established in or on dill (0.03 ppm) [40 CFR §180.222 (a) and (b)]. No tolerances are needed for residues of prometryn in animal commodities and no food/feed additive tolerances need to be established under 40 CFR §185 and §186.

(1) Guideline 165-1: Confined Rotational Crops

The nature of the residue in rotational crops is adequately understood. The metabolism of prometryn in rotational crops is similar to that of the primary crops and involves dealkylation, oxidation, hydroxylation, deamination, and conjugation.

(2) Guideline 165-2: Field Rotational Crops

Requirements are fulfilled for magnitude of the residue data in rotational root crops and in forage and straw of rotational small grains (wheat and barley). Adequate limited field trial data have been submitted for rotational root crops, provided the registrant amends its labels to specify an 8-month Plant Back Interval (PBI) for rotational root crops. Adequate extensive field trial data have been submitted depicting residues of prometryn in forage and straw of rotational wheat and barley. A sufficient number of field trials were conducted in representative geographic regions at maximum label rates.

The available data support the registrant's suggested tolerance of 0.3 ppm for residues of prometryn *per se* in forage and straw of rotational small grains planted after prometryn-treated cotton, with a 3-month PBI. The data also indicated that tolerances are not required for residues in rotational small grains and processed grain fractions. Additional data are required depicting prometryn *per se* residues in hay from rotational wheat and barley; however, these data will not be required, provided the registrant has no objection to a tolerance of 1.0 ppm in or on hay of rotational small grains. This tolerance was calculated based on the suggested tolerance in forage and a dry-matter conversion.

Additional rotational crop field trial data are required for leafy vegetables, since residues of prometryn *per se* were detected at up to 0.03 ppm in lettuce rotated at the longest PBI (8-9 months) in the limited field trial. The registrant must either conduct extensive field trials with representative leafy vegetables at an 8-month PBI, or an additional limited field trial with lettuce that includes a 12-month PBI. If no residues of prometryn *per se* are present in lettuce at a 12-month PBI (< .01), then a label restriction specifying a 12-month PBI will be adequate and no further data will be required. In the interim, the Agency will require that registered labels be amended to specify a 12-month PBI for rotational leafy vegetables.

(3) Guideline 171-3: Directions for Use

Use directions for prometryn on cotton prohibit grazing in treated areas and the feeding of treated forage to livestock. However, cotton forage is no longer considered to be a significant livestock feed item, and cotton gin by-products (gin trash), considered to be a feed item in beef and dairy cattle diets, are not under control of the grower. Consequently, a label restriction against the feeding of treated cotton material is no longer appropriate. The registrant should submit amended labeling deleting this restriction. Label directions for cotton do not list specific plantback intervals (PBIs) for crops rotated with treated cotton; the registrant should submit revised labels specifying the allowed plant back intervals, (refer to the discussion under Guideline 165-2, Field Rotational Crops).

(4) Guideline 171-4(a): Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on acceptable cotton and celery metabolism studies. Results of the cotton and celery metabolism studies support the registrant's proposed metabolic pathways involving N-dealkylation and hydrolysis of prometryn. Prometryn is absorbed by the roots and is translocated to the foliage, but does not appear to be translocated from older shoots to new shoot growth. The residue of concern in plants consists of the parent, prometryn *per se*, which is the currently regulated residue.

The Agency notes that if other major uses are registered in the future, additional metabolism studies will be required, and regulation (i.e., inclusion in the tolerance expression) of residues in addition to the parent may be required. (MRIDs 41293301, 41711301, 41711302)

(5) Guideline 171-4(b): Animal Metabolism

The nature of the residue in animals is adequately understood, based on acceptable poultry and ruminant metabolism studies. As in plants, the residue of concern (and that which should be regulated) in animals is the parent, prometryn *per se*. The major portion of the terminal residues in milk, muscle, and liver of poultry and goats, goat kidney, poultry fat and eggs are comprised of the N-acetyl cysteine conjugate of GS-11354, the cysteine conjugate of GS-11354, melamine, GS-17794, the N-acetyl cysteine conjugate of prometryn and GS-26831. The metabolism of prometryn in animals involves N-dealkylation along with hydrolysis and/or amino acid conjugation. (MRIDs 41293302, 41293303)

(6) Guideline 171-4(c) and (d): Residue Analytical Methods - Plants/Animals

Two enforcement methods are published in PAM, Vol. II, neither of which has undergone Agency validation. Method A is a spectrophotometric method that includes a reference for GC determination for specific triazine compounds. Method A is unsuitable as an enforcement method because it is not specific for prometryn. Method B is a GC method using a microcoulometric sulfur detection system that determines residues of prometryn, atrazine, and simazine in milk. For purposes of reregistration, adequate analytical methodology is available for determining residues of prometryn in plant commodities. A registrant developed GC method, (Method AG-559), using a flame photometric detector in the sulfur mode (FPD/S) has undergone a successful independent laboratory validation.

The Agency has determined that Method AG-559 would be acceptable for enforcement purposes, pending completion of a successful Agency method validation trial. Now that the nature of the residue in plants is adequately understood and the residue to be regulated is prometryn *per se*, Method AG-559 will undergo an Agency method validation

trial. Method AG-559 has undergone radiovalidation using samples from the celery metabolism study; however, these samples contained no detectable residues of prometryn. An additional radiovalidation of Method AG-559 has been requested using samples from the most recent cotton metabolism study. No tolerances are needed for prometryn residues in animal commodities, therefore, enforcement analytical methods for residues in animals are not presently required.

Adequate GC data collection methods are available for prometryn and the metabolites GS-11354 and GS-26831. Method AG-559 is the most recent of these methods. Residue data submitted for tolerance reassessment were collected using either a spectrophotometric method (Method A) or GC methods using microcoulometric, thermionic, or FPD/S detectors. The registrant provided adequate method validation data to verify the suitability of these methods for data collection.

The FDA PESTDATA database indicates that prometryn is completely recovered (>80%) using multiresidue method PAM, Vol. I Section 302 and partially recovered (50-80%) using Sections 303 and 304, with the recovery varying depending upon the choice of Florisil system used.

(7) Guideline 171-4(e): Storage Stability

The requirements for storage stability data are not fully satisfied for reregistration. Information regarding sample storage intervals and conditions is needed for celery and cottonseed samples from submitted studies. If the registrant submits information indicating that the storage intervals for celery or cottonseed samples from the studies previously submitted exceeded 37 months, or if storage conditions differed from those represented in the storage stability data, the Agency may require additional storage stability data or new residue field trials.

Storage stability studies have been conducted using fortified control samples of celery, cottonseed, fresh and dried parsley, and pigeon peas. Residues of prometryn and its metabolites GS-11354 and GS-26831 are stable in cottonseed and celery samples stored frozen at -20 °C for up to 37 months, and in fresh and dried parsley samples stored frozen for up to 21.7 months. Residues of prometryn *per se* are stable in pigeon peas stored at -12 °C for up to 42 days. Storage stability data on celery and parsley (tolerance petition pending) are adequate to support dill.

(8) Guideline 171-4(k): Magnitude of the Residue in Plants

The reregistration requirements for magnitude of the residue in plants are fulfilled for the following commodities: dill, parsley and pigeon peas. Adequate field trial data depicting residues of prometryn following applications made according to the maximum registered use

patterns have been submitted for these commodities. Geographic representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Provided that the storage conditions and intervals incurred during celery and cotton field trials are supported by the available storage stability data, reregistration requirements for magnitude of the residue in plants will also be fulfilled for celery and cottonseed.

Additional residue data are not required for pigeon pea vines and hay and cotton forage) at this time. The Agency feels that label restrictions prohibiting the feeding of pigeon pea forage and hay to livestock are practical and thus may remain on registered labels and cotton forage is no longer considered a significant feed item.

The March 1987 Prometryn Reregistration Standard Guidance Document required additional residue data to support uses on corn; however in June 1987, the registrant canceled its labeled uses on corn. A summary of the available data and reregistration status is presented below for each commodity.

Leafy Vegetables Group (except Brassica Vegetables)

Celery: Acceptable residue data are available. However, for purposes of reregistration, information on sample storage conditions and intervals are required. If sample storage intervals exceeded 37 months, or if storage conditions differed from those in the supporting storage stability studies, additional storage stability data or new residue field trials may be required. (MRIDs 00034043, 000935529, 00093548)

Residues of prometryn were <0.04-0.35 in celery samples harvested 51-158 days following seedbed, preemergence, postemergence, and/or posttransplant applications of prometryn (WP) at 1-16 lb ai/A (0.3X-5X). Prometryn residues were <0.02-0.19 ppm in celery samples harvested 37-70 days following a single postplant application of prometryn (EC) at 3.2-6.4 lb ai/A (1X-2X). In studies using the EC formulation, celery samples were analyzed for residues of GS-11354 and GS-26831, which were each <0.02 ppm in all samples. The available data support the established 0.5 ppm tolerance for residues of prometryn *per se* in or on celery.

Legume Vegetables (Succulent or Dried) Group

Pigeon peas: Acceptable data are available to support tolerances in or on pigeon peas. Residues of prometryn *per se* were <0.2 ppm (nondetectable) in pigeon peas and pigeon pea pods harvested 132 days after a single preemergence application of prometryn (80% WP) at 3.2 lb ai/A (1.1X) using ground equipment. Residues of prometryn resulting from a 6.4 lb ai/A (2.2X) preemergence application were <0.2 ppm in pigeon peas (without pods) and 0.28-0.40 ppm in pigeon pea pods. The available data support the established 0.25 ppm tolerance for residues of prometryn *per se* in pigeon peas.

Foliage of Legume Vegetables Group

Pigeon pea forage and hay: Residue data on pigeon pea forage and hay are not required at this time and, therefore, the restrictions prohibiting the grazing or feeding of treated pigeon peas forage or hay to livestock should remain on registered product labels.

Herbs and Spices Group

Dill: Prometryn is registered on dill grown in California with a regional tolerance of 0.3 ppm. The registered use reflects a single preemergent or postemergence application of prometryn at 1.6 lb ai/A in a minimum of 20 gal/A with a PHI of 48 days. The available data support the established 0.3 ppm tolerance for residues of prometryn *per se* in fresh and dried dill grown in California.

Miscellaneous Commodities

Cotton: Acceptable residue data are available to support the 0.25 ppm tolerance for residues of prometryn *per se* in or on cottonseed and cotton forage. However, information must be submitted regarding sample storage conditions and intervals for all samples from the reviewed studies. If sample storage intervals exceeded 37 months, or if storage conditions differed from those used in supporting storage stability studies, additional storage stability data or new field trials may be required. (MRIDs 00027329, 00027330, 00093531, 00125011).

Residues of prometryn in 86 cottonseed samples were nondetectable (<0.04 ppm) and 0.04-0.06 ppm in 13 other samples collected 26-231 days following preemergence, postemergence, and/or lay-by soil applications (one to five) of prometryn (WP) at 0.8-9.0 lb ai/A (0.13X-1.5X). Residues of prometryn were <0.04 - 0.84 ppm in 80 cotton forage, foliage, and whole plant samples harvested 20-122 days following one to five preemergence, postemergence, and/or lay-by soil applications of prometryn at 0.25-9.0 lb ai/A (0.04X-1.5X). Residues of prometryn *per se* were 1.1 ppm in a single forage sample following five applications of prometryn totaling 6.15 lb ai/A (~1X). In addition, residues of the metabolites GS-11354 and GS-26831 were nondetectable (<0.1 ppm) in or on cotton forage. No residue data are available for cotton gin by-products (gin trash).

The available residue data support the established tolerances of 1.0 ppm for residues of prometryn *per se* in or on cottonseed and cotton forage, respectively. However, since cotton forage is no longer considered to be a significant animal feed item, the 1.0 ppm tolerance for prometryn residues on cotton forage will be proposed for revocation.

Although data on cotton gin trash are not available, based on the available residue data for cotton forage and data from the cotton metabolism studies, the Agency will use an estimated 1.0 ppm residue for cotton gin trash for purposes of a risk assessment. Metabolism

data for cotton plants indicated that the TRRs (total radioactive residue) in plants treated at 0.8X were 0.38 ppm in mature stalks, 0.34 ppm in ginned seed, 0.29 ppm in empty bolls, and 0.27 ppm in ginned fiber all of which are components of gin trash. The registrant must either propose a 1.0 ppm tolerance or submit the required studies.

(9) Guideline 171-4(l): Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for cottonseed. A summary of the available processing data is presented below.

Cottonseed: Acceptable cottonseed processing studies have been submitted. Residues of prometryn were nondetectable (<0.04 or <0.1 ppm) in 19 samples each of meal, crude oil, and refined oil processed from seed bearing residues of <0.04-0.07 ppm. Residues of prometryn were 0.06-0.08 ppm in four hull samples derived from seeds having residues of <0.04 ppm; however, residues were <0.04 ppm (non-detectable) in 15 hull samples derived from seeds of plants treated multiple times and at exaggerated rates. Prometryn residues do not concentrate in any cottonseed processed commodities. Therefore, no food or feed additive tolerances are required for the processed commodities of cottonseed.

(10) Guideline 171-4(j): Magnitude of the Residue in Meat, Milk, Poultry and Eggs

There are no existing tolerances established for prometryn residues in eggs, milk, animal fat, meat, and meat byproducts. Animal feeding studies were not required because detectable residues of prometryn and its triazine-containing analogs were not expected in meat, milk, or eggs. This conclusion was based on (1) maximum theoretical dietary burdens of 0.11-0.15 ppm for dairy and beef cattle, 0.04 ppm for poultry, and 0.05 ppm for swine calculated from the 0.25 ppm tolerance on cottonseed and the percent of cotton feed items in the animals' diets; (2) the levels of prometryn fed to the animals in the ruminant (50 ppm) and poultry (83 ppm) metabolism studies; and, (3) the TRR levels in milk, egg, and tissue samples from the metabolism studies.

The Agency has recalculated the maximum theoretical dietary burden of prometryn to be 0.755 ppm for dairy cattle and 0.577 ppm for beef cattle. The information used to calculate these theoretical dietary burdens included the percentage dry matter (% DM) in each feed item; the percentage of each feed item in the respective ruminant diets; and maximum residues in the feed items based on established tolerances for cottonseed, an estimate of maximum residues in cotton gin trash, and proposed tolerances for rotational small grains (barley and wheat) forage, hay, and straw.

Based on this reassessment of the theoretical dietary burden of ruminants for prometryn and on residues found in goat tissues in a ruminant metabolism study, the Agency concludes that residues of prometryn *per se* in meat and milk can be classified under Category 3 of 40 CFR §180.6(a). That is, there is no reasonable expectation of finite residues in meat and milk. No tolerances are required, and therefore a ruminant feeding study need not be submitted.

Because there are no residues of prometryn in or on poultry feed items, a feeding study is not required at this time for poultry and no tolerances are required for poultry meat and eggs.

b. Occupational Exposure

The acute toxicological database indicates that prometryn is in toxicity category III for acute oral, dermal, inhalation and eye irritation, and in toxicity category IV for dermal irritation. Prometryn is not a skin sensitizer. The vapor pressure for prometryn is low, 1.0×10^{-6} mm Hg at 20°C.

