United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-97-007
June 1997

Reregistration Eligibility Decision (RED)

Pendimethalin

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 pendimethalin which includes the active ingredient pendimethalin. 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 is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

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 Jane Mitchell (703) 308-8061. Address any questions on required generic data to the Special Review and Reregistration Division representative Jane Mitchell, (703) 308-8061.

Sincerely yours,

Lois Rossi, Director
Special Review
and Reregistration Division

Enclosures

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

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

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

PENDIMETHALIN

LIST A

CASE 0187

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

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PENDIMETHALIN REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

James G. Salmon	Biological Analysis Branch
Stephen M. Jarboe	LUIS
Jihad A. Alsadek	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Betsy Grim	Environmental Risk Characterization Branch
Daniel D. Rieder	Environmental Risk Characterization Branch
James Breithaupt	Environmental Risk Characterization Branch
Renee Costello	Environmental Risk Characterization Branch

Health Effects Risk Assessment

Mary Clock	Risk Characterization and Analysis Branch
Richard Griffin	Risk Characterization and Analysis Branch
Marion Copley	Toxicology Branch I
William B. Greear	Toxicology Branch I
John Leahy	Occupational and Residential Exposure Branch
Bonnie Cropp-Kohlligian	Reregistration Support Chemistry Branch

Registration Support Risk Assessment

Larry Fried	Registration Support Branch
Edward Allen	Fungicide-Herbicide Branch

Risk Management

Jane D. Mitchell	Reregistration Branch
Andy Ertman	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., 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.

GLOSSARY OF TERMS AND ABBREVIATIONS

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

ABSTRACT

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide pendimethalin, N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzeneamine. This decision includes a comprehensive reassessment of the required target data base and the use patterns of currently registered products. On August 3, 1996, the President signed the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food, Drug, and Cosmetics Act and the Federal Insecticide, Fungicide and Rodenticide Act. These two Federal statutes provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (RED) signed subsequent to August 3rd are accordingly being evaluated under the new standards imposed by FQPA.

Pendimethalin is a selective herbicide used on various agricultural and non-agricultural sites to control broadleaf weeds and grassy weed species in crop and noncrop areas. It is applied to soil preplant, preemergence, and postemergence, (including layby) with ground and aerial equipment.

In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effect from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider potential for increased susceptibility of infants and children to the toxic effects of pesticide residue. The Agency considered the appropriateness of an additional uncertainty factor, which can be applied in situations where available data indicate infants and children may have an increased sensitivity to the pesticide. In general, the data base for pendimethalin does not indicate a potential for increased toxicological sensitivity from either pre- or post-natal exposures. No developmental toxicity was observed in either the rat or rabbit developmental toxicity studies, nor was there evidence in the two-generation reproduction study of developmental or reproductive toxicity at dose levels below those in which parental toxicity was observed. Therefore, the Agency has determined that an additional uncertainty factor is not warranted.

Regarding aggregate risks, the Agency considered chronic exposure through the diet, including drinking water, and short term exposure through residential uses. The estimated aggregate risks from these exposures do not exceed the Agency's levels of concern. EPA does not have, at this time, available data to determine whether pendimethalin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on common mechanism of toxicity, pendimethalin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pendimethalin has a common mechanism of toxicity with other substances.

The Agency has concluded that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, all products are eligible for reregistration. To mitigate risks of exposure to occupational/residential handlers and children, the Agency is requiring, among other changes, reduction in the maximum application rate for residential and recreation area turf, the use of personal protective equipment, and longer restricted-entry intervals. Additional data for product chemistry, residue chemistry, environmental fate, and occupational/residential exposure are being required to confirm the Agency's risk assessment and conclusions.

Before reregistering the products containing pendimethalin, 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.

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of pendimethalin including the risk to infants and children for any potential dietary, drinking water, dermal or oral exposures, as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes pendimethalin, 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 pendimethalin. Section V discusses the reregistration requirements for pendimethalin. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

!	**Common Name:**	**Pendimethalin**
!	**Chemical Name:**	[n-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine)
!	**Chemical Family:**	**Dinitroaniline**
!	**CAS Registry Number:**	40487-42-1
!	**OPP Chemical Code:**	108501
!	**Empirical Formula:**	$C_{13}H_{19}N_3O_4$
!	**Trade and Other Names:**	Prowl, Squadron
!	**Basic Manufacturer:**	American Cyanamid

B. Use Profile

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

For : Pendimethalin

Type of Pesticide: **Herbicide**

Mode of Action: **A microtubule disruptor**

Use Sites:
Terrestrial food crop: apricot, carrot (including tops), cherry, fig, garbanzos (including chick peas), garlic, nectarine, olive, onion, peach, pear, pecan, pistachio, plum, prune, shallot, walnut (English/black)

Terrestrial food+feed crop: almond, apple, beans, dried-type,beans, succulent (lima), beans, succulent (snap), citrus fruits, corn, field, corn, sweet, cotton,

cowpea/blackeyed pea, garbanzos (including chick peas), grapes, peanuts, peas, potato, (white/Irish), rice, sorghum, soybeans, sugarcane, sunflower

Terrestrial feed crop: alfalfa, lupine, small seeded legumes

Terrestrial non-food crop: Christmas tree plantations, commercial/industrial lawns, golf course turf, industrial areas (outdoor), jojoba, nonagricultural outdoor buildings/structures, ornamental and/or shade trees, ornamental herbaceous plants, ornamental lawns and turf, ornamental nonflowering plants, ornamental sod farm (turf), ornamental woody shrubs and vines, paths/patios, recreation area lawns, tobacco

Terrestrial non-food+outdoor residential: nonagricultural rights-of-way/fencerows/hedgerows, ornamental and/or shade trees, ornamental ground cover, ornamental lawns and turf, ornamental woody shrubs and vines, paved areas (private roads/sidewalks), residential lawns

Aquatic food: rice

Target pests: barnyardgrass; bluegrass, annual; buffalograss; buttonweed; carpetweed; chickweed, common; chickweed, mouseear; clover, hop; corn speedwell; crabgrass; crowfootgrass; cudweed; dodder; eveningprimrose; fiddleneck; field sandbur; filaree; florida pusley; foxtail, giant; foxtail, green; foxtail, yellow; goosegrass; henbit; johnsongrass (seedling); junglerice; knotweed, prostrate; kochia; lambsquarters; london rocket; lovegrass; millet, wild proso; oxalis; panicum, browntop; panicum, fall; panicum, Texas; pigweed; pigweed, redroot; puncturevine; purslane; red rice; shattercane; shepherdspurse; signalgrass; signalgrass, broadleaf; smartweed, pennsylvania; sprangletop; sprangletop, mexican; sprangletop, red; spurge, annual; spurge, prostrate; stinging nettle; swollen fingergrass; velvetleaf; witchgrass; woodsorrel, yellow; wooly cupgrass

Formulation types registered: technical grade active ingredient liquid

Manufacturing product	90.0%
Liquid	60.0%
Solid	86.8%
End use product	
Emulsifiable concentrate	21.9 to 42.3%
Liquid	34.4%
Granular	0.7 to 2.0%
Soluble concentrate/liquid	22.0%
Water dispersible granules (Dry flowable)	Up to 60.0%
Wettable powder	50.0%

Methods and Rates - **(Please refer to LUIS Report Appendix A.)**

Types of treatment

Broadcast; chemigation; Conservation tillage; Containerized plant treatment; Directed spray; Soil incorporated treatment; Soil treatment; Spray

Equipment - Aircraft; Backpack sprayer; Boom sprayer;Center pivot irrigation; Hand move irrigation;Low pressure ground sprayer; Low pressure hand wand; Low volume sprayer; Moving wheel irrigation; Solid set irrigation; Sprayer; Spreader.

Timing -Bulbs; Dormant; Early fall; Early postemergence; Early preplant; Fall; Foliar; Late fall; Late summer; Layby; Nonbearing; Nurserystock; Postemergence; Postplant; Posttransplant; Preemergence; Preplant; Ratoon; Seed bed; Spring; Summer; When needed.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of **pendimethalin**. 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.

The table below summarizes the pesticide use by site.