There are toxicological endpoints of concern for prometryn. The endpoint for both short-term and intermediate-term occupational exposure is a NOEL of 12 mg/kg/day taken from a rabbit developmental study indicating increased resorption, abortion, and significant changes in other reproductive parameters at the LEL. The LEL is 72 mg/kg/day and as discussed in Section III(B)(1)(i) "Dermal Absorption," the Agency has deemed a 15% factor appropriate for estimating dermal exposure.

Summary of Potential Occupational Exposure

- For Handlers (Mixers, Loaders, Applicators, etc.) Exposures

The Agency has determined that there is an exposure potential for handlers (mixers, loaders, applicators) during the usual use-patterns associated with prometryn. Exposures to mixers, loaders and applicators are likely when liquid (used in aerial application) and wettable powder (used in aerial and groundboom applications) formulations are used.

Mixer/loader/applicator (M/L/A) exposure data for prometryn were not required in the Registration Standard or subsequent DCI's, because the toxicological criteria had not been triggered. To address the recently identified toxicological endpoint, surrogate mixer/loader and applicator data available in the latest release of the Pesticide Handlers Exposure Database (PHED, ver 1.1) were used to estimate daily exposures for handlers. Handler exposure includes mixer/loaders, applicators, and flaggers exposed during applications of prometryn formulated as wettable powders, liquid formulations, or enclosed in a water soluble packets.

The mixer/loader exposure scenarios identified for prometryn are (1) wettable powders for aerial applications; (2) wettable powders for groundboom applications; (3) water soluble packets for aerial application; (4) closed mixing/loading for groundboom application; (5) liquid - closed mixing/loading used for aerial application; (6) liquid - closed mixing/loading for groundboom application; (7) liquid-open-pour aerial application; and (8) liquid-open-pour groundboom application.

The handler daily dermal exposures (DDE) (mg/kg/day) are calculated using the following formula:

$$\text{Daily Dermal Dose (DDD)} = \frac{\textbf{Unit exposure} \text{ (mg/lb ai) x amt. ai/acre x acres treated/day x \% absorbed}}{\text{60 kg body weight}}$$

The Agency considered the following scenarios as applicable for the use of prometryn:

Open bag - wettable powder formulation:

- Aerial application

$$\frac{\textbf{0.1737 mg/lb ai} \text{ x 0.8 to 3.2 lb/A x 350 acres x 15\%}}{\text{60 kg}}$$

$$= \quad \text{0.12 to 0.49 mg/kg/day}$$

- Groundboom application

$$\frac{\textbf{0.1737 mg/lb ai} \text{ x 0.8 to 3.2 lb/A x 100 acres x 15\%}}{\text{60 kg}}$$

$$= \quad \text{0.12 to 0.14 mg/kg/day}$$

Water Soluble Packet - wettable powder formulation:

- Aerial application

$$\frac{\textbf{0.01 mg/lb ai} \text{ x 0.8 to 3.2 lb/A x 350 acres x 15\%}}{\text{60 kg}}$$

$$= \quad \text{0.007 to 0.03 mg/kg/day}$$

Closed Mixing/Loading:

- Groundboom application

$$\frac{\textbf{0.01 mg/lb ai} \times 0.8 \text{ to } 3.2 \text{ lb/A} \times 100 \text{ acres} \times 15\%}{60 \text{ kg}} = 0.0002 \text{ to } 0.008 \text{ mg/kg/day}$$

Liquid - Closed mixing/loading:

- Aerial application

$$\frac{\textbf{0.0086 mg/lb ai} \times 0.8 \text{ to } 3.2 \text{ lb/A} \times 350 \text{ acres} \times 15\%}{60 \text{ kg}} = 0.006 \text{ to } 0.024 \text{ mg/kg/day}$$

- Groundboom application

$$\frac{\textbf{0.0086 mg/lb ai} \times 0.8 \text{ to } 3.2 \text{ lb/A} \times 100 \text{ acres} \times 15\%}{60 \text{ kg}} = 0.002 \text{ to } 0.007 \text{ mg/kg/day}$$

Liquid - open pour:

- Aerial application

$$\frac{\textbf{0.0425 mg/lb ai} \times 0.8 \text{ to } 3.2 \text{ lb/A} \times 350 \text{ acres} \times 15\%}{60 \text{ kg}} = 0.03 \text{ to } 0.119 \text{ mg/kg/day}$$

- Groundboom application

$$\frac{\textbf{0.0425 mg/lb ai} \times 0.8 \text{ to } 3.2 \text{ lb/A} \times 100 \text{ acres} \times 15\%}{60 \text{ kg}} = 0.009 \text{ to } 0.034 \text{ mg/kg/day}$$

Unit exposure changes were also used to estimate inhalation exposure and for the application of prometryn by groundboom equipment. The exposure scenarios are presented in Table 1 (of this section) along with the corresponding exposure assessment. The data have been normalized to simulate workers wearing long pants, long-sleeve shirts, and chemical-resistant gloves. Shoes and socks are assumed. Additional assumptions include a maximum of 100 acres treated per day for groundboom applications and 350 acres treated per day for aerial applications. The handler body weight is assumed to be 60 kg. Fifteen percent dermal absorption was used for estimating dermal exposure.

o Post-Application Exposures

There are currently no data to evaluate post-application exposure to field residues of prometryn. Post-application exposure data were not required in the Registration Standard or subsequent DCI's, because, at that time, no toxicological criteria had been triggered for prometryn. More recently, the toxicological criteria have been triggered.

The Agency has determined that there is a potential for exposure to persons entering treated sites after application is complete. For many uses of prometryn, the potential for post-application exposure is diminished because the herbicide is incorporated into the soil after it is applied. If prometryn is appropriately incorporated, post-application exposures should be limited to those situations where the task being performed disturbs the soil sub-surface. When lay-by treatments are made, they are applied as directed sprays. If such applications are made correctly, post-application exposures should be limited to those situations where the task being performed involves contact with the area to which the spray was directed. There may possibly be more potential for post-application exposure to prometryn following lay-by applications to celery, since such applications can be made over the crop and celery is often thinned by hand.

3. Risk Characterization

a. Chronic Dietary Risk

The DRES chronic analysis used tolerance level residues to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. No refinements using anticipated residues or percent crop treated were applied to these analyses. Furthermore, this analysis also includes commodities for which revocation of tolerance is recommended.

The TMRC (mg/kg/day) and %RfD for the general US population is 0.00018 mg/kg/day (0.45% of RfD), while the TRMC for non-nursing infants and children (1-6 years), the DRES subgroups most highly exposed, is 0.000360 mg/kg/day (0.90% RfD), and 0.000406 mg/kg/day (1.02% RfD), respectively.

A second chronic analysis was conducted not including the proposed revocation of tolerances on corn. The TRMC (mg/kg/day) and %RfD for the US population is 0.000036 mg/kg/day (0.09% RfD), while for females 13+ years, nursing, and children (1-6 years), the DRES subgroups most highly exposed, is 0.000047 mg/kg/day (0.12% RfD), and 0.000049 mg/kg/day (0.12% RfD), respectively.

Both chronic analyses suggest a negligible chronic dietary risk from the use of prometryn.

b. Acute Dietary Risk

The DRES acute exposure analysis evaluates individual consumption as reported by respondents in the USDA 77-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis assumes uniform distribution of prometryn in the commodity supply. Since the toxicological effect to which the high end exposure is compared is a developmental endpoint (increased resorptions and abortions, and significant changes in other reproductive parameters), these analyses considered only females (13+ years).

In the analysis, tolerance level residues were used to calculate the exposure of the average and highest exposed individual and compared to the NOEL of 12 mg/kg body weight/day. MOEs calculated for both the average and highest exposed individuals are greater than 100, indicating that acute dietary exposure from the use of prometryn on food poses only a minor risk.

c. Occupational Risk

The toxicological endpoint of concern for occupational exposure is systemic toxicity resulting from short-term (one day to one week) and intermediate-term (one week to several months) exposure. A NOEL of 12 mg/kg/day was used to estimate MOEs, based on systemic toxicity from a rabbit developmental study. A dermal absorption rate of 15 percent was assumed.

Margins of exposure (MOEs) were calculated using the following formula:

Intermediate Length Exposure MOE =

$$\frac{\text{NOEL}}{\text{Dose}} = \frac{12 \text{ mg/kg/day}}{\text{Maximum Daily Exposure}}$$

(1) Risk to Handlers (Mixers, Loaders, Applicators, etc)

Margins of exposure (MOEs) for occupational exposure were calculated for handlers using the NOEL (12 mg/kg/day) for short-term and intermediate exposure. The calculated MOE's are presented in Table 1 of this section.

MOEs for mixers and loaders are higher than 100 for all scenarios, with the exception of three mixer/loader scenarios. There was an increase in inhalation exposure in the unit exposure for wettable powders. Margins of exposure (MOE) are at levels the Agency considers to be of concern without a respirator for the following exposure scenarios: mixing and loading wettable powder formulations to support aerial application at both 0.8 and 3.2 lb ai/A, and to support groundboom application at 3.2 lb ai/A; and mixing and loading (open-pour) liquid formulations to support aerial application at 3.2 lb ai/A.

Exposures for the above listed scenarios of concern were also calculated assuming that a dust/mist filter (dust mask (TC-21C) with an 80% protection factor is worn during the above exposure scenarios of concern. The following MOE's result:

- for mixing/loading wettable powder to support aerial application at 3.2 lb ai/A, [the MOE = 24], at 0.8 lb ai/A [MOE = 100];

- for mixing/loading wettable powder formulations to support groundboom applications at 3.2 lb ai/A [the MOE = 83];

- for mixing/loading (open-pour) liquid formulations to support aerial application at 3.2 lb ai/A [the MOE = 98].

For flaggers, MOEs range from 231 to 923, based on the amount of active ingredient to which the flagger is exposed. For aerial and ground-boom applicators, MOEs are 600 to 3000 and 800 to 3000, respectively. The MOEs are presented in a range because the amount of active ingredient applied per acre is dependent on soil type.

(2) Risk from Post-Application Exposures

There are no data currently available to estimate risks resulting from post-application exposures to residues of prometryn. The Agency has determined that, since there are identified toxicological end-points of concern and entry to treated areas should not be permitted immediately following application. These entry restrictions will remain in effect until the additional reentry data or information are submitted and the post application restrictions can be reevaluated.

Table 1. Summary Exposure/Risk Values for Prometryn

Based on 15% dermal absorption factor (clothing includes long-sleeved shirt, long pants, and chemical resistant gloves)

Exposure Scenario	Dermal Exposure[a] (mg/lb ai)	Inhalation Exposure[b] (mg/lb ai)	Application Rate[c] (lb ai/cycle)	Daily Amt.[d] Treated	Daily Dermal Dose[e] (mg/kg/day)	Daily Inhalation Exposure[f] (mg/kg/day) [with respirator]	Combined dermal and inhalation exposure (mg/kg/day)	SHORT-TERM and INTERMEDIATE TERM EXPOSURE MOEs[g]
MIXER/LOADER EXPOSURE								
Open bag - Wettable Powders (Aerial Application)	0.1737	0.0037	0.8-3.2 lb ai/A, 1x/season	350 acres	0.12 - 0.49	0.017 - 0.069 [0.0033 - 0.014]	0.14 - 0.56 [0.12 - 0.504]	21 - 86 [24 - 100]
Open bag - Wettable Powders (Groundboom Application)	0.1737	0.0037	0.8-3.2 lb ai/A, 1x/season	100 acres	0.035 - 0.14	0.005 - 0.02 [0.001 - 0.004]	0.04 - 0.16 [0.036 - 0.144]	75 - 300 [83 - 333]
Water Soluble Packets (Aerial Application)	0.01	not significant	0.8-3.2 lb ai/A, 1x/season	350 acres	0.007 - 0.03	-	0.007 - 0.03	400 - 1714
Closed Mixing/Loading (Groundboom Application)	0.01	not significant	0.8-3.2 lb ai/A, 1x/season	100 acres	0.002 - 0.008	-	0.002 - 0.008	1500 - 6000
Liquid - Closed Mixing/Loading (Aerial Application)	0.0086	not significant	0.8-3.2 lb ai/A, 1x/season	350 acres	0.006 - 0.024	-	0.006 - 0.024	500 - 2000
Liquid - Closed Mixing/Loading (Groundboom Application)	0.0086	not significant	0.8-3.2 lb ai/A, 1x/season	100 acres	0.002 - 0.007	-	0.002 - 0.007	1714 - 6000
Liquid-open-pour (Aerial Application)	0.0425	0.001	0.8-3.2 lb ai/A, 1x/season	350 acres	0.03 - 0.119	0.005 - 0.019 [0.001 - 0.004]	0.036 - 0.138 [0.031 - 0.123]	87 - 333 [98 - 387]
Liquid-open-pour (Groundboom Application)	0.0425	0.001	0.8-3.2 lb ai/A, 1x/season	100 acres	0.009 - 0.034	0.0013 - 0.005	0.01 - 0.04	300 - 1200
APPLICATOR EXPOSURE								
Aerial Application Ver 1.01	0.004	0.0002	0.8-3.2 lb ai/A, 1x/season	350 acres	0.003 - 0.011	0.0009 - 0.004	0.004 - 0.02	600 - 3000
Groundboom Application Ver 1.01	0.0147	0.006	0.8-3.2 lb ai/A, 1x/season	100 acres	0.003 - 0.012	0.001 - 0.0032	0.004 - 0.015	800 - 3000
Flaggers wearing-coveralls Ver 1.01	0.01	0.0013	0.8-3.2 lb ai/A, 1x/season	350 acres	0.007 - 0.028	0.006 - 0.024	0.013 - 0.052	231 - 923

[a] Dermal unit exposures are reported as the best fit mean to simulate workers wearing long pants, long-sleeved shirts, and chemical resistant gloves, 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), unless otherwise noted (a protection factor of 80% was assumed for the use of a dust mask TC-21C for the wettable powder formulation.

[c] Luis Report dated 6/23/94.

[d] Values represent the typical area or the typical volume of spray solution which is assumed to be used in a single day to complete treatments for each exposure scenario of concern.

[e] Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Appl. Rate (lb ai)} * \text{Amt.treated} * 15\%}{60 \text{ kg}}$

[f] Daily Inhalation Exposure (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Appl. Rate (lb ai/cycle)} * \text{Amt. Treated}}{60 \text{ kg}}$

[g] MOE = NOEL/Combined Dermal and Inhalation Exposure (mg/kg/day); NOEL = 12 mg/kg/day.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to assess the hazard of prometryn to nontarget terrestrial and aquatic organisms; however, some data requirements are considered as confirmatory information: 71-4(a) avian reproduction (upland gamebird) and 72-4(a) fish early life-stage.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

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

Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} mg/kg	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Mallard Duck	98.8	>4640 mg/kg	00082966	Practically nontoxic	Yes

Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC_{50} ppm	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite Quail	98.1	>5000	404575-02	Practically nontoxic	Yes
Mallard Duck	80.7	42,766	00070686	Practically nontoxic	Yes

These results indicate that prometryn is practically nontoxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled. (MRIDs 00082966, 40457502, and 00070686)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Present product labeling of prometryn allows more than one application of the end-use product per growing season, and the terrestrial field-dissipation half-lives indicate that it is persistent for greater than 4 days.

Avian Reproduction Findings						
Species	**% A.I.**	**NOEL ppm**	**LOEL ppm**	**Endpoints affected**	**MRID No.**	**Fulfills Guideline Requirement**
Northern Bobwhite	98.1	250	500	Egg production, hatchling weight and number of 14-day survivors	410359-02	No
Mallard Duck	98.1	500	1000	Egg production	410359-01	Yes

The northern bobwhite reproductive study indicates that prometryn can cause reductions in egg production, hatchling weight and number of 14-day survivors at levels greater than 250 ppm; the mallard duck reproductive study indicates that prometryn can cause reductions in egg production at levels greater than 500 ppm.

The guideline requirements are not fulfilled; the northern bobwhite study is unacceptable and must be repeated due to high control mortality (25%). In addition, there are questions regarding the adequacy of the study design to address concerns with this class of triazine herbicides as endocrine disruptors. This is especially valuable for performing an accurate risk assessment, as the bobwhite quail appears to be more sensitive to prometryn than the mallard duck. Therefore, the toxicity values for the bobwhite quail cannot be used in a risk assessment. Although the mallard study is acceptable, a confirmatory bobwhite study is recommended to accurately assess the chronic avian risk.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD_{50} is used to estimate toxicity to mammals. This LD_{50} is reported below.

Mammalian Acute Oral Toxicity Findings			
Species	**LD_{50} mg/kg**	**MRID #**	**Toxicity Category**
Rat (small mammal surrogate)	1802	060314	III

The available data indicates that prometryn is slightly toxic to small mammals on an acute oral basis. (MRID 00060314)

(4) Insects

A honey bee acute contact LD_{50} study is required if the use will result in honey bee exposure.

Nontarget Insect Acute Contact Toxicity Findings					
Species	**% AI**	**LD_{50} μg a.i./bee**	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Honey Bee	TGAI	> 96.7	425285-01	Practically Non-toxic	Yes

There is sufficient information to characterize prometryn as practically non-toxic to bees. The guideline requirement is fulfilled. (MRID 42528501)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

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

Freshwater Fish Acute Toxicity Findings					
Species	**% A.I.**	**LC_{50} ppm a.i.**	**MRID No.**	**Toxicity Category**	**Fulfills guideline requirement**
Rainbow trout	99	2.9	00070686	Moderately toxic	Yes
Bluegill sunfish	99	10.0	00070686	Slightly toxic	Yes

The results of the 96-hour acute toxicity studies indicate that prometryn is moderately to slightly toxic to both cold and warm water fish. The guideline requirements are fulfilled. (MRID 00070686)

Freshwater Fish Chronic Toxicity Findings					
Species	**% A.I.**	**NOEC**	**LOEC**	**MRID #**	**Fulfills Guideline Requirements**
Fathead minnow	98.1	800 ppb	1390 ppb	405737-20	No

The freshwater fish chronic test study does not satisfy guideline requirements and thus, cannot be used in risk assessments. The guideline requirement is not fulfilled. The study is unacceptable due to the relative standard deviation (RSD) for fish weights in the solvent control being 80.5%. A test is unacceptable if any control RSD is greater than 40%. A confirmatory fish early life-stage is required in order to fully assess the chronic toxicity of prometryn to fish.

(2) Freshwater Invertebrates

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

Freshwater Invertebrate Acute Toxicity Findings					
Species	**% A.I.**	**EC_{50} ppm a.i.**	**MRID No.**	**Toxicity Category**	**Fulfills guideline requirement**
Daphnia magna	98.9	18.59	00070146	Slightly toxic	Yes

There is sufficient information to characterize prometryn as slightly toxic to aquatic invertebrates on an acute basis. The guideline requirement is fulfilled. (MRID 00070146)

Freshwater Invertebrate Chronic Toxicity Findings						
Species	**% A.I.**	**NOEC ppm**	**LOEC ppm**	**MRID No.**	**Toxicity Category**	**Fulfills guideline requirement**
Daphnia magna	98.1	1.0	2.0	405737-20	Moderately toxic	Yes

The data indicate that prometryn is moderately toxic to invertebrates on a chronic basis. The guideline requirement is fulfilled. (MRID 40573720)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine/marine organisms is required when an end-use product is intended for direct application to the estuarine/marine environment or is expected to reach this environment in significant concentrations. The terrestrial food use of prometryn on cotton and celery may result in exposure to the estuarine environment.

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

Estuarine/Marine Acute Toxicity Findings					
Species	**% A.I.**	**LC_{50}/EC_{50} ppm a.i.**	**MRID No.**	**Toxicity Category**	**Fulfills guideline requirement**
Eastern oyster	99	> 1	402284-01	Moderately toxic	Supplemental
Mysid	98.1	1.7	405737-18	Moderately toxic	Yes
Sheepshead minnow	98.1	5.1	405737-17	Moderately toxic	Yes

There is sufficient information to characterize prometryn as moderately toxic to marine/estuarine fish and invertebrates. The guideline requirement is fulfilled. (MRIDs 40228401, 40573717 and 40573718)

c. Toxicity to plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides which have terrestrial or aquatic food or non-food (except residential) use patterns and under any of the following conditions: 1) the vapor pressure of the TGAI is equal to or greater than 1.0×10^{-5} mm at 25ºC and the TEP is not incorporated immediately after application; 2) the TEP is applied aerially, by forced air, air blast or through sprinkler irrigation; and, 3) endangered or threatened plant species are associated with the site of application. Terrestrial plant testing is also required for all pesticides which carry phytotoxicity warnings on their labels.

Nontarget Terrestrial Plant Toxicity Findings

Test (most sensitive species)	% A.I.	EC_{50} lbs a.i./A	MRID No.	Status
Seedling emergence--monocot (Oat)	98.1	0.07	410359-04	Core
Seedling emergence--dicot (cabbage)	98.1	0.014	410359-04	Core
Vegetative vigor--monocot (onion)	98.1	0.161	410359-03	Core
Vegetative vigor--dicot (cucumber)	98.1	0.006	410359-03	Core

These data indicate that prometryn is toxic to terrestrial plant species at levels significantly below the maximum label rate of 3.2 lbs a.i./A. The guideline requirements (123-1a and 123-1b) are fulfilled. (MRIDs 41035903 and 41035904)

(2) Aquatic

Tier II aquatic plant testing is required for an herbicide applied to terrestrial or aquatic food or non-food (except residential), or for any pesticide when the label carries a phytotoxicity warning. The following species should be tested: *Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and a freshwater diatom. (For cases of testing based on label phytotoxicity warnings, only *Lemna gibba* and *Selenastrum capricornutum* testing is required).

Nontarget Aquatic Plant Toxicity Findings				
Species	**% A.I.**	**EC_{50} ppb**	**MRID No.**	**Status**
Navicula pelliculosa (Freshwater diatom)	98.1	1.0 ppb	426202-01	Core
Lemna gibba	98.1	11.8 ppb	425209-01	Core
Selenastrum capricornutum	98.1	12.0 ppb	425209-03	Core
Skeletonema costatum	98.1	7.6 ppb	426202-02	Core
Anabaena flos-aquae	98.1	40.1 ppb	405209-02	Core

These findings indicate prometryn is very highly toxic to aquatic plant species. The guideline requirements are fulfilled. (MRIDs 42620201, 42520901, 42520902, 42620202 and 42520903)

2. Environmental Fate

a. Environmental Fate Assessment

Prometryn has the potential to leach to ground water and move offsite into surface water.

Although the individual data submissions on prometryn and its degradates appear to be scientifically sound, the environmental fate of prometryn remains somewhat uncertain because the studies yield contradictory results that have not been reconciled. Batch equilibrium data and published literature suggest that prometryn and its degradates are very mobile in sandy soils with low organic matter and clay. However, prometryn was not observed to leach below 18 inches in the field. Rapid dissipation was observed in the terrestrial field dissipation studies carried out in Texas.

According to laboratory data, prometryn is a persistent chemical. It resists abiotic hydrolysis, direct photolysis, and biodegradation under anaerobic conditions. Its half-life under aerobic conditions is in excess of 270 days.

The following prometryn degradates have been identified: 2,4-bis(isopropylamino)-6-hydroxy-s-triazine (GS-11526), and 2-amino-4-isopropylamino-6-methylthio-s-triazine (GS-11354). Field studies appear to confirm that the degradate GS-11526 is mobile in soils with low to moderate clay contents. Results from the small-scale ground water studies and the laboratory mobility data, taken as a whole, suggest prometryn is moderately mobile in sandy soils with low organic matter and clay. Prometryn parent does not appear to leach beyond 12 to 18 inches, but GS-11526 was found at all depths down to 24 to 26 inches.

Mobility data for parent prometryn is inconclusive. Batch equilibrium studies indicate that prometryn is mobile in agricultural sand, loamy sand, silt loam, and silty clay loam soils.

Prometryn sorption was most strongly correlated to the soil's cation exchange capacity, which is derived primarily from the soil's clay and organic matter content. This is confirmed in published literature [Rao and Davidson, 1982] where batch equilibrium results from 38 soils suggest that prometryn sorption is correlated to both CEC and soil organic matter. Although the K_{oc} values in the submitted batch equilibrium data suggest that prometryn does not bind strongly to organic matter, the larger Rao and Davidson data set suggests that organic matter plays a major role in prometryn adsorption. K_D and K_{oc} values in the Rao and Davidson study tended to be higher than in the study submitted to the Agency, suggesting that prometryn would only be mobile in sandy soils low in both clay and organic matter. A submitted column leaching study also suggested that unaged prometryn was immobile in a low organic matter sandy loam soil, but these results have not been satisfactorily explained. The studies of Senesi and Testini (1982, 1984) have indicated that s-triazines, including prometryn, are capable of binding to humic acids ionically through a proton donation process, but can also bind covalently through an electron donation process to humic acid molecules with a decreased capacity to form ionic and hydrogen bonds. According to the Herbicide Handbook (1979), acid soils will bind prometryn more efficiently than neutral or basic soils, but this was not consistently confirmed in the results reported by Rao and Davidson. Prometryn does not volatilize from soil.

Batch equilibrium studies indicate that prometryn degradates are mobile in agricultural sand, loamy sand, silt loam, and silty clay loam soils. These degradates are unlikely to volatilize from soil.

Prometryn dissipated more quickly in the field than in the lab, with calculated half-lives of 14-to-103 days. Prometryn dissipated with a calculated first-order half-life of 71 days in an uncropped California sandy loam with 0.9% organic matter, and 103 days in the California sandy loam under cotton. In a Texas silt loam with 2.1% organic matter, prometryn dissipation appeared to be either biphasic or higher order, with a period of rapid early dissipation (estimated first half-life = 14-to-30 days) followed by an extended presence at low concentrations in the soil. The cause of this rapid early phase dissipation is unexplained, but may be due to an unidentified physical dissipation process (i.e., loss of surface soil due to wind-blown dust in the bareground plot, plant uptake or volatilization from plant surfaces in the cropped plot, leaching via preferential flow pathways in either plot); none of these potential routes of dissipation has been evaluated.

As expected, prometryn was more mobile in the coarse, low organic matter California soil, with low concentrations found at depths up to 18 inches. In Texas, no prometryn was detected below 12 inches, and little was detected below 6 inches. In both Texas and California, GS-11526, the primary degradate, appeared to be mobile, moving through the soil profile at concentrations near the limit of quantitation (0.010 ppm). The secondary degradate, GS-11354, does not appear to be mobile and is found only at low concentrations. The pattern of degradate formation and decline suggests that prometryn dissipation may be due to a combination of 1) slow biodegradation with degradate leaching, 2) binding to clay and

organic matter, and 3) leaching or runoff of the parent compound. While dissipation through irreversible adsorption is questionable for this chemical, with a maximum reported K_{ads} of 3.18 in a silty clay loam soil, soil binding did occur in the aerobic soil metabolism study, and may depend upon whether prometryn, GS-11354 and GS-11526 can react with soil components or degrade before leaching can occur.

Graphical analysis of GS-11526 detections below 15 cm indicates that such detections may not have been random experimental error, as suggested by study authors. These detections demonstrate a pattern consistent with the leaching of very low concentrations of GS-11526, while deep detections of prometryn and GS-11354 appear to be random experimental error. Reviewer-developed graphs of GS-11526 concentration vs. depth of detection of GS-11526 in the four field dissipation studies are attached. The graphs suggest that, at least in some cases, a decline in GS-11526 concentration in the surface layer may be accompanied by an increase in GS-11526 concentration at greater depth, followed by slow dissipation of the degradate.

Prometryn does not bioaccumulate in fish.

b. Environmental Chemistry, Fate and Transport

(1) Degradation

(a) Hydrolysis

A study of prometryn hydrolysis at 1.5 ppm showed that prometryn did not hydrolyze in sterile aqueous buffer solutions (pH 5, 7 and 9) incubated 30 days in the dark at 25 ± 1°C. This study satisfies the hydrolysis data requirement. (MRID 40573704)

(b) Photodegradation in water (Guideline 161-2)

A study of photolysis of prometryn at 1.74 ppm in sterile aqueous buffered solution at pH 7 found that prometryn was relatively stable to direct photolysis when irradiated with natural sunlight for 30 days. Prometryn comprised 95.91% of the recovered radioactivity in the irradiated solution and 100% in the dark controls. This study satisfies the photolysis in water data requirement. (MRID 40573705)

(c) Photodegradation in soil (Guideline 161-3)

A study of prometryn photolysis on soil at 53 ppm showed that prometryn was relatively stable on a sandy loam soil irradiated with natural sunlight for 30 days. Prometryn comprised an average of 96.55% of the extractable radioactivity in the irradiated soil and 100% in the dark control. This study satisfies the photodegradation on soil data requirement. (MRID 40573706)

(d) Aerobic soil metabolism (Guideline 162-1)

The acceptable aerobic metabolism study of prometryn indicates that prometryn has two primary degradates: GS-11526, 26.2% of the applied at 360 days post-treatment and GS-11354, 1.1% of the applied at 30 days post-treatment.