Quantitative Usage Analysis for Pendimethalin[1]
(March 1997)

Application Crop/Site No/Year	Acres Grown (000)	% Acres Treated Average	% Acres Treated Maximum Likely	Acres Treated Average (000)	Acres Treated Maximum Likely (000)	Lbs AI Average (000)	Lbs AI Maximum Likely (000)	Rate (Lbs AI)
Agriculture --								
Alfalfa 1.3	24,276	0.3	0.5	72.8	121.4	150	250	1.6
Almonds 1.0	390	1.0	2.0	3.9	7.8	6	13	1.5
Apples 1.3	503	0.1	0.6	0.5	3.0	1	2	1.5
Beans/Peas (Green) 1.0	690	6.8	8.0	47.2	55.4	45	65	1.0
Beans/Peas (dry) 1.0	2,052	3.7	4.7	75.9	96.6	66	70	0.9
Citrus, Others[2] 1.3 1.0	70	0.3	1.4	0.2	1.0	0.25	3	
Cole crops 1.0	283	0.7	2.5	2.0	7.1	1.6	7	0.8
Corn 1.0	78,156	4.7	5.0	3,700.0	3,900.0	4,000	4,900	1.1
Cotton 1.1	11,121	35.0	50.0	3,900.0	5,550.0	3,000	3,800	0.7
Cucurbits 1.1	233	0.9	1.7	2.1	4.0	2.8	5	1.2
Garlic 1.0	25	60.0	70.0	15.0	17.5	15	16	1.0
Grapefruit 1.3	176	2.0	3.5	3.5	6.2	6.6	15	1.5
Grapevines 1.0	817	0.6	1.2	4.9	9.8	5	10	1.0
Idle crop land 1.0	7,395	0.1	0.2	7.4	14.8	6	15	0.8
Melons, All 1.5	383	3.1	7.6	11.7	29.2	10	30	0.6
Mint 1.5	154	12.0	15.0	18.5	23.1	40	45	1.4
Onions 1.9	152	25.0	35.0	38.0	53.2	100	130	1.4
Oranges 1.0	571	0.8	1.2	4.6	6.9	6	9	1.3
Peaches	186	0.4	1.1	0.7	2.0	0.6	2	0.9

1.0								
Peanuts	1,651	35.0	40.0	577.9	660.4	550	650	0.9
1.1								
Potatoes	1,326	18.0	24.0	238.7	318.2	235	275	1.0
1.0								
Rice	3,130	9.0	13.0	281.7	406.9	300	350	1.0
1.1								
Sorghum	12,183	0.2	0.7	24.4	85.3	23	39	0.9
1.0								
Soybeans	58,414	26.0	30.0	15,200.0	17,525.0	13,700	15,000	0.9
1.0								
Sugarcane	857	29.2	40.1	250.0	350.0	350	575	1.4
1.0								
Sunflowers	2,044	19.0	21.0	388.4	429.2	400	500	1.0
1.0								
Sweet corn	761	6.0	8.0	45.7	60.9	42	67	0.9
1.0								
Tobacco	785	43.0	55.0	337.6	431.8	300	395	0.9
1.0								
Vegetables, Other[3]	110	0.9	5.0	1.0	5.0	1.0	7	
1.3 1.0								
Walnuts	184	0.3	1.1	0.6	2.0	1	3	1.7
1.0								
Turf Farms[4]	225					37	45	
Horticulture[4]	430					34	40	
TOTAL AGRICULTURE (LBS. A.I.)						23,436	27,333	
Non-Agriculture[4]--								
Golf Courses	1,550					263	335	
Lawn	33,000					1,886	2400	
Landscape	19,000					108	130	
TOTAL (LBS. A.I.)						25,692	30,198	

Note:

1. The estimates might not exactly correspond because of rounding.

The table shows that the average annual domestic pendimethalin usage on the different agricultural crops ranges from 23 to 27 million pounds of active ingredient. Between 2 and 3 million pounds of this chemical are used on non-agricultural sites (84 percent on lawns). The highest usage sites for this herbicide are soybeans, corn, cotton, peanuts, sunflower, sugarcane, rice, tobacco, and potatoes.

2. Citrus other includes tangelos, tangerine, kumquats and limes.

3. Vegetables other includes artichoke, asparagus, okra, oriental vegetables, and rhubarb.

4. Percentage crop treated, application rates and number of applications are not available for turf, horticulture, and non-agricultural sites.

Pears, seed crops, tomatoes, and wheat (spring and winter) are covered by the data, but they show one percent or less of the acres treated with pendimethalin.

Reference: Pesticide usage estimates, different USDA and EPA data sources including foreign usage

data.

D. Data Requirements

Data requested in the March 1985 Registration Standard for pendimethalin include studies on **product chemistry, ecological effects, environmental fate, and residue chemistry.** These data were required to support the uses listed in the Registration Standard. A Data Call-In Notice was issued October 1990 requiring additional data on product chemistry, residue chemistry, toxicology, ecological effects and environmental fate. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Pendimethalin was patented by American Cyanamid in 1972 and first registered in the United States in 1974. Pendimethalin is a dinitroaniline herbicide which selectively controls certain broadleaf weeds and grassy weed species in certain crop and noncrop areas. It is applied to soil preplant, preemergence, and postemergence, (including layby) with ground and aerial equipment. A Registration Standard was issued in March 1985. Additional data were required in a Data Call-In Notice issued in October 1990. This Reregistration Eligibility Decision Document reflects a reassessment of all data which were submitted in response to the Registration Standard and the subsequent Data Call-In Notice.

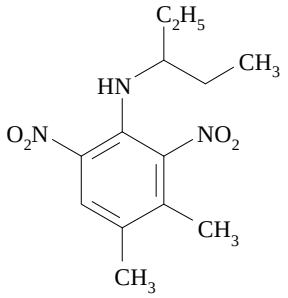
III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

All pertinent data requirements are satisfied for the 90% Technical (T) and the pendimethalin TGAI; however, additional product-specific data (physical/chemical properties) are outstanding for the 86.8% and 60% Formulating Intermediaries (FIs). The registrant must submit the data required in the attached data summary tables for the 86.8% and the 60% FIs, and either certify that the suppliers of beginning materials and the manufacturing processes for the pendimethalin technical product and manufacturing products (MPs) have not changed since the last comprehensive product chemistry review or submits complete updated product chemistry data packages.

1. Description of Chemical

Pendimethalin [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] is a selective herbicide registered for control of broadleaf weeds and grassy weed species.



Empirical Formula:	$C_{13}H_{19}N_3O_4$
Molecular Weight:	281.3
CAS Registry No.:	40487-42-1
Chemical Code:	108501

2. Identification of Active Ingredient

Pendimethalin is an orange-yellow crystalline solid with a melting point of 54-58° C. It is soluble in chlorinated hydrocarbons and aromatic solvents such as methylene chloride, acetone, and xylene, but only soluble in water at <0.5 ppm at 20° C. Pendimethalin is stable under acidic and alkaline conditions.

3. Manufacturing-Use Products

There are three pendimethalin manufacturing-use products (MPs) registered to American Cyanamid Company under Chemical Code 108501: the 90% technical (T);(EPA Reg. No. 241-245), and the 86.8% and 60% formulation intermediates (FIs); (EPA Reg. Nos. 241-291 and 241-281), respectively.

4. Regulatory Background

The Pendimethalin Reregistration Standard dated 7/20/84 and Guidance Document dated 3/85 required additional data for the American Cyanamid 90% T. The Pendimethalin Reregistration Standard Update review dated 3/19/90 required additional data concerning Guidelines 62-2 and 62-3 for the 90% T.

In addition, because pendimethalin contains dinitroanilines, a discussion of the potential for formation of nitrosamines and analysis of the 90% T for the presence of nitrosamines formed during manufacture and storage of the product was required. Submitted data indicate that no volatile nitrosamines are present (<0.5 ppm) and that total nonvolatile nitrosamines are present at less than 100 ppm.

Refer to the Generic Data Call-In Notice for the outstanding product chemistry data requirements for the 90% technical, the 86.8% and 60% formulation intermediates.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base is adequate and will support reregistration eligibility. There are no data gaps at this time.

a. Acute Toxicity

The table below summarizes the results of acute toxicity studies on pendimethalin and the toxicity categories for the different routes of administration:

Table 1. Acute Toxicity Values of Technical Pendimethalin

TEST	RESULT	CATEGORY
Oral LD_{50} in rat (MRID 00026657)	LD_{50}(M) = 1250 mg/kg LD_{50}(F) = 1050 mg/kg	III
Dermal LD_{50} in rabbit (MRID 00026657)	LD_{50} > 5000 mg/kg	IV
Inhalation LC_{50} in rat (MRID 00073342)	LC_{50} > 320 mg/L (nominal concentration)	IV
Eye irritation in rabbit (MRID 00026657)	Slight conjunctival irritation	III
Dermal irritation in rabbit (MRID 00026657)	No irritation	IV
Dermal sensitization (MRID 00153767)	Nonsensitizing	N/A

b. Subchronic Toxicity

Feeding Studies in Rats: In a 30-day feeding study in rats (MRID 000106754), pendimethalin technical (98.7%) was administered to groups of 10 males and 10 females RH Wistar rats in the diet at levels of 0, 800, 1,600 or 3,200 ppm (corresponding to 0, 80, 160, or 320 mg/kg/day). Urine was darker than controls in the 1,600 and 3,200 ppm groups. At 3,200 ppm there appeared to be increased liver weight. **The LOEL is 3,200 ppm (320 mg/kg/day) based on increased liver weight. The**

NOEL is 1,600 ppm (160 mg/kg/day). Although this study is classified as Supplementary it provides useful information.

In a 13-week feeding study in rats (MRID 00156081), AC 92,553 (pendimethalin, 92.1%, Lot #AC3528-129-1) was administered to groups of 30 male and 30 female Charles River CD(SD)BR rats in the diet at levels of 0, 100, 500, or 5,000 ppm (corresponding to 0, 10, 50, or 500 mg/kg/day). At 5,000 ppm, rats displayed a dark yellow discoloration of the urine and yellow discoloration of abdominal fat. Body weight gain and food consumption were decreased. The hematocrit and hemoglobin levels were decreased and the number of platelets slightly increased in males. There was an increase in pale or mottled livers in males and dark red thyroids in both sexes at 5,000 ppm. The absolute weight of the liver was increased in males and females. Diffuse hypertrophy of the liver was also observed. **The LOEL is 5,000 ppm (500 mg/kg/day) based on decreased body weight gain and food consumption, decreased hematocrit and hemoglobin with an increase in platelets in males, red thyroids, increased liver weight, and hypertrophy of the liver. The NOEL is 500 ppm (50 mg/kg/day).**

In a second 13-week feeding study in rats (MRID 00059468), AC 92,553 technical (pendimethalin) was administered to groups of 25 male Long-Evans rats in the diet at levels of 0, 25, 50, 100, 500, or 2,500 ppm (corresponding to 0, 2.5, 5.0, 10.0, 50.0, or 250 mg/kg/day). The 2,500 ppm group was raised to 5,000 ppm (500 mg/kg/day) from week 8-13. There were no adverse effects noted with respect to mortality, body weight and gross and microscopic examination of mammary glands. **The LOEL was not determined. The NOEL was greater than 2,500 ppm (250 mg/kg/day).** Although this study is classified as Supplementary it provides useful information.

In a third 13-week study in rats (MRID 00059469), AC 92,553 technical pendimethalin was administered to Sprague-Dawley rats in the diet at 0 or 2,500 ppm (corresponding to 0 or 250 mg/kg/day). There were no adverse effects noted with respect to mortality, body weight and gross and microscopic examination of the mammary gland. **The LOEL was not determined. The NOEL was greater than 2,500 ppm (250 mg/kg/day).** Although this study is classified as Supplementary it provides useful information.

In a special 92-day thyroid function feeding study (MRID 42054601), AC 92,553 (pendimethalin, 92.6%, Lot #AC5213-72A) was administered to groups of 80 male CD[Crl:CD(SD)] rats at dose levels of

0, 100, or 5,000 ppm (corresponding to 0, 4.98, or 245.4 mg/kg/day) for 92 days. Groups of 20 male rats were sacrificed at 15, 29, 57 and 92 days. At 100 ppm there was decreased total T_4, rT_3, total free T_4 and increased percent T_3, increased follicular cell height and decreased area occupied by colloid. At 5,000 ppm there were decreased body weight and food consumption compared to controls, increased thyroid weight, decreased total T_4, total T_3, rT_3, total free T_4 and [^{125}I]-T_4 to transthyretin bonding, increased percent free T_4, percent free T_3 and [^{125}I]-T_4 to albumin binding, increased follicular cell height and decreased area occupied by colloid and ultrastructural thyroid changes. Most parameters were reversible after treatment subsided except for decreased body weight. **The NOEL was establised at 100 ppm (4.98 mg/kg/day). The LOEL was determined to be 5000 ppm.**

In a special 56-day feeding study (28-day treatment, 28-day recovery) to determine thyroid function (MRID 43135001), groups of 65-70 (5-15 per sacrifice time) male Crl:CD(SD) rats were treated at dose levels of 0, 500 or 5000 ppm (0, 31 or 292 mg/kg/day) of AC 92,553 (pendimethalin, 92.6%, Lot #AC5213-72A) in the diet for 28 days. A recovery period of up to 28 days was employed. Animals were sacrificed at many timepoints during the study beginning as early as day 3. There were no deaths or clinical signs of toxicity during or after the treatment period at either dose. At 500 ppm there was decreased total T_4 (38%), rT_3 (25%) and total free T_4 (28%) and increased percent free T_3 (13%), increased follicular cell height (40%) and decreased area occupied by colloid (51%) during treatment. At 5000 ppm, body weight (8%), body weight gain (29%) and food consumption (15%) were decreased compared to controls during the treatment period. Thyroid changes during treatment with 5000 ppm included: increased absolute (15%) and relative (23%) thyroid weight; decreased total T_4 (74%), total T_3 (25%), rT_3 (36%), total free T_4 (40%), and [^{125}I]-T_4 to transthyretrin binding; increased percent free T_4 (117%), percent free T_3 (26%) and [^{125}I]-T_4 to albumin binding; increased follicular cell height (75%) and decreased area occupied by colloid (45%); ultrastructural thyroid changes were consistent with mild to moderate TSH stimulation except for the accumulation of dense-bodies in the cytoplasm which may be reaction products of AC 92,553. Many of these effects were observed as early as day 3. Most parameters were reversible post treatment except for a slight decreased body weight compared to controls (7%) at 5000 ppm. There were no changes in TSH, total free T_3 or diameter of follicular cells. **The LOEL was 500 ppm (31 mg/kg/day) based on thyroid effects. The NOEL could not be determined.**

In a special 14-day feeding study to determine thyroid function (MRID 43135003), AC 92,553 (pendimethalin, 92.6%, Lot #AC5213-72A) was administered in the diet to groups of 10 male Crl:CD(SD) rats at dose levels of 0, 100 or 5,000 ppm (corresponding to 0, 10 or 500 mg/kg/day). At 5000 ppm AC 92, 533 for 14 days, TSH was increased and T_4 and T_3 were decreased. No treatment related effects were observed for rT_3 levels, thyroid weight, ^{131}I uptake in MIT, DIT or T_4. There was a significant increase of ^{131}I uptake by the thyroid of rats in the 5000 ppm group and an increase in incorporation of ^{131}I in T_3. Total T_3 and T_4 levels in the thyroid were not affected by treatment at 5,000 ppm. **The LOEL is 5,000 ppm (500 mg/kg/day) based on thyroid effects. The NOEL is 100 ppm (10 mg/kg/day)**.

In a second special 14-day feeding study to determine biliary excretion and hepatic metabolism, AC 92,553 (pendimethalin, 92.98%, Lot #AC6539-77A) was administered to groups of 10 male Crl:CD(SD) rats at dose levels of 0, 100, or 5,000 ppm (corresponding to 0, 10, or 500 mg/kg/day). Ingestion of 5,000 ppm produced decreases in serum T_3 and T_4 with a compensatory increase in TSH. Also increased were liver weight, bile flow and cumulative biliary excretion of ^{125} I-T_4 with a slight increase in T_4-glucuronytransferase activity detected by generation of ^{125} I-T_4 glucuronide from ^{125} I-T_4 <u>in vitro</u> by hepatic microsomes. The increase in enzyme activity was also demonstrated <u>in vivo</u> by a significant increase in biliary excretion of ^{125} I-T_4-glucuronide. **The LOEL is 5,000 ppm (500 mg/kg/day) based on thyroid effects. The NOEL is 100 ppm (10 mg/kg/day).**

<u>Feeding Studies in Dogs:</u> In a 90-day feeding study (MRID 00026672), pendimethalin was administered to groups of 8 dogs at dose levels of 0, 62.5, 250 or 1,000 mg/kg/day. Body weight loss was apparent at 250 and 1,000 mg/kg/day. **The LOEL is 250 mg/kg/day based on body weight loss. The NOEL is 62.5 mg/kg/day.** Although this study is classified as Supplementary it provides useful information.