Non-extractable residues increased with time and reached 30.8% of the applied, while volatiles remained less than 0.5% of the applied. The study indicates an aerobic half-life of approximately 270 days. This study satisfies the aerobic soil metabolism data requirement. (MRID 00148338)

(e) Anaerobic soil metabolism (Guideline 162-2)

Prometryn at 10.6 ppm did not degrade under anaerobic conditions on sandy loam soil that was incubated in the dark at 25 ± 1°C for 71 days. The treated soil was aged aerobically for 30 days prior to the introduction of anaerobic conditions. At 71 days post-flooding (102 days post-treatment), prometryn comprised an average of 86.3% of the applied radioactivity (98.6% of the extractable radioactivity) in the flooded soil plus floodwater. No residues other than prometryn were isolated from the soil extracts or floodwater. The anaerobic soil metabolism data requirement has been satisfied. (MRID 41155901)

(2) Mobility

(a) Leaching and adsorption/desorption (Guideline 163-1)

Mobility/Adsorption/Desorption: Batch equilibrium studies were carried out on prometryn and two degradates GS-11354 and GS-11526 in agricultural sand, loamy sand, silt loam and silty clay loam soils. In MRID 41875901, prometryn was very mobile, with Freundlich K_{ads} values of 0.86-3.18 and K_{oc} values of 117-448. This study may be upgraded if this result can be reconciled with the column leaching study (MRID 40573713) which shows prometryn to be relatively immobile in soil. GS-11354 was also very mobile, with Freundlich K_{ads} values of 0.63-1.43. GS-11526 was very mobile in agricultural sand, loamy sand, silt loam, and mobile in silty clay loam, with Freundlich K_{ads} values of 0.65-7.10. (MRIDs 41875902, 41875903)

Mobility (column leaching): Two supplements to a column leaching study of prometryn aged in sandy loam (MRID 40573713) were submitted. The study suggests that prometryn is immobile in sandy loam (0.7% organic matter). The registrant did not reconcile the results of the column study with the results of the batch equilibrium study, as required when the study was reviewed. No conclusions may be drawn from this study about the mobility of the degradates, due to negligible degradation of prometryn under the conditions of the experiment. (MRIDs 41875904 and 41875905)

(b) Laboratory volatility (Guideline 163-2)

Prometryn at 9.7 ppm exhibited minimal volatilization from sandy soil that was incubated for 30 days in the dark at 25 ± 0.2ºC under continuous airflow (150 mL/minute). After 30 days of incubation, only 0.99% of the applied radioactivity had volatilized on average, of which more than 99% was prometryn; the remainder of the radioactivity remained associated with the soil. The laboratory volatility data requirement has been satisfied. (MRID 41875906)

(3) Accumulation

(a) Accumulation in fish (Guideline 165-4)

Prometryn residues did not accumulate to a significant degree in bluegill sunfish continuously exposed to prometryn at 0.05 ppm for 28 days in a flow through system. The maximum mean bioconcentration factors were 54x for edible tissues, 130x for non-edible tissues, and 85x for the whole fish. These values are lower than might be expected considering the high octanol/water coefficient of prometryn (log K_{ow} = 3.46). While the study did not fully characterize unknowns, the low degree of bioconcentration of this chemical is sufficient to suggest that prometryn does not bioaccumulate in fish. The data requirement for fish bioaccumulation is satisfied. (MRIDs 41027701 and 40573715)

(4) Field Dissipation

(a) Terrestrial field dissipation (Guideline 164-1)

California Terrestrial Field Dissipation Studies. Prometryn degraded with a half-life of 103 days (in the 0-15 cm depth) in sandy loam soil (70.2% sand, 17.8% silt, 12.0% clay, 0.9% organic matter, pH 7.4, CEC 8.4 meq/100 g) on cotton in California. The site received five weekly applications of prometryn (4 lbs a.i./gal EC) at 0.7-to-3.1 lbs a.i./A/application (total nominal application 7.8 lbs a.i./A). Prometryn was generally not detected below the 45-cm depth. The degradate GS-11526 was detected (0.322 ppm) in the 0-15 cm depth. It was detected at low concentrations (<0.02 ppm) at soil depth as deep as 120-cm throughout the study period. The degradate GS-11354 was present at 0.053 ppm in the 0-15 cm depth. It was not detected at depth > 15-cm. The data requirement for a terrestrial field dissipation study has been satisfied. (MRID 41546401)

Supplemental Study to MRID 41546401: (Terrestrial Field Dissipation; Cotton; California) At 654 days post treatment, prometryn residues were found at low levels (0.010-0.015 ppm) in the upper six inches of a cotton field in a California sandy loam. Degradate residues (GS-11526) were found at low levels (<0.010 ppm) from 6-12 inches. Neither prometryn nor its degradate were found below the twelve inch depth. Samples were taken to a depth of forty-eight inches. In the original study, the registrant calculated the

initial half-life of prometryn as 103 days. Dissipation appears to slow with reduced prometryn concentration in the soil. (MRID 42253903)

Prometryn degraded with a half-life of 71 days (in the 0-15 cm depth) in bareground sandy loam soil (70.2% sand, 17.8% silt, 12.0% clay, 0.9% organic matter, pH 7.4, CEC 8.4 meq/100 g) in California. The site received a single application of prometryn (4 lbs a.i./gal EC) at a nominal application rate of 6.52 lbs a.i./A. Prometryn was generally not detected below the 45-cm depth. The degradate GS-11526 was detected (0.408 ppm) in the 0-to-15 cm depth. The degradate GS-11354 was present at 0.025 ppm in the 0-15 cm depth. It was not detected at depths greater than 15-cm. The data requirement for a terrestrial field dissipation study has been satisfied. (MRID 41546402)

Supplemental Study to MRID 41546402: (Terrestrial Field Dissipation; Bare Ground; California) At 654 days post treatment, prometryn residues were found at low levels (less than 0.010-to-0.013 ppm) in the upper six inches of a bareground plot in a California sandy loam. No degradate residues were found, nor was prometryn found below the six inch depth. Samples were taken to a depth of forty-eight inches. In the original study, the registrant calculated the initial half-life of prometryn as 71 days. Dissipation appears to slow with reduced prometryn concentration in the soil. (MRID 42253904)

Texas Terrestrial Field Dissipation Studies. Prometryn degraded with an observed half-life of 14-to-30 days (in the 0-to-6 inch depth) in silt loam soil (18% sand, 64% silt, 18% clay, 2.1% organic mater, pH 7.7, CEC 13.4 meq/100g) on cotton in Texas. The site received five weekly applications of prometryn (4 lbs a.i./gal EC) at 0.53-to-3.1 lbs a.i./A/application (total nominal application 6.03 lbs a.i./A). Prometryn was not detected below the 12-inch depth. The degradate GS-11526 was detected (0.473 ppm) in the 0-to-6 inch depth, as well as the 24-36 inch depth. The degradate GS-11354 was present at 0.06553 ppm in the 0-6 inch depth. It was not detected at depths greater than 6 inches. The data requirement for a terrestrial field dissipation study has been satisfied. (MRID 41546403)

Supplemental Study to MRID 41546403: (Terrestrial Field Dissipation; Cotton, Texas) At 668 days post treatment, prometryn residues were found at low levels (less than 0.010-to-0.021 ppm) in the upper six inches of a cotton field in a Texas silt loam. No degradate residues were found, nor was prometryn found below the six inch depth, although samples were taken to forty-eight inches. Prometryn dissipation appears to be either biphasic or higher-order, with a period of more rapid early dissipation followed by an extended presence at low concentrations in the soil. Linear interpretation of the data indicated a half-life of 86 days; however, prometryn was more than 80% dissipated at 60 days. (MRID 42253901)

Prometryn degraded with an observed half-life of 14 days (in the 0-to-6 inch depth) in bareground silt loam soil (18% sand, 64% silt, 18% clay, 2.1% organic matter, pH 7.7, CEC 13.4 meq/100g) in Texas. The site received a single application of prometryn

(4 lbs a.i./gal EC) at a nominal application rate of 7.0 lbs a.i./A. Prometryn was detected to the 12 inch depth. The degradate GS-11526 was detected (0.735 ppm) in the 0-to-6 inch depth, as well as at depths of up to 36 inches (0.013-to-0.02 ppm). The degradate GS-11354 was present at 0.041 ppm in the 0-to-6 inch depth. It was not detected at depths greater than 6 inches. The data requirement for a terrestrial field dissipation study has been satisfied. (MRID 41546404)

Supplemental Study to MRID 41546404: (Terrestrial Field Dissipation; Bare Ground; Texas) At 668 days post treatment, residues of prometryn (0.013-to-0.015 ppm) and its primary degradate, GS-11526 (<0.010-to-0.024 ppm) were found in the upper six inches of a bare ground plot in a Texas silt loam. No residues were found below the six inch depth at concentrations greater than or equal to .010 ppm. Prometryn dissipation appears to be either biphasic or higher order, with a period of rapid early dissipation followed by an extended presence at low concentrations in the soil. Linear interpretation of the data indicated a half-life of 70 days, even though prometryn was almost 90% dissipated at 60 days. (MRID 42253902)

(b) Long-term field dissipation (Guideline 164-5)

This study is deferred pending review of a small-scale retrospective groundwater study by the Agency's Groundwater section.

(5) Spray drift

(a) Droplet size spectrum (Guideline 201-1)

This study is being conducted by the Industry Spray Drift Task Force.

(b) Droplet size evaluation (Guideline 202-1)

This study is being held in reserve pending the work currently being conducted by industry's Spray Drift Task Force.

c. Water Resources

(a) Ground water

The mobility data, taken as a whole, suggest that prometryn will be most mobile in sandy, alkaline soils which contain little organic matter or clay. Therefore, the use of prometryn on celery is likely to pose little risk to ground water, not only because it is a minor use, but also because celery is generally grown in soils with high organic matter contents. The use on dill or pigeon peas may not pose a threat to ground water either, as the labels warn that use on sand or loamy sand soils might injure the crop.

However, the use of prometryn on cotton presents a potential threat to groundwater in certain use areas. In California, Arizona and New Mexico, prometryn labels instruct potential users not to apply the product to sand or loamy sand soils, reducing the risk of ground-water contamination. However, prometryn may be more likely to reach ground water if used on cotton in sand or loamy sand soils in the mid-South and Southeast, such as those found in the Atlantic Coastal Plain. Although soils in this region tend to be acid, their porosity and lack of organic matter combined with occasional heavy rainfall make them susceptible to prometryn leaching. Available records show that little or no prometryn is now used in the Carolinas and Georgia.

The registrant completed two small-scale retrospective ground-water studies for prometryn on cotton in 1989. The studies, which evaluated the effects of long-term use of the chemical, were conducted on fields in the San Joaquin Valley of California and in Mississippi that were underlain by sandy loam and loam soils. Parent prometryn and degradate GS-11354 were not detected in limited sampling of the ground-water of either site, with the exception of a single sub-part-per-billion detection of prometryn in the irrigation source water of the California site. The degradate GS-11526 was detected three times at the California site only, at a maximum concentration of 0.61 ppb.

The root-zone leaching screening model PATRIOT was used to roughly compare the relative leaching potential of prometryn and several other triazine pesticides. The simulation was run for the Cajon soil series of Tulare County, California, using 10 years of historical rainfall data from Bakersfield (actual field conditions would require more intensive irrigation to support the crop). Under this scenario, PATRIOT predicted that the average annual leaching of prometryn would be less than that of atrazine and propazine, but greater than that of simazine and cyanazine. Comparison of prometryn to other cotton herbicides, using the ranking method GUS (Gustafson, 1989), indicates that prometryn might have a leaching potential greater than that of several other cotton herbicides, such as norflurazon, cyanazine, and others. The ranking of prometryn was similar to that of diuron, and only less than the rankings of pyrithiobac-sodium and fluometuron.

(b) Surface water

Substantial amounts of prometryn could be available for runoff to surface waters for several months post-application. This will be especially true in areas where runoff is most likely, for example, sloping silty or clay soils which are subject to occasional intense rainfall. Although prometryn runoff may occur in any area meeting this description, records indicate that there is an area of relatively heavy prometryn use in northeastern Louisiana, northwestern Mississippi and southeastern Arkansas. As this area is on the banks of the Mississippi River, it appears likely that there will be significant overland flow in most years, and that prometryn could be carried to surface water in this flow. The combination of runoff and heavy prometryn use give this area's unique potential for surface water contamination with prometryn.

The low to moderate soil/water partitioning of prometryn (K_{ads} of 0.86 to 3.18; K_{oc}s of 120 to 450) indicates that most of prometryn runoff may generally occur via dissolution in runoff water as opposed to adsorption to eroding soil. Its resistance to hydrolysis, direct photolysis in water, and anaerobic soil metabolism combined with only a very moderate susceptibility to aerobic soil metabolism and a low volatilization potential should make it somewhat persistent in surface waters. Based upon its low to moderate soil/water and sediment/water partitioning, most of any prometryn in surface water will probably be dissolved in the water column instead of adsorbed to suspended and bottom sediment. The reported BCFs for prometryn (54X to 130X) indicate that its potential for bioaccumulation is low.

The 2 major atrazine degradates of prometryn in the aerobic soil metabolism study (GS-11526 and GS-11354) appear to be at least as mobile and in some cases more mobile than prometryn. Consequently they will probably runoff primarily via dissolution in runoff water and will probably exist in surface waters primarily dissolved in the water column. The occurrence of the GS-11526 degradate at 26.2% of applied at the end of the aerobic soil metabolism study suggests that it may be somewhat persistent and therefore available for runoff for a substantial period.

In a 1989 reconnaissance study, the USGS (Goolsby and Thurman, 1991) collected samples from numerous locations throughout 10 states in the midwestern corn belt and analyzed them for several herbicides including prometryn. Prometryn was not detected at a detection limit of 0.05 μg/L in pre-application samples collected from 55 sites, in post-application samples collected from 129 sites, and in fall samples collected from 142 sites.

Prometryn is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore no MCL has been established for it and water supply systems are not required to sample and analyze for it. In addition, no drinking water health advisories have been established for prometryn. However, the low to moderate soil/water partitioning of prometryn suggests that it would not be effectively removed by the great majority of surface water supply systems which employ only primary treatment processes.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate

exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC_{50}.

The acute effect levels typically are:

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

The chronic test results are the:

o NOEC for avian and mammal reproduction studies, and either the NOEC for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration MATC), the geometric mean of the NOEC and the LOEC for chronic aquatic studies.

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

Levels of Concern (LOC) and associated Risk Presumption

o Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ≥	0.5	High acute risk
acute RQ≥	0.2	Risk that may be mitigated through restricted use
acute RQ≥	0.1	Endangered species may be affected acutely
chronic RQ≥	1.0	Chronic risk (nonendangered and endangered species may be affected chronically),

o Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ≥	0.5	High acute risk
acute RQ≥	0.1	Risk that may be mitigated through restricted use
acute RQ≥	0.05	Endangered species may be affected acutely
chronic RQ≥	1.0	Chronic risk (nonendangered and endangered species may be affected chronically)

o Plants

IF THE	LOC	PRESUMPTION
RQ≥	1.0	High risk
RQ≥	1.0	Endangered plants may be affected

Currently, no separate criteria for restricted use or chronic effects for plants exist.

b. Exposure and Risk to Non-target Terrestrial Animals

(a) Birds

Residues found on dietary food items following prometryn application may be compared to LC_{50} values to predict hazard. The maximum concentration of residues of prometryn which may be expected to occur on selected avian or mammalian dietary food items following a single foliar application at different application rates is provided in the table below:

Residues on Avian and Mammalian Dietary Food Items in PPM		
Use Sites - Celery, cotton, dill, pigeon peas	**Application rates (3.2lb a.i./A) with maximum of 4.0 lb a.i./A, on celery in Hawaii**	**AVIAN RQs**
Range Grasses (short)	768 ppm maximum; (960 ppm maximum in Hawaii)	acute: bobwhite= 0.15 (0.2 Hawaii) mallard= 0.02 (0.02 Hawaii) chronic: mallard= 1.5 (1.9 Hawaii)
Range Grass (long)	352 ppm maximum; (440 ppm maximum in Hawaii)	acute: bobwhite= 0.1 (0.1 Hawaii) mallard= 0.01 (0.1 Hawaii) chronic: mallard= 0.7 (0.9 Hawaii)
Fruit/Vegetable Leaves (other than legumes)	400 ppm maximum; (500 ppm maximum in Hawaii)	acute: bobwhite= 0.08 (0.1 Hawaii) mallard= 0.01 (0.01 Hawaii) chronic: mallard= 0.8 (1.0 Hawaii)
Forage Legumes and Insects	186 ppm maximum; (232 ppm maximum in Hawaii)	acute: bobwhite= 0.04 (0.05 Hawaii) mallard= 0.00 (0.00 Hawaii) chronic: mallard= 0.4 (0.5 Hawaii)
Seeds	38 ppm maximum; (48 ppm maximum in Hawaii)	acute: bobwhite: 0.01 (0.01 Hawaii) mallard= 0.00 (0.00 Hawaii) chronic: mallard= 0.18 (0.1 Hawaii)
Fruits	22 ppm maximum; (28 ppm maximum in Hawaii)	acute: bobwhite: 0.00 (0.00 Hawaii) mallard= 0.00 (0.00 Hawaii) chronic: mallard= 0.04 (0.06 Hawaii)

Acute adverse effects to birds are not expected from the use of prometryn at maximum application rates. However, prometryn poses a chronic risk to birds. The chronic LOC (LOC = 1) was exceeded for birds feeding on short grasses and fruit/vegetable leaves for celery use in Hawaii (RQ = 1.5, 1.9 for short grasses and RQ = 1.0 for fruit/vegetable leaves). It is likely that these risk quotients would be even higher for the northern bobwhite which appear to be more sensitive to prometryn than the mallard. At this time, a thorough assessment of the chronic effects of prometryn on avian species cannot be completed. In order to confirm the chronic assessment and decrease the uncertainty, a valid northern bobwhite study (Guideline 72-4(a)) is required. These additional data are considered confirmatory based on what is already known about prometryn.