In a 30-day feeding study in dogs (MRID 000106754) AC 92,553 technical (pendimethalin, 98.7%) was administered to groups of 2 male and 2 female beagles in the diet at dose levels of 0, 0.625% or 1.25% (corresponding to 0, 125 or 250 mg/kg/day). A third test group received 5% in the diet (corresponding to 1,000 mg/kg/day) for 30 days. The protocol was changed so that dogs received the compound by gelatin capsule from days 17 to 30. Food consumption and body weight were decreased in all treated groups compared to controls. **The LOEL was 125 mg/kg/day based on decreases in body weight and food consumption.**

The NOEL could not be determined. Although this study is classified as Supplementary it provides useful information.

Feeding Study in Mice: In a 30-day feeding study in mice (MRID 000106754), pendimethalin technical (98.7%) was administered to groups of 10 male and 10 female CF-1 mice in the diet at levels of 0, 500, 1,000 or 2,000 ppm (corresponding to 0, 75, 150 or 300 mg/kg/day). There were no adverse effects with respect to mortality, body weight, food consumption and organ weight. **The LOEL was not determined. The NOEL is greater than 2,000 ppm (300 mg/kg/day).** Although this study is classified as Supplementary it provides useful information.

Dermal Study in Rabbits: In a 21-day dermal toxicity study (MRID 00026663), AC 92,553 (pendimethalin) was dermally applied to the back of 3 or 4 New Zealand white rabbits/group at dose levels of 0, 250, 500 or 1000 mg/kg/day. There were no adverse effects with respect to mortality, food and water intake, hematology, urinalysis and gross and microscopic pathology. **The systemic LOEL was not determined. The systemic NOEL is greater than 1000 mg/kg/day.**

c. Chronic Toxicity/Carcinogenicity

Feeding Studies in Rats: In a 2-year study in rats (MRID 40174401), AC 92,533 (pendimethalin, 91.9%, Lot #AC3528-129-1), was administered to groups of 55 male and 55 female Crl:CD(SD)BR rats in the diet at levels of 0, 100, 500 or 5,000 ppm (corresponding to 0, 5, 25, or 250 mg/kg/day). Ten rats/sex/group were interim sacrificed at 12 months. At 5,000 ppm, survival in males was slightly decreased and body weight gain was decreased. There was decreased food consumption, increased gamma glutamyl transferase and cholesterol, increase in liver weight and/or liver body and/or brain weight ratios, generalized icterus, dark adipose tissue in females, diffusely dark thyroids, follicular cell hyperplasia of the thyroid. At 500 ppm there was pigmentation of thyroid follicular cells in males and females. **The LOEL is 5000 ppm (250 mg/kg/day) based on decreased survival, body weight gain and food consumption, increased gamma glutamyl transferase and cholesterol, increase in absolute and/or relative liver weight, generalized icterus, dark adipose tissue in females, diffusely dark thyroids and follicular cell hyperplasia of the thyroid. The NOEL is 500 ppm (25 mg/kg/day). There are thyroid follicular cell adenomas at 5000 ppm (250 mg/kg/day).**

In a second 2-year feeding study in rats (MRID 42027802), AC 92,533 (pendimethalin, 92.6%, Lot #AC5213-72A) was administered to

groups of 125 male Sprague-Dawley (Crl:CD(SD)BR) at dose levels of 0, 1250, 2500, 3750, or 5000 ppm (corresponding to 0, 51, 103, 154, and 213 mg/kg/day). Fifteen rats/group were interim sacrificed at 1, 13, 26, 39 and 52 days. There was decreased colloid and increased cysts of the thyroid follicular cells and an increase in liver weight at 1250 ppm and above. At 2500 ppm and above there was increased pigment and hypertrophy of follicular cells, increased thyroid weight and an increase in eosinophilic and basophilic foci of cellular alteration, hepatocellular enlargement and hepatocellular intracytoplasmic inclusions. There was a decrease in body weight gain at 3750 ppm and above and hyperplasia of follicular cells. At 5000 ppm GGT and total cholesterol were increased and there was an increase in thyroid follicular adenomas. **The LOEL is less than or equal to 1250 ppm (≤51 mg/kg/day) based on non-neoplastic thyroid follicular cell changes and increased liver weight. The NOEL was not determined.**

Feeding Study in Mice: In an 18-month feeding study in mice (MRID 40909901), AC 92,533 (pendimethalin, 92.6%, Lot #AC5218-72A) was administered to groups of 65 male and 65 female Charles River CD-1 mice at dose levels of 100, 500, or 5,000 ppm (corresponding to 12.3, 62.3 and 622.1 mg/kg/day in males and 15.6, 78.3 and 806.9 mg/kg/day in females). There were 2 control groups consisting of 65 mice/sex each. Ten mice/sex were sacrificed at 12 months in one control and all treated groups. (One control group only consisted of 55 mice/sex.) At 5,000 ppm there was increased mortality in females, decreased body weight in females, increased absolute thyroid, liver and gall bladder weights and/or relative body and brain weight ratios in males and females and amyloidosis in males. **The LOEL is 5,000 ppm (622.1 mg/kg/day [M]; 806.99 mg/kg/day [F]) based on mortality, body weight decrease, organ weight changes and amyloidosis. The NOEL is 500 ppm (62.3 mg/kg/day [M]; 78.3 mg/kg/day [F]).**

Oral Study in Dogs: In a 2-year oral study in dogs (MRID 00058657, 44106801), AC 92,533 (pendimethalin, 91.4%, Lot #77-02) was administered via capsule to groups of 4/sex beagle dogs at dose levels of 0, 12.5, 50 or 200 mg/kg/day. In addition to routine histopathology, special stains were used on liver slides, including the Gomori's and Hall's method to evaluate lesions observed in this organ. Slight pigment accumulation (probably chemical) in hepatocytes is observed in the 50 and 200 mg/kg/day doses and is considered of no toxicologic concern. **The NOEL is ≥200 mg/kg/day with no LOEL established.**

d. Developmental Toxicity

Oral Study in Rats: Pendimethalin (94.2% a.i.) was administered in corn oil to groups of 30 mated Sprague-Dawley CD strain rats by gavage at daily dose levels of 0, 125, 250, or 500 mg/kg/day from gestation day 6 through 15 (MRID 00025752). Females were observed for signs of toxicity, and body weights were measured during gestation. Animals were sacrificed on gestation day 21 and reproductive observations were made and uteri were examined for live fetuses and intra-uterine deaths. Fetuses were weighed, sexed, and examined for external, visceral and skeletal alterations. There were no maternal or developmental effects noted at any dose level tested, and based on these results, the **NOELs for developmental and maternal toxicity are 500 mg/kg/day (highest dose tested).** Although this study is classified as Supplementary, when considered in conjunction with the rabbit developmental toxicity study (MRID 00117444) it will satisfy guideline requirement 83-3. It is not upgradable because an adequate dose range may not have been tested.

Oral Study in Rabbits: Pendimethalin was administered in corn oil to groups of 20 artificially inseminated New Zealand White strain rabbits by gavage at dose levels of 0, 15, 30, or 60 mg/kg/day from gestation day 6 through 18 (MRID 00117444, 44106803, 44106804). Females were observed for signs of toxicity, and body weights were measured during gestation. Animals were sacrificed on gestation day 29 and reproductive observations were made and uteri were examined for live fetuses and intra-uterine deaths. Fetuses were weighed, sexed, and examined for external, visceral and skeletal alterations. No maternal toxicity was reported at doses 60 mg/kg/day (highest dose tested). However, the range-finding study indicated that doses 125 mg/kg/day were associated with increased mortality (3/5, 5/5 and 4/5 in the 125, 250, and 500 mg/kg/day groups, respectively compared with 0/5 in the control group). **The maternal LOEL is greater than 60 mg/kg/day and the maternal NOEL is equal to or greater than 60 mg/kg/day.** There was no increase in developmental effects at any dose. **The developmental LOEL is greater than 60 mg/kg/day and the developmental NOEL is equal to or greater than 60 mg/kg/day.** This study is acceptable and satisfies the guideline 83-3 requirements for a rabbit developmental toxicity study. Although there is no evidence of maternal or developmental toxicity at any dose in the main study, there was maternal mortality at 125 mg/kg/day (about twice the high dose) in a range-finding study.

e. Reproductive Toxicity

Feeding Studies in Rats: In a 2-generation reproduction study (MRID 417252203), AC 92,533 (pendimethalin, 92.6%, Lot #AC5213-

72A) was administered to groups of 25 male and 25 female Sprague-Dawley derived OFA-SD (IOPS-CAW) rats at dose levels of 0, 500, 2500 or 5000 ppm (corresponding to 0, 34, 172 and 346 mg/kg/day) in males and 0, 43, 216, 436 mg/kg/day in females). There were no clinical signs or changes in organ weight data. There was a minimal (5%) decrease in body weight gain and food consumption (possibly due to palatability) at 2500 ppm. At 5000 ppm the decrease in body weight gain was as high as 20 %. Although there were decreases in food consumption and body weight, food efficiency data are required to support a conclusion regarding palatability/parental systemic toxicity. **The parental NOEL could not be definitely determined.** There were decreased pup weights during much of lactation at 5000 ppm. **The LOEL for reproductive effects is 5000 ppm (346 and 436 mg/kg/day in males and females, respectively). The NOEL for reproductive effects is 2500 ppm (172 and 216 mg/kg/day, in males and females, respectively).**

In a 3-generation reproduction study (MRIDs 00026671, 00040304, 00059470) AC 92,533 technical (pendimethalin) was administered to groups of 10 male and 20 female Long-Evans rats at dose levels of 0, 500 or 5000 ppm (corresponding to 0, 25 and 250 mg/kg/day). At 5000 ppm there was a decrease in body weights in male and female parental animals. **The LOEL for parental toxicity is 5000 ppm (250 mg/kg/day) based on decreased body weights. The NOEL for parental toxicity is 500 ppm (25 mg/kg/day).** Pup body weight gain was decreased during lactation. There were possible decreases in pups born alive and pup survival. **The LOEL for reproductive toxicity is 5000 ppm (250 mg/kg/day) based on pup body weight gain and possible decreased pups born alive and pup survival . The NOEL for reproductive toxicity is 500 ppm (25 mg/kg/day).**

f. Mutagenicity

There are acceptable studies to satisfy the initial mutagenicity testing requirements for all three categories (gene mutations, structural chromosomal aberrations, and other genotoxic effects). The Carcinogenicity Peer Review Committee concluded that pendimethalin was not mutagenic in mammalian somatic cells and germ cells. No other mutagenicity studies are required at this time.

In a reverse gene mutation assay in bacteria (MRID 00153768), strains (TA1535, TA1537, TA1538, TA98, TA100) of S. typhimurium were exposed to AC 92,533 (pendimethalin, 92.2%, Lot #AC3528-129-1) at concentrations of 50, 158, 500, 1581 or 5000 μg/plate in the presence

and absence of mammalian hamster S9. Subsequent tests with TA98, TA1538 and TA100 used dose levels of 250, 500, 1000, 3000 or 5000 μg/plate. AC 92,533 was tested up to the limit dose of 5000 μg/plate. A precipitate was formed at 5000 μg/plate. The positive controls did induce the appropriate responses in the corresponding strains. **This study was considered positive since there was evidence of a 2-fold dose-related increase in the number of induced mutant colonies over background at all doses from 50 to 5000 μg/plate.**

In a *Salmonella*/microsome plate incorporation assay and in an *Escherichia coli* WP2(uvrA) reverse mutation assay (MRID 43177801), strains TA98, TA100, TA1535, TA1537, TA1538 and WP2(uvrA) were exposed to pendimethalin at concentrations of 25, 50, 100 250, 500 and 750 μg/plate, with and without exogenous metabolic activation. Preparations for metabolic activation S9 were made from Aroclor 1254 induced male Sprague-Dawley rat livers. The test material was delivered in DMSO. No cytotoxicity was seen at any concentration of pendimethalin tested. The upper concentration was limited by test material solubility (a precipitate was observed at concentrations of 750 μg/plate and above). Positive and vehicle control values were appropriate. **There was no evidence of an increase number of mutant colonies over solvent control values at any concentration of pendimethalin tested, either with or without S9 mix.**

In a *Salmonella*/microsome plate incorporation and disk assay and in an *Escherichia coli* WP2(uvrA) reserve mutation assay (MRID 43135005), strains TA98, TA100, TA1535, TA1537, and WP2(uvrA) were exposed to pendimethalin (90.7% , Lot #AC8088-149) at 50, 158, 500, 1581 and 5000 μg/plate or 1000 μg/paper disk/plate, with and without exogenous metabolic activation. Preparations for metabolic activation were made from Aroclor 1254 induced male rat livers. The test material was delivered in Dimethylsulfoxide (DMSO). Cytogenetic determinations were not made or discussed in this study. The highest concentration was limited by solubility (a precipitate was seen at 1581 and 5000 μg/plate). Positive and vehicle controls were appropriate. **There was no evidence of induced mutant colonies over background vehicle control values at any concentration of pendimethalin tested in any strain with or without S9 mix.**

In a *Salmonella*/microsome plate incorporation and disk assay and in an *Escherichia coli* WP2(uvrA) reverse mutation assay (MRID 43135006), strains TA98, TA100, TA1535, TA1537, TA1538, and WP2(uvrA) were exposed to pendimethalin (99.5%, Lot #AC5042-52F) at

concentrations of 50, 100, 250, 500, and 750 μg/plate without exogenous metabolic activation and to the same concentrations plus an additional concentration of 25 μg/plate with exogenous metabolic activation. A confirmatory assay tested concentrations of 25, 50, 100, 250, 500 and 750 μg/plate both with and without S9 mix. Preparations for metabolic activation were made from Aroclor 1254 induced male rat livers. The test material was delivered in DMSO. No cytogenicity was seen at any concentration tested up to 5000 μg/plate. The upper concentration tested was limited by solubility of the test material. Positive and vehicle control values were appropriate. **No evidence of a mutagenic response was seen at any dose in any strain with or without S9 mix in either assay.**

In a forward mutation study (MRID 43177802) at the HGPRT locus in Chinese hamster ovary CHO-K1-BH4 cells in culture, cells were exposed to pendimethalin (90.9%, Lot #AC5042-37D) at concentrations of 1, 5, 7.5, 10, 20, 30, 40, and 50 μg/ml in the absence of an exogenous metabolic activation system and to 10, 25, 50, 75, 100, 125, 150, and 175 μg/ml in the presence of an exogenous metabolic activation system (S9-mix). Preparations for metabolic activation were made from Aroclor 1254 induced male Sprague-Dawley rat liver. The test material was delivered in DMSO. Cytotoxicity was unacceptably high at 30, 40 and 50 μg/ml in the absence of S9 mix and at 125, 150, and 175 μg/ml with S9 mix; therefore, mutagenicity was not evaluated at these concentrations. A yellow precipitate was seen at concentrations ≥50 μg/ml. Positive, negative, and vehicle control values were appropriate. **There was no evidence of induced mutant colonies over background either with or without S9 mix at any concentration evaluated in this study.**

In a chromosomal aberration study (MRID 00153770), Chinese hamster ovary (CHO) cells were exposed to AC 92,533 (pendimethalin, 92.2%, Lot #AC3528-129-1) at dose levels ranging from 5 to 25 μg/plate with or without rat liver S9 and at 12.5 to 100 μg/ml with rat liver S9. **There was no induction of chromosomal aberrations in CHO cells at dose levels of up to 25 μg/plate without S9 and up to 100 μg/ml with S9.**

In a mouse micronucleus study (MRID 42027801), AC 92,533 (pendimethalin, 92.98%, Lot #AC6539-77A) was administered to 5 male and 5 female ICR mice by gavage at dose levels of 313,625 or 1250 mg/kg. Administration of AC 92,533 did not cause a significant increase in the frequency of micronucleated polychromatic erythrocytes (MPEs) in bone marrow cells harvested 24, 48, or 72 hours posttreatment. Deaths and other signs of compound toxicity were seen in high-dose males and

females. Although there was no evidence of a cytotoxic effect on the target organ (bone marrow cells), the findings of overt toxicity at 1250 mg/kg (80% of the LD_{50}) clearly indicated that the maximum tolerated dose was achieved. Therefore, **AC 92,533 was adequately tested and found to be nonclastogenic in the mouse micronucleus assay.**