(b) Mammals

Small mammal exposure is addressed using acute oral LD_{50} values converted to estimate a LC_{50} value for dietary exposure, unless acceptable longer-term feeding data are available. A 28-day mouse feeding study was available for prometryn; therefore, the results of this study (NOEL = 3000 ppm) were used to calculate the risk quotient.

Mammalian Dietary Risk Quotients (based on Dietary RQ = EEC/28-day dietary NOEL)		
Small Mammal	RQ	
	3.2 lb a.i./A	4.0 lb a.i./A
Mammals consuming range grasses (e.g. voles)	0.26	0.32
Mammals consuming seeds (e.g. mice)	0.01	0.02
Mammals consuming forage and insects (e.g. shrews)	0.06	0.08

The Endangered Species LOC has been exceeded by RQs for small mammals consuming grasses indicating that endangered small mammal species feeding on grasses in or around treated areas could be adversely impacted by the use of prometryn on cotton or celery.

(c) Insects

A honey bee study was submitted to the Agency. There is sufficient information to characterize prometryn as practically non-toxic to honeybees. (MRID 42528501)

(1) Exposure and Risk to Non-Target Aquatic Animals

Expected Aquatic Concentrations: Prometryn displays slight to moderate toxicity to most aquatic organisms tested to date. Estimated environmental concentrations were modelled using the PRZM2 and EXAMS II programs. These programs simulated two sites, for celery and cotton, which provide a reasonable worst-case scenario for the runoff of prometryn. The results reported in the table, below, are 1 in 10 year maximum values with 1% spray drift.

ESTIMATED ENVIRONMENTAL CONCENTRATIONS (EECs) FOR PROMETRYN							
Crop	Application Method	Application Rate in lbs a.i./A (number of applications)	Initial EEC (ppb)	4-day EEC(ppb)	21-day EEC(ppb)	60-day EEC(ppb)	90-day EEC(ppb)
Celery	Ground	3.2 (1)	261.3	258.8	245.0	222.4	209.2
Cotton	Ground	2.8 (1)	276.8	271.5	252.6	224.3	212.8
Cotton	Aerial	2.8 (1)	182.9	179.9	167.3	148.3	140.0

(a) Freshwater fish

Risk Quotients (RQ) for Freshwater Fish		
Crop/application rate (#)	Species	Acute RQ (96-hr)
Celery/3.2 lb a.i./A (1)	Bluegill Rainbow trout	0.02 0.09
Cotton/2.8 lb a.i./A (1)	Bluegill Rainbow trout	0.02 0.06
Cotton/2.8 lb a.i./A (2)	Bluegill Rainbow trout	0.03 0.09

As indicated in the above estimated residue table, the high risk and restricted use acute LOCs for freshwater fish have not been exceeded for the maximum application rate. However, the endangered species LOC for freshwater fish has been exceeded. At this time, a thorough assessment of the chronic effects of prometryn on fish cannot be completed. The submitted fish early life-stage study is 'invalid' based on several discrepancies, not the least of which is the Relative Standard Deviation (RSD) factor being over twice that which is currently acceptable. In order to complete a chronic assessment, a valid fish early life-stage (Guideline 72-4(a)) is required. Because prometryn displays slight to moderate toxicity to aquatic organisms, this additional fish early life-stage data would be considered confirmatory.

(b) Freshwater Invertebrates

Risk Quotients (RQ) for Freshwater Invertebrates			
Crop/application rate (#)	Species	Acute RQ (96-hr)	Chronic RQ (21-day)
Celery/ground 3.2 lb a.i./A (1)	*Daphnia magna*	0.01	0.24
Cotton/ground 2.8 lb a.i./A (1)	*Daphnia magna*	0.01	0.25
Cotton/aerial 2.8 lb a.i./A (1)	*Daphnia magna*	0.012	0.17

As indicated in the above estimated residue table, the freshwater invertebrate acute high risk, restricted use and endangered species LOCs have not been exceeded at any application rates. Therefore, freshwater aquatic invertebrates are not likely to be acutely affected by the use of prometryn. Also, the freshwater invertebrate chronic LOC (LOC = 1) has not been exceeded by any of the application rates. Chronic adverse effects to freshwater invertebrates are not expected to occur from the use of prometryn.

(c) Estuarine and Marine Animals

Risk Quotients (RQ) for Estuarine and Marine Organisms		
Crop/application rate (#)	Species	Acute RQ (96-hr)
Celery/ground 3.2 lb a.i./A (1)	Sheepshead minnow Oyster Mysid	0.05 0.26 0.15
Cotton/ground 2.8 lb a.i./A (1)	Sheepshead minnow Oyster Mysid	0.05 0.27 0.15
Cotton/aerial 2.8 lb a.i./A (1)	Sheepshead minnow Oyster Mysid	0.04 0.18 0.10

As indicated in the above estimated residue table, the high risk acute LOC for marine/estuarine fish and invertebrates has not been exceeded. The restricted use LOC for marine/estuarine invertebrates (molluscs) has been exceeded for all three application rates/methods. This LOC also applies to freshwater mollusc species, such as clams and mussels. The endangered species LOC for all invertebrates has been exceeded for all rates and methods and for fish for ground application. This indicates that the use of prometryn may cause adverse effects to endangered marine/estuarine fish and invertebrates. Prometryn use may also cause adverse effects to freshwater and marine mollusc species.

(2) Exposure and Risk to Non-Target Plants

(a) Terrestrial and Semi-aquatic

Application rate (#)	Species	RQ
3.2 lb a.i./A	Monocot - emergence Dicot - emergence Monocot - vigor Dicot - vigor	45.7 228.6 19.9 533.3

Adverse effects are expected to occur to non-target terrestrial plants, including any endangered species, from the use of prometryn at current label rates.

(b) Aquatic

Species	RQ from ground application, 3.2 lb a.i./A (GENEEC EEC = 57.5 ppb at 96 hours)	RQ from aerial application, 3.2 lb a.i./A (GENEEC EEC = 61.1 ppb at 96 hours)
Navicula pelliculosa	57.5	61.1
Lemna gibba	4.9	5.2
Selenastrum capricornutum	4.8	5.1
Skeletonema costatum	9.6	8.0
Anabaena flos-aquae	1.4	1.5

Adverse effects are expected to occur to aquatic plants from the use of prometryn.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

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

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

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all of the registered uses of prometryn on celery, pigeon peas, cotton, and dill are eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for prometryn. Where labeling revisions are imposed, specific language is set forth in Section V of this document. The Agency has determined that all uses are eligible for reregistration.

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.222(a)

The tolerances listed in 40 CFR §180.222(a) are for residues of prometryn *per se*. Adequate data are available to support the established tolerances in cottonseed, celery and pigeon peas, pending submission of additional storage stability information for cottonseed and celery.

No tolerances for residues of prometryn in milk, eggs, animal fat, meat, and meat byproducts have been established, and none are recommended at this time. A summary of the prometryn tolerance reassessment and modifications in commodity definitions are presented in Table 1 of this section.

New Tolerances Needed Under 40 CFR §180.222(a)

Provided that the registrant has no objection to a tolerance of 1.0 ppm in or on cotton gin by products (cotton gin trash), no additional data are required. The registrant must propose a tolerance for residues in this commodity.

Tolerances Listed Under 40 CFR §180.222(b)

The tolerance listed in 40 CFR §180.222(b) is for a regional registration as defined in 180.1(n) for residues of prometryn *per se* in dill. Adequate data are available to support the established tolerance.

New Tolerances Needed Under 40 CFR §180.222(c)

Based on residue data from extensive rotational field studies, tolerances will be required for the inadvertent residue of prometryn *per se* in rotational crops. These tolerances should be listed in 40 CFR §180.222(c). Available data support the suggested tolerances of 0.3 ppm for residues of prometryn *per se* in the forage and straw of rotational small grains. The registrant must propose tolerances of 0.3 ppm for residues of prometryn in the forage and straw of rotational small grains. The Agency will not require extensive field trials to determine appropriate tolerances for residues in the hay of rotational small grains, provided the registrant has no objection to proposing a tolerance of 1.0 ppm in rotational small grain hay.

Table 1. Tolerance Reassessment Summary for Prometryn

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR 180.222(a):			
Celery	0.5	0.5	
Corn, field (forage and fodder) Corn, sweet (forage and fodder) Corn, pop (forage and fodder) Corn, fresh (Inc. sweet, K+CWHR) Corn, grain	0.25	Revoke	Tolerances for residues in corn commodities will be proposed for revocation, since use sites for corn have been removed from all product labels.
Cotton, forage	1.0	Revoke	The tolerance should be revoked since cotton forage is no longer considered to be a significant feed item.
Cottonseed	0.25	0.25	*Cotton, undelinted seed*
Pigeon peas	0.25	0.25	*Pigeon pea, seed*
Tolerance listed under 40 CFR 180.222(b):			
Dill	0.3	0.3	Regional Registration
New Tolerance Required under 40 CFR §180.222(a):			
Cotton, gin byproducts	None	1.0 [b]	*Tolerance to be proposed by registrant for cotton, gin by products (gin trash)*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
New Tolerances Required under 40 CFR §180.222(c):			
Small grains, forage and straw	None	0.3	The registrant must propose tolerances for the inadvertent residues of prometryn, *per se*, in forage and straw of small grains rotated with cotton.
Small grains, hay	None	1.0	The registrant must propose a tolerance for inadvertant residues of prometryn *per se*, in hay or submit additional data.

[a] The 1.0 ppm tolerance was calculated based on the proposed tolerances in or on forage and a dry-matter conversion. Provided the registrant has no objection to a 1.0 ppm tolerance, residue data will not be required.

[b] The 1.0 ppm tolerance was calculated based on residues in rotational small grain hay and dry matter conversion. The registratnt must propose the suggested tolerance of 1.0 ppm, or submit the additional required data.

Codex Harmonization

No maximum residue limits (MRLs) for prometryn have been established by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

2. Restricted Use Classification

Prometryn is not currently classified as a restricted use pesticide. Although the restricted use risk quotients are at the threshold for small mammals, fresh water invertebrates and estuarine/marine organisms (oysters and mysid shrimp), the Agency has determined that the numbers do not warrant the chemical's reclassification at this time.

3. Reference Dose

The RfD has been set at 0.04 mg/kg/day by the Office of Pesticide Program's RfD/Peer Review Committee, based upon a NOEL of 3.75 mg/kg/day in a chronic toxicity study in dogs. The LEL was 37.5 mg/kg/day based on bone marrow atrophy and degenerative changes in the liver and kidneys. An uncertainty factor of 100 was used to account for inter- and intra-species variability.

4. Endangered Species Statement

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

5. Worker Protection Requirements

a. Occupational/Residential Labeling Rationale/Risk Mitigation

(1). Compliance with Worker Protection

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

At this time all of the registered uses of prometryn are within the scope of the Worker Protection Standard (WPS).

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

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

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

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

Occupational-Use Products (WPS and NonWPS Uses)

To the Agency's knowledge, at this time all of the registered uses of prometryn are within the scope of the Worker Protection Standard (WPS).

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

1. If the Agency has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent Agency guidelines.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc):

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

    - These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

    - The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There are special toxicological concerns about prometryn that warrant the establishment of active-ingredient-based minimum engineering-control and PPE requirements for certain handlers of certain formulations. The MOE's were calculated as being unacceptable for (1) occupational mixers/loaders who are supporting ground and aerial application of using wettable powder formulations, and (2) occupational mixers/loaders who are supporting aerial application using liquid formulations. The risks associated with mixing and loading wettable powder formulations cannot be adequately mitigated with the use of personal protective equipment. Therefore, the Agency is requiring that wettable powder formulations be formulated ONLY as water-soluble packets. This mandatory engineering-control requirement should adequately mitigate the risks associated with mixing and loading wettable powder formulations. To mitigate the risks associated with mixing and loading liquid formulations to support aerial applications, the Agency is requiring minimum (baseline) PPE of chemical-resistant apron and a respirator equipped with a dust/mist filter in addition to the PPE required for other handlers of prometryn. The MOE's were calculated as being acceptable for applicators and flaggers for all formulations. Since the exposure studies used to calculate these risks included the use of chemical-resistant gloves, long-sleeve shirts, long pants, shoes, and socks, these PPE and work clothing will be required for all handlers of prometryn.

Handler PPE for Homeowner-Use Products

There are no registered products containing prometryn that are intended for homeowner use.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

To the Agency's knowledge, at this time all registered uses of prometryn are within the scope of the Worker Protection Standard (WPS).

Restricted-Entry Interval: Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established on the basis of the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the

promulgation of the WPS: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

For occupational end-use products containing prometryn as an active ingredient, the Agency is establishing a 24-hour REI for celery and a 12-hour REI for all other uses of the product. The basis for this requirement is that prometryn has a toxicological endpoint of concern for systemic toxicity for short-term and intermediate exposures and no post-application exposure data are available.

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

The WPS interim REI in effect until now was 12 hours. The WPS interim REI was established through labeling modifications specified in PR Notice 93-7, which implemented the labeling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides.

For those uses of prometryn that are incorporated into the soil, the Agency notes that if prometryn has been correctly incorporated, the WPS permits workers to enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil subsurface.

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

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

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

There are no special concerns about prometryn since the MOEs for most handlers are acceptable with the use of long-sleeve shirt, long pants, shoes socks, and chemical-resistant

gloves. Therefore, for early entry following applications of prometryn, the Agency is establishing PPE for dermal protection based on the acute toxicity of the active ingredient. Since prometryn is classified as category III for eye irritation potential, protective eyewear is not required.

Occupational Use Products (nonWPS Uses)

To the Agency's knowledge, at this time there are no registered uses of prometryn outside the scope of the Worker Protection Standard.

Homeowner-Use Products

There are no registered products containing prometryn that are intended for homeowner use. The Agency is requiring labeling statements to assure that such products are not sold or used by homeowners.