In an alkaline elution assay (MRID 43135007), three rats per dose per sacrifice time were given single intraperitoneal doses of pendimethalin (90.7%, Lot #AC8088-149) at 1250, 2500 or 5000 mg/kg/body weight. (The alkaline elution assay detects DNA single strand breaks and DNA/DNA and DNA/protein crosslinks). The test compound was delivered in corn oil. Testicular cells were harvested 2, 6 and 24 hours after treatment. At the 6 hr sacrifice time, all rats receiving 2500 or 5000 mg/kg were lethargic while those receiving 1250 mg/kg appeared normal. At 24 hr, rats receiving 5000 mg/kg appeared lethargic and ungroomed with dehydrated intestinal tissue while all other rats at lower doses appeared normal. No testicular cell cytotoxicity as measured by trypan blue exclusion was evident at any test material dost or sacrifice time. All positive and vehicle control rats appeared normal at all sacrifice times and no testicular cytotoxicity was seen. **There was no evidence of DNA single strand break induction or DNA/DNA or DNA/protein crosslink formation at any dose or sacrifice time.**

g. Metabolism

In a metabolism study (MRID 00046275), when [^{14}C]pendimethalin was administered to rats, about 70% of the radioactivity was excreted in the feces and 20% in the urine within 24 hours. The excretion of radioactivity in the urine peaked at 6 to 12 hours wherein 11.2% of the dose was excreted. The maximum residual radioactivity in the tissues was found in the 6-hour samples (except for fat at 12 hours). The levels of radioactivity detected in liver, kidney, muscle, fat, and blood at 6 hours were 29.8, 16.9, 1.3, 12.2, and 5.4 ppm, respectively. Within 96 hours, the radioactivity found in the tissues was 0.3 ppm or less, except for fat which was 0.9 ppm. The major portion of the radioactivity that was excreted in the feces was identified as the parent compound. Pendimethalin is metabolized in rats mainly through oxidation of the 4-methyl group attached to the benzene ring as well as oxidation of the alkyl side chain of the N-substituted dinitroaniline compound.

h. Toxicological Endpoints of Concern Used in Risk Assessment

The Health Effects Division's Reference Dose (RfD), Cancer Peer Review (CPR), and Toxicological Endpoint Selection (TES) Committees have evaluated the toxicity data available for pendimethalin and have identified the following endpoints for risk assessment.

Reference Dose: The HED RfD Committee met on 11/20/95 and 1/5/96 to discuss and evaluate the toxicology data submitted in support of pendimethalin reregistration and to reassess the Reference Dose. At that time (RfD memo final 2/6/96) the Committee recommended that the RfD for pendimethalin be established based on the chronic toxicity study in dogs with a NOEL of 12.5 mg/kg/day. At the next higher dose level (50 mg/kg/day), increase in serum alkaline phosphatase and liver weight and other hepatic lesions were observed. An Uncertainty Factor of 100 was applied to account for both interspecies extrapolation and intraspecies variability and the RfD was calculated to be 0.13 mg/kg/day.

On 7/25/96, the Committee met again (RfD memo final 8/5/96) to consider pendimethalin. At this time, the Committee changed the NOEL of the chronic toxicity study in the rat (MRID 40174401) from 5 to 25 mg/kg/day and the NOEL of the chronic oral toxicity study in the dog (MRID 00058657) was changed from 12.5 mg/kg/day to 200 (the highest dose tested) based on new data submitted by the registrant.

At the 7/25/96 meeting, the Committee also agreed that a new

Reference Dose be established based on the results of the subchronic thyroid special studies. The special studies were considered the most appropriate because they addressed the critical endpoint (hormonal/histologic) not addressed in the chronic rat study.

The results of the following rat studies (summarized under Toxicology Assessment above) were combined to establish the Reference Dose: (1) subchronic oral 92-day thyroid function study (MRID 420554601), (2) subchronic oral 56-day thyroid function study (MRID 43135001), and (3) 14-day intrathyroidal metabolism study (MRID 4313503).

Choice of NOEL: Subchronic exposure to pendimethalin for 28 days (56-day study) resulted in an LOEL at the lowest dose tested of 500 ppm (31 mg/kg/day) based on several hormonal and histologic thyroid changes observed throughout the 28 day treatment period. TSH and organ weights showed no overt changes at this dose. The NOEL in the 92-day study is 100 ppm (4.98 mg/kg/day) while the 5000 ppm group exhibited thyroid hormonal, histologic, and organ weight changes. The NOEL in the 14-day intrathyroidal study was 100 ppm (10 mg/kg/day) with thyroid hormonal, histologic and organ weight changes also observed at 5000 ppm. The difference in the NOELs of 4.98 and 10 mg/kg/day (both based on dietary concentrations of 100 ppm) is due to the time weighted average of compound intake. For the 14-day study, the rats received a higher dose of the compound than older rats due to increased body weight.

The RfD Committee concluded that the 14-day NOEL of 10 mg/kg/day accurately reflects a true NOEL for thyroid effects since these effects have been demonstrated to have an early onset (before 14 days). On this basis, the Committee decided to consider all three studies together and establish the **LOEL at 31 mg/kg/day and the NOEL at 10 mg/kg/day.** An Uncertainty Factor of 100 was applied to account for interspecies extrapolation and intraspecies variability. **The RfD was calculated to be 0.10 mg/kg body weight/day.**

Carcinogenicity Classification and Risk Quantification: The HED Carcinogenicity Peer Review Committee (CPRC) met on 3/18/92 to evaluate the data concerning the carcinogenic potential of pendimethalin (CPRC memo final 7/24/92). The Committee agreed that pendimethalin should be classified as a Group C (possible human) carcinogen, "based on statistically significant increased trend and pairwise comparison between the high dose group and controls for thyroid follicular cell adenomas in

male and female rats." The Committee also concluded (memo 2/6/96), based on an evaluation of new mechanistic studies submitted to the Agency, that the hypothesis that thyroid tumors are due to a thyroid-pituitary imbalance can be supported. However, instead of attempting to quantify potential carcinogenic risk as a separate endpoint, the Committee recommended using the 0.10 mg/kg/day RfD, which is protective of both the chronic, non-carcinogenic effects as well as the carcinogenic effect seen in the rat. The Committee concluded that since pendimethalin was not mutagenic in mammalian somatic cells and germ cells and mechanistic studies were available which supported a non-linear approach to risk assessment, risks (both cancer and non-cancer) could be evaluated by the RfD approach which is based on thyroid hormonal effects after short-term pendimethalin exposure. The same study used to establish the RfD is used for assessing short-term risks, e.g. 1-7 days and 7-90 days. The use of mechanistic data on thyroid effects is consistent with criteria given in the Agency's Science Policy on thyroid carcinogens (recently presented to the Science Advisory Board).

Other Toxicological Endpoints: The HED Toxicology Endpoint Selection Committee (TESC) met on 7/25/96 to evaluate the toxicological data for pendimethalin with particular reference to endpoints other than Reference Dose.

Dermal Absorption: There were no dermal absorption studies and no appropriate toxicity studies available to allow an estimation of the dermal absorption by a route to route comparison of toxicity. However, structurally related chemicals: oryzalin, trifluralin, and ethalfluralin have dermal absorption studies (in monkeys) indicating that absorption is 2.3, 1.0, and 2.8 %, respectively. The solubilities (water) for pendimethalin and related chemicals oryzalin, trifluralin, and ethalfluralin are similar: 0.5 ppm, 2.5 ppm, < 1 ppm, and 0.3 ppm, respectively. Therefore, for risk characterization purposes, it is estimated that pendimethalin absorption will be **no greater than 10%**.

Occupational/Residential Inhalation Exposure: Based on the LC_{50} of greater than 320 mg/L, pendimethalin is placed in Toxicity Category IV. Therefore, inhalation exposure should be considered (for risk assessment) only if it is greater than 5% of the dermal exposure. If so, the inhalation exposure estimates should be compared to the NOEL of 10 mg/kg/day established in the 14-day intrathyroidal study (LOEL of 31 mg/kg/day from the 56-day thyroid function study which demonstrated thyroid hormonal effects occurring as early as day 3). **This risk**

assessment is required only if inhalation exposure is greater than 5% of the dermal exposure.

Acute (One Day) Dietary Exposure: The TES Committee concluded that there are no toxicologic endpoints for acute (one-day) dietary exposure to pendimethalin. This risk assessment is not required.