Additional Labeling Requirements

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

6. Spray Drift Advisory

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

7. Groundwater and Surface Water Advisories

The laboratory mobility data for prometryn, taken as a whole, suggest that prometryn will be most mobile in sandy, alkaline soils which contain little organic matter or clay. In California, Arizona and New Mexico, prometryn labels instruct potential users not to apply the product to sand or loamy sand soils. Prometryn was not detected in ground water during a retrospective ground-water monitoring study performed by the registrant in Missouri, at a site which was underlain by sandy loams and loamy sands. In light of the registrant's stewardship in conducting numerous groundwater studies and the data in-house, the Agency has determined that groundwater and surface water label advisories are not necessary at this time. However, the Agency will require labelling prohibiting the use of prometryn on sand and sandy loam soils in certain areas of the country.

8. Rotational Crops Intervals

The following requirements (labeling and submission of data) are being imposed for rotational crops (rotational leafy vegetables, rotational small grains, and rotational root crops):

o For Rotational Leafy Vegetables:

Data are required. The registrant must conduct an additional limited field trial which includes a 12-month PBI. If residues of prometryn, *per se* in rotational leafy vegetables rotated at 12 months are <0.01 ppm, then no additional data will be required, and amended labels specifying a 12-month PBI must be submitted. Extensive rotational crop field trials are required if shorter PBIs are desired.

o For Rotational Small Grains:

The available data suggest that rotational crop tolerances of 0.3 ppm are required for residues of prometryn, *per se* in forage and straw of rotational small grains. These tolerances must be accompanied by amended labels stipulating a 3-month PBI for rotational small grains.

No additional data are required depicting residues in rotational small grain hay, provided the registrant proposes a tolerance of 1.0 ppm in hay of rotational small grains.

9. Environmental Hazard

The Agency is requiring labeling to ensure that prometryn use will not endanger sensitive terrestrial and aquatic plant species. Refer to Section V of this document.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of prometryn for the above eligible uses has been reviewed and determined to be substantially complete for all uses. The following additional confirmatory data are needed to fulfill the guideline requirements for the studies listed below:

o	Guideline 71-4(a)	Avian reproduction (upland gamebird)
o	Guideline 72-4(a)	Fish early life-stage
o	Guideline 85-2	Dermal absorption
o	A confirmatory post-application/reentry exposure study for celery. The study shall consist of:	
	Guideline 132-1(a)	Foliar dislodgeable residue dissipation,
	Guideline 132-1(b)	Soil residue dissipation, and
	Guideline 133-3	Dermal exposure to be conducted concurrently
o	Guideline 165-2	Limited field rotational crop study (for leafy vegetables)

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into a herbicide for the following use(s):_____
(fill blank only with those uses that are being supported by MP registrant)."

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

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding the support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding the support of such use(s)."

B. End-Use Products

1. Additional Product-Specific Requirements

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

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

2. Labeling Requirements for End-Use Products

a. Occupational Labeling

(1) Personal Protective Equipment Requirements for Pesticide Handlers (mixers, loaders, applicators, etc);

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

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

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

Minimum (Baseline) Personal Protective Equipment Requirements: All of the registered uses of prometryn are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The minimum (baseline) PPE for occupational handlers of prometryn end-use products is:

> "Applicators and other handlers must wear:
> --long sleeve shirt and long pants,
> --Chemical resistant gloves (see instructions * below), and
> --Shoes plus socks
>
> * The glove statement for prometryn is the statement established through the instructions in Supplement Three of PR Notice 93-7."

In addition, on the liquid-formulation end-use products that contain instructions for aerial applications, the Agency is requiring the following additional minimum (baseline) PPE for mixers and loaders supporting aerial applications:

"In addition, mixers and loaders supporting aerial applications must wear:
--Chemical-resistant apron, and
--Respirator (see instructions ** below)

** The following type of respirator is appropriate to mitigate prometryn inhalation concerns: "A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

Actual End-Use Product Personal Protective Equipment Requirements: The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) personal protective equipment, if any, specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

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

■ **Products Intended Primarily For Homeowner Use:**

To assure that such products are not sold to or used by homeowners the following labeling statement will be required: "For agricultural or commercial use only. Not for use by homeowners."

(2) Entry Restrictions; Labeling

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

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

(3) Occupational-Use Products (Products NOT Intended Primarily For Homeowner Use):

--Uses Within the Scope of the WPS:

Restricted-Entry Interval: A 24-hour restricted entry interval (REI) is required for celery and a 12 hour REI is required for all other uses. This REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

Early-Entry Personal Protective Equipment (PPE): The PPE required for early entry following applications of prometryn is:

--Coveralls over long-sleeve shirt and long pants,
--Chemical-resistant gloves,
--Shoes plus socks.

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

--Uses Not Within the Scope of the WPS: All of the registered uses of prometryn are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

(4) Other Occupational Labeling Requirements

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

Application Restrictions:

"Do not apply this product in a way that will make contact with workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls:

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

User Safety Requirements:

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

User Safety Recommendations:

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

- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Soil Incorporation Statement:

Registrants may add the following statement to their labeling in the Agricultural Use Requirements box immediately following the restricted entry interval:

"Exception: If the product is soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

b. Other Labeling Requirements

The Agency is requiring the following statements to be located on all prometryn end-use product labeling:

(1) Environmental Hazard Labeling

"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 washwater or rinsate. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from treated areas."

(2) Rotational Crops

For Rotational Root Crops:

Labels must specify a Plant back interval (PBI) of 8 months for rotational root crops.

(3) Spray Drift Labeling

The following language must be placed on each product label that can be applied aerially:

"Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors

determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions regarding spraying."

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. "The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor."

2. "Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees."

More stringent regulations should be observed in the states requiring them.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets.

When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can

influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

C. Homeowner Limitation Statement

The following statement must be added to all end-use products: "For agricultural or commercial use only; not for use by homeowners."

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 prometryn 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 REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES											
CELERY			Use Group: TERRESTRIAL FOOD CROP								
Broadcast, At planting, Sprayer	FlC	NA	1.6 lb A	*	1	NS	NS	NS NS 0.5	CA		
	FlC	NA	1.6 lb A	*	1	NS	NS	NS NS 0.5	CA		C46
	FlC	NA	1.6 lb A	*	1	NS	NS	NS NS NS	CA		
	FlC	NA	2 lb A	*	1	NS	NS	NS NS NS	CA		C46
	FlC	NA	1.6 lb A	*	1	NS	NS	NS NS NS	CA		C46, CAE
	WP	NA	1.6 lb A	*	1	NS	NS	NS NS NS	CA		C46
Broadcast, Postemergence, Sprayer	FlC	NA	1 lb A	*	1	NS	NS	NS NS 0.5	CA		
	FlC	NA	1 lb A	*	1	NS	NS	NS NS 0.5	CA		C46
	FlC	NA	1 lb A	*	1	NS	NS	NS NS NS	CA		
	FlC	NA	1.25 lb A	*	1	NS	NS	NS NS NS	CA		C46
	FlC	NA	.8 lb A	*	1	NS	NS	NS NS NS	CA		C46, CAE
	WP	NA	1 lb A	*	1	NS	NS	NS NS NS		CA	C46
	WP	NA	1 lb A	*	1	NS	NS	NS NS NS	CA		C46
Broadcast, Postplant, Sprayer	FlC	NA	1.6 lb A	*	1	NS	NS	NS NS 0.5	CA		
	FlC	NA	1.6 lb A	*	1	NS	NS	NS NS 0.5	CA		C46
	FlC	NA	1.6 lb A	*	1	NS	NS	NS NS NS	CA		
	FlC	NA	2 lb A	*	1	NS	NS	NS NS NS	CA		C46
	FlC	NA	1.6 lb A	*	1	NS	NS	NS NS NS	CA		C46, CAE
	WP	NA	1.6 lb A	*	1	NS	NS	NS NS NS	CA		C46

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
CELERY (con't)				**Use Group: TERRESTRIAL FOOD CROP (con't)**								
Broadcast, Posttransplant, Sprayer	FlC	NA	2 lb A 1.6 lb A	F C	NS	1/1 yr	NS	NS	NS 0.5	CA, TX		C46
	FlC	NA	4 lb A 3 lb A	F C	NS	1/1 yr	NS	NS	NS NS	HI		C46
	FlC	NA	UC UC	F C	NS	1/1 yr	NS	NS	NS NS	HI		C46, CAE
	FlC	NA	3.2 lb A 2.4 lb A	F C	NS	NS	NS	NS	NS 0.5	HI		
	FlC	NA	2 lb A 1.6 lb A	F C	NS	NS	NS	NS	NS NS	AZ		C46
	FlC	NA	3.2 lb A 2.4 lb A	F C	NS	NS	NS	NS	NS NS	HI		
	FlC	NA	3.2 lb A 2.4 lb A	F C	NS	NS	NS	NS	NS NS	HI	CA	C46
	WP	NA	3.2 lb A 2.4 lb A	F C	1	NS	NS	NS	NS NS	HI		C46
	WP	NA	3.2 lb A 2.4 lb A	F C	NS	NS	NS	NS	NS NS	HI		C46
Broadcast, Preemergence, Sprayer	FlC	NA	1.6 lb A	*	1	NS	NS	NS	NS 0.5	CA		
	FlC	NA	1.6 lb A	*	1	NS	NS	NS	NS 0.5	CA		C46
	FlC	NA	1.6 lb A	*	1	NS	NS	NS	NS NS	CA		
	FlC	NA	2 lb A	*	1	NS	NS	NS	NS NS	CA		C46
	FlC	NA	1.6 lb A	*	1	NS	NS	NS	NS NS	CA		C46, CAE

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

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. Dose	Max. Rate unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
CELERY (con't)					Use Group: TERRESTRIAL FOOD CROP (con't)							
	WP	NA	1.6 lb A	*	1	NS	NS	NS	NS	CA		C46
Broadcast, Seed bed, Sprayer	FlC	NA	.8 lb A	*	1	NS	NS	NS	0.5	FL		
	FlC	NA	.8 lb A	*	NS	1/1 yr	NS	NS	0.5	FL		C46
	FlC	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	FL		
	FlC	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	FL		C46, CAE
	FlC	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	FL	CA	C46
	WP	NA	.8 lb A	*	1	1/1 yr	NS	NS	NS	FL		C46
	WP	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	FL		C46
COTTON (UNSPECIFIED)					Use Group: TERRESTRIAL FOOD+FEED CROP							
Broadcast, At planting, Aircraft	FlC	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	0.5	013	AZ, CA	C46, G74
			2.8 lb A	M								
			2.4 lb A	C								
Broadcast, At planting, Sprayer	FlC	NA	2.8 lb A	F	1	NS	NS	NS	0.5	013	AZ, CA	G74
			2.8 lb A	M								
			2.4 lb A	C								
	FlC	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	0.5	013	AZ, CA	C46, G74
			2.8 lb A	M								
			2.4 lb A	C								
	FlC	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	013	AZ, CA	C46, CAE, G74
			2.8 lb A	M								
			2.4 lb A	C								
	FlC	NA	3.5 lb A	F	NS	1/1 yr	NS	NS	NS	013	AZ, CA	C46, G74
			3.5 lb A	M								
			3 lb A	C								

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
COTTON (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	FlC	NA	2.8 lb A	F	NS	NS	NS	NS	NS	013	AZ, CA	C46, G74
			2.8 lb A	M								
			2.4 lb A	C								
	FlC	NA	2.8 lb A	F	NS	NS	NS	NS	NS	013	AZ, CA	G74
			2.8 lb A	M								
			2.4 lb A	C								
	WP	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	013	AZ, CA	C46, G74
			2.8 lb A	M								
			2.4 lb A	C								
	WP	NA	2.8 lb A	M	NS	1/1 yr	NS	NS	NS	013	AZ, CA	C46, GL8
			2.4 lb A	C								
Broadcast, Fall, Aircraft	FlC	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	0.5	TX	C46, G74
Broadcast, Fall, Sprayer	FlC	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	0.5	TX	C46, G74
	FlC	NA	2 lb A	*	NS	1/1 yr	NS	NS	NS	NS	CA	C46, CAE, G74
			2 lb A	F								
			2 lb A	M								
			1.6 lb A	C								
	FlC	NA	.8 lb A	*	NS	NS	NS	NS	NS	0.5	TX	G74
	FlC	NA	.8 lb A	*	NS	NS	NS	NS	NS	NS	TX	C46, G74
	FlC	NA	.8 lb A	*	NS	NS	NS	NS	NS	NS	TX	G74
	WP	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	NS	TX	C46, GL8
	WP	NA	.8 lb A	*	NS	NS	NS	NS	NS	NS	TX, AR, LA, MS	C46, GL8
Broadcast, Layby, Aircraft	FlC	NA	1.6 lb A	M	NS	1/1 yr	NS	NS	NS	0.5	AZ, CA, 013	C46, G74
			1.6 lb A	C								

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
COTTON (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
Broadcast, Layby, Sprayer	FlC	NA	1.6 lb A 1.6 lb A	M C	NS	1/1 yr	NS	NS	NS 0.5	AZ, CA, 013	C46, G74
	FlC	NA	1.6 lb A 1.6 lb A	M C	NS	1/1 yr	NS	NS	NS 0.5	AZ, CA, 013	G74
	FlC	NA	1.6 lb A 1.6 lb A 1.6 lb A	F M C	NS	1/1 yr	NS	NS	NS NS	AZ, CA, 013	C46, CAE, G74
	FlC	NA	2 lb A 1.6 lb A	M C	NS	1/1 yr	NS	NS	NS NS	AZ, CA, 013	C46, G74
	FlC	NA	1.6 lb A 1.6 lb A	M C	NS	NS	NS	NS	NS NS	AZ, CA, 013	G74
	WP	NA	1.6 lb A 1.6 lb A	M C	NS	1/1 yr	NS	NS	NS NS	AZ, CA, 013	C46, GL8
Broadcast, Plant bed, Sprayer	WP	NA	1 lb A	*	NS	1/1 yr	NS	NS	NS NS	AL, AR, LA, MO, MS, TN	C46, GL8
Broadcast, Postemergence, Low pressure ground sprayer	FlC	NA	.5 lb A	*	NS	NS	NS	1 lb 7	NS		C46, G74
Broadcast, Postemergence, Sprayer	FlC	NA	.5 lb A	*	NS	NS	NS	1 lb NS	0.5	013 TX, AR, LA, MS, MO, TN	C46, GL8
	WP	NA	.64 lb A	*	NS	1/1 yr	NS	NS	NS NS		C46, GL8
Broadcast, Postplant, Aircraft	FlC	NA	2.8 lb A 2.8 lb A 2.4 lb A	F M C	NS	1/1 yr	NS	NS	NS 0.5	013 AZ, CA	C46, G74
Broadcast, Postplant, Sprayer	FlC	NA	2.8 lb A 2.8 lb A 2.4 lb A	F M C	1	NS	NS	NS	NS 0.5	013 AZ, CA	G74