Short Term Dermal Occupational/Residential Exposure: The TES Committee concluded that, based on the results of the rat thyroid studies discussed above under Reference Dose, short term (1-7 day) occupational and residential exposure estimates for pendimethalin should be compared to the NOEL of 10 mg/kg/day established in the 14-day intrathyroidal study (LOEL of 31 mg/kg/day from the 56-day thyroid function study which demonstrated thyroid hormonal effects occurring as early as day 3). **This risk assessment is required.**

The TES Committee concluded that a 10% dermal absorption factor should be used as discussed above under Dermal Absorption.

Intermediate Term Dermal Occupational/Residential Exposure: The TES Committee concluded that, based on the results of the rat thyroid studies, intermediate term (one week to several months) occupational and residential exposure estimates for pendimethalin should be compared to the NOEL of 10 mg/kg/day established in the 14-day intrathyroidal study (LOEL of 31 mg/kg/day from the 56-day thyroid function study). **This risk assessment is required.**

The TES Committee concluded that a 10 % dermal absorption factor should be used.

Chronic Dermal Occupational/Residential Exposure: The TES Committee concluded that, based on the results of the rat thyroid studies, chronic (90 days or more) occupational and residential exposure estimates for pendimethalin should be compared to the NOEL of 10 mg/kg/day established in the 14-day intrathyroidal study (LOEL of 31 mg/kg/day from the 56-day thyroid function study). **This risk assessment is required.**

The TES Committee concluded that a 10 % dermal absorption factor should be used.

i. Incident Reports

A search in the Office of Pesticide Programs' Incident Data System (2/28/96) indicated 12 reports with 3 of these involving 5 humans (the remainder concern fish, wildlife or domestic animals). The symptoms included signs of systemic illness: vomiting, diarrhea, chills and shakiness. Three people were hospitalized when they were exposed to a mixture of pesticides including pendimethalin and nitrogen. The data base does not indicate the associated use patterns or activities in which the poisoned individuals were involved.

The California Pesticide Illness Surveillance Program for 1982-1992 contained six reports. In three of these reports the effects were systemic (vomiting, diarrhea, etc.), two had skin effects, and one involved eye effects.

Pendimethalin ranked 41st on a list of the top 200 active ingredients for which the National Pesticide Telecommunications Network (NPTN) received calls during 1982-1991. There were 682 calls, with 91 concerning human poisoning due to pendimethalin.

2. Exposure Assessment

Agricultural food/feed

Pendimethalin [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] is a herbicide registered for use on numerous food/feed crops. Pendimethalin is manufactured by American Cyanamid Co. under the trade names Pentagon®, Prowl®, Pursuit®, and Squadron®. Formulations registered for food/feed uses include emulsifiable concentrates (EC), soluble concentrates/liquid (SC/L), Granulars (G) and water dispersable granules (WDG) or dry flowables (DF). Pendimethalin is applied to soil as preplant, preemergence, and postemergence applications, including at layby, with ground or aerial equipment.

There are eight pendimethalin end-use products (EPs) with food/feed uses registered to American Cyanamid Co. These EPs are presented in Table 2 below.

Table 2. End-Use Products Registered to American Cyanamid Co.

EPA Reg. No.	Acceptance Date	Formulation Class	Product Name
241-243	7/95	4 lb/gal EC	Prowl® Herbicide
241-244	2/87	3 lb/gal EC	Prowl® 3E Herbicide
241-268	7/95	60% WDG	Pentagon® DG Herbicide
241-297	2/91	2 lb/gal SC/L	Squadron® Herbicide
241-315	1/93	2.7 lb/gal EC	Pursuit® Plus Herbicide
241-327	2/95	2 lb/gal SC/L	Squadron® Herbicide
241-331	10/95	3 lb/gal EC	Pursuit® Plus EC Herbicide
241-337[a]	5/95	3.3 lb/gal EC	Prowl® 3.3 EC Herbicide

[a] Including SLN Nos. ID930012, MT930003, NV920004, NY940003, OR930001, OR930002, UT920004, WA920015, WA920034, WY920005.

Agricultural and Residential non-food

Products containing pendimethalin are intended for both occupational and homeowner uses. Pendimethalin is used on landscape and grounds plantings, ornamentals, turfgrass (residential, golf-course, landscape, and sod-farms). Homeowners use pendimethalin to control weeds on lawns, including spot treatment. Treatments are also made to homeowner lawns, landscape and grounds and golf courses by commercial applicators/sprayers. Large scale applications of pendimethalin are made to ornamental crops. Other ways of applying pendimethalin include backpack sprayer, low pressure hand wand (spot treatment), ground boom, or broadcast spreader.

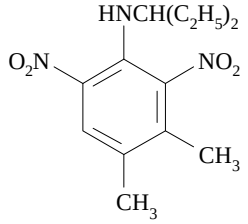
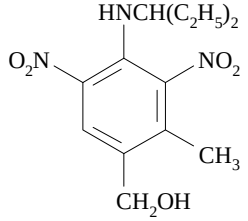
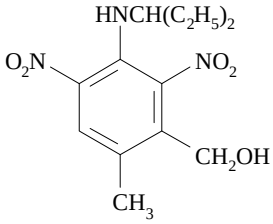
a. Dietary Exposure

The Pendimethalin Guidance Document was issued 3/85. Pendimethalin was the subject of a product and residue chemistry Reregistration Standard Update issued 4/13/90. These documents summarized regulatory conclusions regarding the available residue chemistry data. The 1990 Update specified that additional data were required for reregistration purposes. Several submissions of data have been received since the Update. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of pendimethalin.

Tolerances of 0.1 ppm (except 0.05 ppm for rice grain) are established for the combined residues of pendimethalin [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol in/on beans, corn

(field and fresh), cottonseed, onions (dry bulb), peas, peanuts, potatoes, grain sorghum, soybeans, sugarcane, and sunflower seeds [40 CFR §180.361(a)]. A tolerance of 0.25 ppm has been established for the combined residues of pendimethalin and its metabolites 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol and 3-[(1-ethylpropyl)amino]-6-methyl-2,4-dinitrobenzyl alcohol in/on peanut hulls [40 CFR §180.361(b)]. A tolerance with regional registration of 0.1 ppm has been established for the combined residues of pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol in/on garlic [40 CFR §180.361(c)]. The molecular structures of pendimethalin and currently regulated metabolites are depicted in Table 3 below.

Table 3. Chemical names and structures of pendimethalin and its metabolites.

Common/Chemical Names	Structures
Pendimethalin N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine	
3,5-Dinitrobenzyl alcohol metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol	
2,4-Dinitrobenzyl alcohol metabolite 3-[(1-ethylpropyl)amino]-6-methyl-2,4-dinitrobenzyl alcohol	

The Agency has recently updated the Raw Agricultural and Processed Commodities and Feedstuffs Derived from Field Crops Table (Residue Chemistry Test Guidelines, OPPTS 860.1000, Table 1 (July 1996)). Additional residue data are now required for some commodities as a result of changes in Table 1; these data requirements have been incorporated into this document. These new data requirements will be imposed at the issuance of the Pendimethalin RED but should not impinge on the reregistration eligibility decision for pendimethalin. The need for additional tolerances and for revisions to exposure/risk assessments will be determined upon receipt of the required residue chemistry data.

171-4 (a): Plant Metabolism

The qualitative nature of the residue in plants is understood based on adequate studies conducted with [^{14}C]pendimethalin on potatoes and sweet corn. The results of these studies are supported by additional corn, cotton, dry bean, lima bean, peanut, potato, red table beet, rice, snapbean, soybean, sugarcane, and wheat metabolism data. Pendimethalin *per se* and its 3,5-dinitrobenzyl alcohol metabolite are the residues of concern.

The current tolerance expressions specify the combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite and, for peanut hulls, the 2,4-dinitrobenzyl alcohol metabolite as well.

GLN 171-4 (b): Animal Metabolism

Adequate goat and poultry metabolism studies are available. The Agency has determined that there is no reasonable expectation of finite pendimethalin residues of concern in animal commodities (40 CFR §180.6(a)(3)). No additional animal metabolism, analytical methods, storage stability, and magnitude of the residue data are required. Tolerances for pendimethalin residues of concern in livestock commodities are not needed.

GLN 171-4 (c) and (d): Residue Analytical Methods-Plants and Animals

Adequate methods are available for data collection and tolerance enforcement. Methods I through IV in PAM Vol. II are gas chromatography/electron capture (GC/ECD) methods. Methods used for data collection are essentially the same as the PAM Vol. II methods.