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
COTTON (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	FlC	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	0.5	013	AZ, CA	C46, G74
			2.8 lb A	M									
			2.4 lb A	C									
	FlC	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	NS	013	AZ, CA	C46, CAE, G74
			2.8 lb A	M									
			2.4 lb A	C									
	FlC	NA	3.5 lb A	F	NS	1/1 yr	NS	NS	NS	NS	013	AZ, CA	C46, G74
			3.5 lb A	M									
			3 lb A	C									
	FlC	NA	2.8 lb A	F	NS	NS	NS	NS	NS	NS	013	AZ, CA	G74
			2.8 lb A	M									
			2.4 lb A	C									
	WP	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	NS	013	AZ, CA	C46, G74
			2.8 lb A	M									
			2.4 lb A	C									
	WP	NA	2.8 lb A	M	NS	1/1 yr	NS	NS	NS	NS	013	AZ, CA	C46, GL8
			2.4 lb A	C									
Broadcast, Preemergence, Aircraft	FlC	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	0.5	013	AZ, CA	C46, G74
			2.8 lb A	M									
			2.4 lb A	C									
Broadcast, Preemergence, Sprayer	FlC	NA	2.8 lb A	M	1	NS	NS	NS	NS	0.5	013	AZ, CA	G74
			2.4 lb A	C									
	FlC	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	0.5	013	AZ, CA	C46, G74
			2.8 lb A	M									
			2.4 lb A	C									
	FlC	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	NS	013	AZ, CA	C46, CAE, G74
			2.8 lb A	M									
			2.4 lb A	C									

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
COTTON (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	FlC	NA	3.5 lb A	F	NS	1/1 yr	NS	NS	NS	013	AZ, CA	C46, G74
			3.5 lb A	M								
			3 lb A	C								
	FlC	NA	2.8 lb A	F	NS	NS	NS	NS	NS	013	AZ, CA	G74
			2.8 lb A	M								
			2.4 lb A	C								
	WP	NA	2.8 lb A	F	NS	1/1 yr	NS	NS	NS	013	AZ, CA	C46, G74
			2.8 lb A	M								
			2.4 lb A	C								
	WP	NA	2.8 lb A	M	NS	1/1 yr	NS	NS	NS	013	AZ, CA	C46, GL8
			2.4 lb A	C								
Broadcast, Seed bed, Aircraft	FlC	NA	UC	*	NS	1/1 yr	NS	NS	NS	0.5	AL, AR, LA, MS, MO, TN	C46, G74
Broadcast, Seed bed, Sprayer	FlC	NA	UC	*	NS	1/1 yr	NS	NS	NS	0.5	AL, AR, LA, MS, MO, TN	C46, G74
	WP	NA	2 lb A	F	NS	1/1 yr	NS	NS	NS	NS	CA	C46, GL8
			2 lb A	M								
			1.6 lb A	C								
Broadcast, Winter, Aircraft	FlC	NA	2 lb A	F	NS	1/1 yr	NS	NS	NS	0.5	CA, TX	C46, G74
			2 lb A	M								
			1.6 lb A	C								
Broadcast, Winter, Sprayer	FlC	NA	2 lb A	F	NS	1/1 yr	NS	NS	NS	0.5	CA, TX	C46, G74
			2 lb A	M								
			1.6 lb A	C								
	FlC	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	NS	TX, AR, LA, MS	C46, CAE, G74
	FlC	NA	.8 lb A	*	NS	NS	NS	NS	NS	0.5	TX	G74

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
COTTON (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	FlC	NA	.8 lb A	*	NS	NS	NS	NS	NS	NS	TX		C46, G74
	FlC	NA	.8 lb A	*	NS	NS	NS	NS	NS	NS	TX		G74
	WP	NA	.8 lb A	*	NS	1/1 yr	NS	NS	NS	NS	TX		C46, GL8
	WP	NA	.8 lb A	*	NS	NS	NS	NS	NS	NS	TX, AR, LA, MS		C46, GL8
Directed spray, Postemergence, Low pressure ground sprayer	FlC	NA	.5 lb A	*	NS	NS	NS	1 lb	7	NS			C46, G74
Directed spray, Postemergence, Shielded applicator	FlC	NA	.5 lb A	*	NS	NS	NS	1 lb	NS	0.5	TX, AR, LA, MS, MO, TN		C46, GL8
	FlC	NA		*	NS	NS	NS	1 lb	NS	NS	TX, LA, AR, MS, MO, TN		C46, G74
Directed spray, Postemergence, Sprayer	FlC	NA	.65 lb A	*	NS	1/1 yr	NS	NS	NS	0.5			C46, G74
	FlC	NA	.65 lb A	*	NS	1/1 yr	NS	NS	NS	NS			C46, CAE, G74
	FlC	NA	.5 lb A	*	NS	NS	NS	1 lb	NS	0.5	013	TX, AR, LA, MS, MO, TN	C46, GL8
	FlC	NA	.65 lb A	*	NS	NS	NS	NS	NS	0.5			G74
	FlC	NA	.65 lb A	*	NS	NS	NS	NS	NS	NS			C46, G74
	FlC	NA	.65 lb A	*	NS	NS	NS	NS	NS	NS			G74
	FlC	NA	.875 lb A	*	NS	NS	NS	NS	NS	NS	013		C46, G74
	WP	NA	.64 lb A	*	NS	1/1 yr	NS	NS	NS	NS			C46, GL8
	WP	NA	.64 lb A	*	NS	NS	NS	NS	NS	NS			C46, GL8

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
COTTON (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
Soil incorporated treatment, Preplant, Aircraft	FlC	NA	2.4 lb A 2.4 lb A 1.6 lb A	F M C	1	NS	NS	NS	0.5	AZ, CA, NM	G74
	FlC	NA	2.4 lb A 2.4 lb A 1.6 lb A	F M C	NS	1/1 yr	NS	NS	NS	0.5 AZ, CA, NM	C46, G74
	FlC	NA	2.4 lb A 2.4 lb A 1.6 lb A	F M C	NS	1/1 yr	NS	NS	NS	NS AZ, CA, NM	C46, CAE, G74
	FlC	NA	2.4 lb A 2.4 lb A 1.6 lb A	F M C	NS	NS	NS	NS	NS	NS AZ, CA, NM	C46, G74
	WP	NA	2.4 lb A 1.6 lb A 1.6 lb A	F M C	NS	1/1 yr	NS	NS	NS	NS AZ, CA, NM	C46, GL8
	WP	NA		*	NS	NS	NS	NS	NS	NS	C46, G74
	WP	NA	2.4 lb A 1.6 lb A 1.6 lb A	F M C	NS	NS	NS	NS	NS	NS AZ, CA, NM	C46, GL8
Soil incorporated treatment, Preplant, Sprayer	FlC	NA	2.4 lb A 2.4 lb A 1.6 lb A	F M C	1	NS	NS	NS	0.5	AZ, CA, NM	G74
	FlC	NA	2.4 lb A 2.4 lb A 1.6 lb A	F M C	NS	1/1 yr	NS	NS	NS	0.5 AZ, CA, NM	C46, G74
	FlC	NA	2.4 lb A 2.4 lb A 1.6 lb A	F M C	NS	1/1 yr	NS	NS	NS	NS AZ, CA, NM	C46, CAE, G74

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)		Max. Appl. Rate (AI unless noted otherwise)		Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
COTTON (UNSPECIFIED) (con't)						Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
	FlC	NA	3	lb A	F	NS	1/1 yr	NS	NS	NS	NS	AZ, CA, NM	C46, G74
			3	lb A	M								
			2	lb A	C								
	FlC	NA	2.4	lb A	F	NS	NS	NS	NS	NS	NS	AZ, CA, NM	C46, G74
			2.4	lb A	M								
			1.6	lb A	C								
	FlC	NA	2.4	lb A	F	NS	NS	NS	NS	NS	NS	AZ, CA, NM	G74
			1.6	lb A	M								
			1.6	lb A	C								
	WP	NA	2.4	lb A	F	NS	1/1 yr	NS	NS	NS	NS	AZ, CA, NM	C46, G74
			2.4	lb A	M								
			1.6	lb A	C								
	WP	NA	2.4	lb A	F	NS	1/1 yr	NS	NS	NS	NS	AZ, CA, NM	C46, GL8
			1.6	lb A	M								
			1.6	lb A	C								
	WP	NA	2.4	lb A	F	NS	NS	NS	NS	NS	NS	AZ, CA, NM	C46, GL8
			1.6	lb A	M								
			1.6	lb A	C								
DILL						Use Group: TERRESTRIAL FOOD CROP							
Broadcast, Postemergence, Sprayer	WP	NA	1.6	lb A	*	NS	NS	NS	NS	NS	NS	CA	C46, H01(48)
Broadcast, Preemergence, Sprayer	WP	NA	1.6	lb A	*	NS	NS	NS	NS	NS	NS	CA	C46, H01(48)
PEAS, PIGEON						Use Group: TERRESTRIAL FOOD CROP							
Broadcast, At planting, Aircraft	FlC	NA	3	lb A	F	NS	1/1 yr	NS	NS	NS	0.5	PR	C46, G74
			2	lb A	M								
Broadcast, At planting, Sprayer	FlC	NA	3	lb A	F	NS	1/1 yr	NS	NS	NS	0.5	PR	C46, G74
			2	lb A	M								

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
PEAS, PIGEON (con't)					Use Group: TERRESTRIAL FOOD CROP (con't)						
Broadcast, Postplant, Aircraft	FlC	NA	3 lb A 2 lb A	F M	NS	1/1 yr	NS	NS	NS 0.5	PR	C46, G74
Broadcast, Postplant, Sprayer	FlC	NA	3 lb A 2 lb A	F M	NS	1/1 yr	NS	NS	NS 0.5	PR	C46, G74
Broadcast, Preemergence, Aircraft	FlC	NA	3 lb A 2 lb A	F M	NS	1/1 yr	NS	NS	NS 0.5	PR	C46, G74
Broadcast, Preemergence, Sprayer	FlC	NA	3 lb A 2 lb A	F M	NS	1/1 yr	NS	NS	NS 0.5	PR	C46, G74
					Use Group: TERRESTRIAL FOOD+FEED CROP						
Broadcast, Preemergence, Sprayer	WP	NA	2.8 lb A 2 lb A	F M	NS	1/1 yr	NS	NS	NS NS	PR	C46, GL8

APPENDIX A REPORT

Case 0467[Prometryn]   Chemical 080805[Prometryn]

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LEGEND
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Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

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)
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

FlC	: FLOWABLE CONCENTRATE
WP	: WETTABLE POWDER

ABBREVIATIONS

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

APPLICATION RATE

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

APPENDIX A REPORT

Case 0467[Prometryn] Chemical 080805[Prometryn]

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USE LIMITATIONS CODES

C46 : Do not apply through any type of irrigation system.
CAE : Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
G74 : Do not feed treated foliage to livestock or graze treated areas.
GL8 : Do not allow the feeding or grazing of foliage by livestock.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

013 : Other
AL : Alabama
AR : Arkansas
AZ : Arizona
CA : California
FL : Florida
HI : Hawaii
LA : Louisiana
MO : Missouri
MS : Mississippi
NM : New Mexico
PR : Puerto Rico
TN : Tennessee
TX : Texas

GUIDE TO APPENDIX B

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

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	ALL	40573701, 42876001, *40661701*, *42579101*, *42919001*
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00135568, 40356002, *40661701*, *42579101*, *42919001*
61-2B	**Formation of Impurities**	ALL	00023963, 40356001, *42876001*, *40661701*, *42919001*
62-1	**Preliminary Analysis**	ALL	00024668, 40573701, 42876002, *40661701*, *42583801*, *42918101*
62-2	**Certification of limits**	ALL	40573701, 42876002, *40661701*, *42583801*, *42918101*
62-3	**Analytical Method**	ALL	00135668, 40573701, 42876002, *40661701*, *42918101*, *42583801*
63-2	**Color**	ALL	00135668, 40356002, *40661701*
63-3	**Physical State**	ALL	00135668, 40356002, *40661701*
63-4	**Odor**	ALL	00135668, 40356002, *40661701*
63-5	**Melting Point**	ALL	00135668, 40356002, *40661701*
63-6	**Boiling Point**	ALL	N/A
63-7	**Density**	ALL	00135668, 40356002, *40661701*
63-8	**Solubility**	ALL	00123217, 00135668, 00148334, 40356002, *40661701*

Data Supporting Guideline Requirements for the Reregistration of Prometryn

REQUIREMENT		USE PATTERN	CITATION(S)
63-9	**Vapor Pressure**	ALL	00123217, 00135668, 00148334, 40356002, *40661701, 42579102*
63-10	**Dissociation Constant**	ALL	00135668, 40356002, *40661701*
63-11	**Octanol/Water Partition**	ALL	40356002, *40661701, 42579103*
63-12	**pH**	ALL	40356002, *40661701*
63-13	**Stability**	ALL	00135668, 40356002, 42622001, *40661701, 42579102*
63-14	**Oxidizing/Reducing Action**	ALL	40356002, *40661701, 43010001*
63-15	**Flammability**	ALL	N/A
63-16	**Explodability**	ALL	40356002, *42840201*
63-17	**Storage stability**	ALL	40356002, 42876003, *42579104, 43001801*
63-18	**Viscosity**	ALL	N/A
63-19	**Miscibility**	ALL	N/A
63-20	**Corrosion characteristics**	ALL	40356002, *42579102*
63-21	**Dielectric breakdown volt**	ALL	N/A
64-1	**Submittal of Samples**	All	N/A

Courier type notes studies Ciba Crop Protection Group has submitted.
***Italic* type notes studies Verolit Chemical Manufacturers, Ltd. has submitted.**

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A,B,C,G	00082966
71-1B	**Acute Avian Oral - Quail/Duck TEP**		N/A
71-2A	**Avian Dietary - Quail**	A,B,C,G	40457502
71-2B	**Avian Dietary - Duck**	A,B,C,G	00070686
71-3	**Wild Mammal Toxicity**		N/A
71-4A	**Avian Reproduction - Quail**	A,B,C,G	Data Gap 41035901 (study is unacceptable), 41035902
71-4B	**Avian Reproduction - Duck**		
71-5A	**Simulated Field Study**		N/A
71-5B	**Actual Field Study**		N/A
72-1A	**Fish Toxicity Bluegill**	A,B,C,G	00070686
72-1B	**Fish Toxicity Bluegill - TEP**	A,B,C,G	40228401
72-1C	**Fish Toxicity Rainbow Trout**	A,B,C,G	00070686
72-1D	**Fish Toxicity Rainbow Trout- TEP**	A,B,C,G	40573718
72-2A	**Invertebrate Toxicity**	A,B,C,G	00070146,
72-2B	**Invertebrate Toxicity - TEP**		N/A
72-3A	**Estuarine/Marine Toxicity - Fish**	A,B,C,G	40573717, 40228401
72-3B	**Estuarine/Marine Toxicity - Mollusk**	A,B,C,G	40228401, 40573719

Data Supporting Guideline Requirements for the Reregistration of Prometryn

REQUIREMENT		USE PATTERN	CITATION(S)
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A,B,C,G	40573718
72-3D	**Estuarine/Marine Toxicity Fish-TEP**		N/A
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**		N/A
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**		N/A
72-4A	**Early Life Stage Fish**	A,B,C,G	Data Gap 40573721 (study is unacceptable)
72-4B	**Life Cycle Invertebrate**	A,B,C,G	40573720
72-5	**Life Cycle Fish**		N/A
72-6	**Aquatic Organism Accumulation**		N/A
72-7A	**Simulated Field - Aquatic Organisms**		N/A
72-7B	**Actual Field - Aquatic Organisms**		N/A
122-1A	**Seed Germination/Seedling Emergence**		N/A
122-1B	**Vegetative Vigor**		N/A
122-2	**Aquatic Plant Growth**		N/A
123-1A	**Seed Germination/Seedling Emergence**	A,B,C,G	41035904
123-1B	**Vegetative Vigor**	A,B,C,G	41035903

Data Supporting Guideline Requirements for the Reregistration of Prometryn

REQUIREMENT		USE PATTERN	CITATION(S)
123-2	**Aquatic Plant Growth**	A,B,C,G	42520901, 42520902, 40520903, 42620201, 42620202
124-1	**Terrestrial Field**		N/A
124-2	**Aquatic Field**		N/A
141-1	**Honey Bee Acute Contact**	A,B,C,G	42528501
141-2	**Honey Bee Residue on Foliage**		N/A
141-5	**Field Test for Pollinators**		N/A
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	ALL	00060314
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	ALL	00060647
81-3	**Acute Inhalation Toxicity - Rat**	ALL	42325503
81-4	**Primary Eye Irritation - Rabbit**	ALL	40776601
81-5	**Primary Dermal Irritation - Rabbit**		00060316
81-6	**Dermal Sensitization - Guinea Pig**		40966001
81-7	**Acute Delayed Neurotoxicity - Hen**		N/A
82-1A	**28-Day Feeding - Rodent**		N/A
82-1B	**90-Day Feeding - Non-rodent**		N/A
82-2	**21-Day Dermal - Rabbit**		40573702
82-3	**90-Day Dermal - Rodent**		N/A
82-4	**90-Day Inhalation - Rat**		N/A

Data Supporting Guideline Requirements for the Reregistration of Prometryn

REQUIREMENT		USE PATTERN	CITATION(S)
82-5A	**90-Day Neurotoxicity - Hen**		N/A
82-5B	**90-Day Neurotoxicity - Mammal**		N/A
83-1A	**Chronic Feeding Toxicity -Dog**		00042794
83-1A	**Chronic Feeding Toxicity - Rodent (mouse)**		40466201, 40457515
83-1B	**Chronic Feeding Toxicity - Rodent (rat)**		41901201
83-2A	**Oncogenicity - Dog**		00042794
83-2B	**Oncogenicity - Rat**		41901201
83-2B	**Oncogenicity - Mouse**		40466201, 40457515
83-3A	**Developmental Toxicity - Rat**		40457517
83-3B	**Developmental Toxicity - Rabbit**		00157995
83-4	**2-Generation Reproduction - Rat**		41445101
84-2A	**Gene Mutation (Ames Test)**		40457518
84-2B	**Structural Chromosomal Aberration**		40466203
84-4	**Other Genotoxic Effects**		40457519, 40457522
85-1	**General Metabolism (rat)**		41255901
85-2	**Dermal Penetration**		N/A
86-1	**Domestic Animal Safety**		N/A
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**		N/A

REQUIREMENT		USE PATTERN	CITATION(S)
132-1B	**Soil Residue Dissipation**		N/A
133-3	**Dermal Passive Dosimetry Exposure**		N/A
133-4	**Inhalation Passive Dosimetry Exposure**		N/A
231	**Estimation of Dermal Exposure at Outdoor Sites**		N/A
232	**Estimation of Inhalation Exposure at Outdoor Sites**		N/A
233	**Estimation of Dermal Exposure at Indoor Sites**		N/A
234	**Estimation of Inhalation Exposure at Indoor Sites**		N/A
ENVIRONMENTAL FATE			N/A
160-5	**Chemical Identity**		N/A
161-1	**Hydrolysis**	A,B,C,G	40573704
161-2	**Photodegradation - Water**	A,B,C,G	40573705
161-3	**Photodegradation - Soil**	A,B,C,G	40373706
161-4	**Photodegradation - Air**		N/A
162-1	**Aerobic Soil Metabolism**	A,B,C,G	00148338
162-2	**Anaerobic Soil Metabolism**	A,B,C,G	41155901
162-3	**Anaerobic Aquatic Metabolism**		N/A
162-4	**Aerobic Aquatic Metabolism**		N/A

Data Supporting Guideline Requirements for the Reregistration of Prometryn

REQUIREMENT		USE PATTERN	CITATION(S)
163-1	**Leaching/Adsorption/Desorption**	A,B,C,G	41875902, 41875903, 41875904, 41875905
163-2	**Volatility - Lab**	A,B,C,G	41875906
163-3	**Volatility - Field**		N/A
164-1	**Terrestrial Field Dissipation**	A,B,C,G	41546401, 42253903, 41546402, 42253904, 41546403, 42253901, 41546404, 42253902
164-2	**Aquatic Field Dissipation**		N/A
164-3	**Forest Field Dissipation**		N/A
164-5	**Long Term Soil Dissipation**	A,B,C,G	IN REVIEW
165-1	**Confined Rotational Crop**	A,B,C,G	42081601
165-2	**Field Rotational Crop**	A,B,C,G	41901202, 43370404
165-3	**Accumulation - Irrigated Crop**		N/A
165-4	**Bioaccumulation in Fish**	A,B,C,G	41027701, 40573715
165-5	**Bioaccumulation - Aquatic NonTarget**		N/A
166-1	**Ground Water - Small Prospective**		N/A
166-2	**Ground Water - Small Retrospective**		N/A
166-3	**Ground Water - Irrigated Retrospective**		N/A
201-1	**Droplet Size Spectrum**		Being conducted by the industry's Spray Drift Task Force
202-1	**Drift Field Evaluation**		Being conducted by the industry's Spray Drift Task Force

REQUIREMENT		USE PATTERN	CITATION(S)
			N/A
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	A,B	00023213, 00024378, 00055672, 00093542, 00125011, 00125013, 41293301, 41711301, 41711302, 41842501, 41842502, 41842503, 41842504, 41842505, 42604401, 43185501, 43407106
171-4B	**Nature of Residue - Livestock**	B	41293302, 41293303
171-4C and 171-4D	**Residue Analytical Method**	A,B	00023280, 00027330, 00056556, 00093535, 00093536, 00105780, 00106829, 00115783, 00121720, 00123218, 00125011, 00125015, 00163474, 00163738, 40471701, 41397201, 41397202, 41397203, 41711302, 42140201
171-4E	**Storage Stability**	A,B	00093535, 00125015, 41291001, 41397204, 42349601, 42140201, 43370405
171-4F	**Magnitude of Residues - Potable H2O**		N/A
171-4G	**Magnitude of Residues in Fish**		N/A
171-4H	**Magnitude of Residues - Irrigated Crop**		N/A
171-4I	**Magnitude of Residues - Food Handling**		N/A
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	00093535, 00093536
171-4K	**Magnitude of the Residue in Plants (Crop Field Trials)**	A,B	

REQUIREMENT	USE PATTERN	CITATION(S)
Leafy Vegetables Group (except Brassica vegetables)		
--Celery		00034043, 00093546, 00093548, 41445102
Legume Vegetables (Succulent or Dried) Group		
--Peas, pigeon		00125015
Foliage of Legume Vegetables Group		
--Pea, vines and hay		feeding restriction is acceptable
Cereal Grains Group		
--Corn, grain		00024696, 00093530
--Corn, fresh (inc. sweet, K+CWHR)		00024696, 00093530
Forage, Fodder, and Straw of Cereal Grains Group		
--Corn, forage and fodder		00024696, 00093530, 00125012
Herbs and Spices Group		
--Dill		00163738, 40471701

Data Supporting Guideline Requirements for the Reregistration of Prometryn

REQUIREMENT		USE PATTERN	CITATION(S)
	Miscellaneous Commodities		
	--Cotton, forage		00027329, 00027330, 00093531, 00106358 00056556, 00065048, 00093531, 00105780, 00106358, 00106841, 00106829, 00125010
	--Cottonseed		No data are required.
	--Cotton, gin by-products		
171-4l	**Magnitude of the Residues in Processed Food/Feed**	A,B	
	--Corn, field		Registrant voluntarily cancelled its uses on corn. The tolerances will be revoked.
	--Cottonseed		00093535, 00093536
171-5	**Reduction of Residues**		N/A
171-6	**Proposed Tolerance**		N/A
171-7	**Support for Tolerance**		N/A
171-13	**Analytical Reference Standard**		N/A

GUIDE TO APPENDIX C

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

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

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

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

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

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

the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
00023213	Muller, P.W.; Payot, P.H. (1966) Fate of 14C-Labelled Triazine herbicides in plants. Pages 61-70,~In~Isotopes Weed Research: Proceedings of IAEA Symposium; 1965-66, Vienna, Austria. N.P. (Also~In~unpublished submission received Jul 1, 1971 under unknown admin. no.; submitted by Shell Chemical Co., Washington, D.C.; CDL:221995-R)
00023280	Mattson, A.M.; Solga, J. (1966) The Determination of Atrazine, Simazine and Prometryne in Cow's Milk by Gas Chromatography. Method dated Nov 11, 1966. (Unpublished study received Jul 15, 1968 under 7F5034; submitted by Geigy Chemical Co., Ardsley, N.Y.; CDL:092912-A)
00023963	Burkhard, N. (1976) Project Report 17/76: Hydrolysis of 2-Chloroand 2-Methylthio-4,6-bis-(alkylamino)-s-triazines under Laboratory Conditions. (Unpublished study received Apr 27, 1977 under 100-588; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:229641-A)
00024378	Best, J.A.; Weber, J.B.; Monaco, T.J. (1975) Influence of soil pH on Triazine availability to plants. Weed Science 23(5): 378-382. (Also~In~unpublished submission received Jul 19, 1978 under 201-403; submitted by Shell Chemical Co., Washington, D.C.; CDL:234470-AD)
00024668	Ross, J.; Balu, K.; Maher, J. (1976) Laboratory Report: Project No. 101904. (Unpublished study received Dec 29, 1976 under 6E1725; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095644-B)
00024696	Richardson, C.; Nalewaja, J.D.; Buchholtz, K.P.; et al. (1964) Atrazine/Prometryne Residues--Corn: AG-A 540. (Unpublished study including AG-A 565, AG-A 586, AG-A 644..., received May 26, 1967 under 100-492; prepared in cooperation with North Dakota State Univ., Dept. of Agronomy and others, submitted by CibaGeigy Corp., Greensboro, N.C.; CDL:000510-B)
00027329	Holstun, J.T., Jr.; Frans, R.E.; Hazlewood, B.P.; et al. (1969) Summary of Cotton Residue Data. (Unpublished study received Nov 27, 1970 under 100-471; prepared in cooperation with U.S. Agricultural Research Service, Crops Research Div., Delta Branch Experiment Station and others, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:000464-B)

BIBLIOGRAPHY

MRID	CITATION
00027330	Gemma, A. (1970) Determination of Prometryne, G-11354, and GS26831 Residues in Cotton and Soybeans by Gas Chromatography. Method No. AG-150 dated Oct 29, 1970. (Unpublished study received Dec 12, 1970 under 100-471; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:000464-C)
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

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

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific

Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

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

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

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

c. Generic Data Exemption -

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

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

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

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

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

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

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

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

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

a. Voluntary Cancellation

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

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

b. Satisfying the Product Specific Data Requirements of this Notice.

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

forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG)

and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

Option 3. Offer to Share in the Cost of Data Development

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

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

Option 4. Submitting an Existing Study

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

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

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

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

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted

according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

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

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

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

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

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

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

Option 6. Citing Existing Studies

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

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

2. Product Specific Data

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

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

(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)

(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

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

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

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

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

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

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

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

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

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

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

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data

requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

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

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

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

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

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

   iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

   unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

PROMETRYN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 prometryn. 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 prometryn 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 prometryn are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on prometryn 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 prometryn products.

INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

Jean Holmes
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: **prometryn**

PROMETRYN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 prometryn. 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 prometryn Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

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

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

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

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

The public reporting and recordkeeping burden for this collection of information is estimated to average *15 minutes* per response annually. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (2136), 401 M St., S.W., Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed *form* to this address.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

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

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

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

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

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources

are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

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

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

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

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

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

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

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

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

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

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

Instructions For Completing The "Requirements Status and Registrant's Response Forms" For The Generic and Product Specific Data Call-In

INTRODUCTION

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

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

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

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

The public reporting and recordkeeping burden for this collection of information is estimated to average *30 minutes* per response annually. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden,

including through the use of automated collection techniques to the Director, OPPE Regulatory Information Division, U.S. Environmental Protection Agency (2136), 401 M St., S.W., Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed *form* to this address.

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

Generic and Product Specific Data Call-In

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

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

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

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

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

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

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

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

Generic and Product Specific Data Call-In

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

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

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

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites

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

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

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

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

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

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

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

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

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

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core

minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

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

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

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

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

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

Option 7. (<u>Waiver Request</u>) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

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

Item 11. **ON BOTH FORMS:** Enter the date of signature.

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

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

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

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

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Prometryn (2,4-Bis(isopropylamino)-(methylthio)-s-triazine), the Agency has batched products that can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., liquid, powder, aerosol, granular, etc.), and labeling (e.g., signal word, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms that are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing

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

Table 1 displays the batches for the active ingredient Prometryn. Although reg. no. 34707-692 is placed into batch #3, the registrant must cite or submit an acute inhalation toxicity study conducted on 34704-692 to support this product.

Table 1.

Batch No.	Registration Number	Percent Active Ingredient	Form
1	100-542	prometryn ... 97.0%	powder
	46386-2	prometryn ... 95.0%	powder
2	100-757	prometryn ... 80.0%	powder
	66222-14	prometryn ... 80.0%	powder
3	100-620	prometryn ... 44.4%	liquid
	1812-274	prometryn ... 45.41%	liquid
	9779-297	prometryn ... 44.4%	liquid
	10163-94	prometryn ... 44.4%	liquid
	34704-692	prometryn ... 44.4%	liquid
	66222-15	prometryn ... 44.0%	liquid
	AZ89001900	prometryn ... 44.4%	liquid

Table 2 lists the products the Agency was unable to batch. This product was considered not to be similar to other products for purposes of acute toxicity or the Agency lacked sufficient information for decision making. The registrants of these products are responsible for meeting the acute toxicity data requirements for these products.

Table 2.

EPA Reg. No.	Active Ingredient	Formulation Type
100-495	prometryn ... 8.4% monosodium acid methanearsonate ... 33.6%	liquid
1812-349	prometryn ... 80.0%	powder
9779-317	prometryn ... 8.4% monosodium acid methanearsonate ... 33.6%	liquid
CA9100020	unknown	unknown

ATTENTION CRM::: PLEASE NOTE:::
REMOVE THIS PAGE AND INSERT THE LIST OF REGISTRANTS RECEIVING THIS DCI

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			
18. Signature of Approving Official		19. Title		20. Phone No. *(Include Area Code)*		21. Date		

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

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EPA	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 E - LIST OF AVAILABLE RELATED DOCUMENTS

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

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jean Holmes at (703)-308-8008.

1. PR Notice 86-5.

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

3. A full copy of this RED document.

4. A copy of the fact sheet for prometryn.

The following documents are part of the Administrative Record for prometryn and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

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

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

1. The Label Review Manual.

2. EPA Acceptance Criteria