The FDA PESTDATA database dated 1/94 (PAM Volume I, Appendix 1) indicates that pendimethalin is completely recovered (>80%) by Multiresidue Methods Section 302 (Luke method; Protocol D) and 303 (Mills, Onley, Gaither

method; Protocol E, nonfatty), and partially recovered (50-80%) by Multiresidue Method Section 304 (Mills fatty food method; Protocol E, fatty).

GLN 171-4 (e): Storage Stability

The Agency concludes that available storage stability data on almonds (representative of oilseeds), alfalfa seed (representative of non-oily seeds), onions, potatoes, soybean forage and hay, wheat straw, and alfalfa forage and hay adequately support the plant magnitude of the residue data. No additional storage stability data are required.

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

The reregistration requirements for magnitude of the residue in/on beans (succulent and dry); bean forage; bean fodder; corn stover (fodder); corn forage; field corn; pop corn; sweet corn (K+CWHR); cottonseed; garlic; onions (dry bulb); peanuts; peanut hay; potatoes; rice grain; rice straw; sorghum stover (fodder); sorghum forage; grain sorghum; soybeans; soybean forage; soybean hay; sugarcane; and sunflower seeds have been satisfied. Tobacco magnitude of the residue data remain outstanding and are considered confirmatory.

Pendimethalin residue data requirements for cotton gin byproducts which result from changes in the Raw Agricultural and Process Commodities and Feedstuffs Derived from Field Crops Table (Table 1 (July 1996)) should be imposed at this time. However, this requirement should not impinge on the reregistration eligibility decision for pendimethalin. The need for additional tolerances and revisions to the exposure/risk assessments will be made upon receipt and evaluation of required data.

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

Adequate data are available to demonstrate that pendimethalin residues of concern do not concentrate in commodities derived from corn, cottonseed, peanuts, potatoes, soybeans, sugarcane, and sunflower seeds. Rice processing data remain outstanding and are considered confirmatory.

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

The Agency has determined that there is no reasonable expectation of finite pendimethalin residues of concern in animal commodities (40 CFR §180.6(a)(3)). Therefore, livestock feeding studies and tolerances on livestock commodities are not required.

Guidelines 165-1 and 165-2: Confined/Field Rotational Crops

Preliminary review of confined rotational crop data (Guideline 165-1); indicates that plantback label restrictions are required unless the registrant wishes to conduct limited field rotational crop studies (Guideline 165-2). These considerations will not preclude the reregistration of pendimethalin.

b. Occupational and Residential Exposure

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

Handler (Mixer/Loader/Applicator) Exposures and Assumptions

The Agency has determined that there is potential exposure to persons handling pendimethalin. Handler exposures may occur to:

! Occupational handlers involved in food, feed, fiber, ornamental, turf, rights-of-way or other treatments, and

! Homeowners making applications to residential turf.

No handler exposure studies were conducted by the Registrant for pendimethalin.

The Agency has determined that there is potential exposure to mixers, loaders, applicators, and other handlers during usual use-patterns associated with pendimethalin. Based on the use patterns described above, thirteen major exposure scenarios were identified for pendimethalin: (1a) mixing/loading water-dispersible granulars (dry flowables) for rights-of-way sprayers; (1b) mixing/loading water-dispersible granulars (dry flowables) for groundboom applications; (2) mixing/loading wettable powders (water soluble packets) for groundboom application (**Note:** all currently registered wettable powder end-use products are packaged in water soluble packets); (3) loading granulars for solid-broadcast applications; (4a) mixing/loading liquid for aerial applications and irrigation systems (the mixer/loader scenario for aerial and irrigation applications were combined since they use the same mixing/loading techniques and similar acres treated and application rates); (4b) mixing/loading liquid formulations for rights-of-way spraying; (4c) mixing/loading liquid formulations for groundboom applications or to impregnate dry bulk fertilizer. (**Note:** impregnating dry bulk fertilizer is included in this scenario since the daily amount of liquid formulation

handled would be approximately the same as the amount handled to support groundboom applications); (5) applying as a spray with aerial (fixed wing) equipment; (6) applying as a spray with rights-of-way equipment; (7) applying as a spray with groundboom equipment; (8) applying granulars with a tractor-drawn broadcast spreader; (9) flagging during aerial spray application; (10) mixing/loading/applying as a spray with backpack sprayer; (11) mixing/loading/applying with a low-pressure handwand sprayer; (12) mixing/loading/applying with a push-type granular broadcast spreader; and (13) mixing/loading/applying using a high-volume turf sprayer (similar to those used for turfgrass applications by commercial handlers).

Daily dermal exposure is calculated using the following formula:

Daily Exposure (mg ai/day) =

Unit Exposure (mg ai exposure/lb ai amount handled) x Use Rate (lb ai/Acre) x Daily Area Treated (Acre/day)

A body weight of 70 kg was applied to the Daily Dermal Exposure to find the Daily Dermal Dose.

Absorbed Daily Dermal Dose is calculated using the following formula:

Absorbed Daily Dermal Dose (mg ai/kg bw/day) =

Unit Exposure (mg ai/lb ai) x Use (lb ai/A) x Daily Acres Treated (A/day) / Body Wt (kg) x 0.10 (dermal absorption rate)

The following assumptions were made regarding the area treated:

For aerial applications: 800 acres per day (upper-end estimate for field corn, soybeans, and grain sorghum);

For groundboom applications: 80 acres per day;

For rights-of-way applications: 10 acres per day;

For spot treatments using backpack and low-pressure handwand sprayers: 1,000 square feet per day by homeowner applicators and one acre per day by commercial applicators; and

For residential turf applications: one acre per day by homeowner applicators using a broadcast spreader and eight acres per day by commercial applicators using high-volume turf sprayers.

Other assumptions regarding worker exposure include the following:

! Commercial handlers would be expected to have short- and intermediate-term exposures whereas homeowner handlers would be expected to have only short-term exposures. However, since the toxicological endpoint is the same for short-term and intermediate-term exposures, the exposures and risks are represented in the same tables.

! Aerial applicators are in enclosed cockpits (there are no data available for the open cockpit scenario).

! Wettable powder formulations are contained in water-soluble packaging (all currently registered wettable powder products are in water soluble packaging).

! Adult male body weight = 70 kg

! Based on pendimethalin product labels and available use information, the Agency believes that a reasonable worst-case frequency of occupational exposure would be six days per week for 1-2 months for postpplication workers cultivating, irrigating, and performing other routine reentry tasks following applications to agricultural crop sites; or, for nursery and landscape workers working with ornamentals, a worst-case frequency of exposure would be intermittent exposure of 1-2 weeks at a time, several times per season, but not continuous throughout the season. This is characteristic of intermediate-term rather than chronic exposure.

! For residential exposures, a reasonable worst-case frequency of exposure would be 2-3 weeks, 4 times per year for reentry to lawns treated with pendimethalin. This is based on a maximum of 3-4 applications per year to residential turf. This is also characteristic of intermediate-term exposure.

For these reasons and since chronic occupational or residential exposure is not expected, a cancer risk assessment for workers is not required at this time.

Table 4. Exposure Scenario Descriptions for Uses of Pendimethalin

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Exposure			
Mixing Water Dispersible Granulars (Dry Flowables) (1a and 1b)	PHED V1.1	80 acres groundboom, and 10 acres rights-of-way	**Baseline:** "Best Available" grades: Hands grades A,B,C, dermal acceptable grades. Hands = 7 replicates; Dermal = 16 to 26 replicates. **Low confidence in dermal data**. PHED data used for baseline, no protection factors (PFs) were necessary.
Mixing Wettable Powders (Water Soluble Packets) (2)	PHED V1.1	80 acres groundboom	**Baseline:** "Best Available" grades: Hands, dermal all grades. Hands = 5 replicates; Dermal = 6 to 15 replicates. **Low confidence in dermal data**. PHED data used for baseline, no PFs were necessary.
Loading Granulars (3)	PHED V1.1	80 acres solid broadcast	**Baseline:** "Best Available" grades: Hands all grades and dermal and inhalation acceptable grades. Hands = 10 replicates; Dermal = 29 to 36 replicates; Inhalation = 58 replicates. **Low confidence in dermal data and high confidence for inhalation data.** PHED data used for baseline, no PFs were necessary.
Mixing Liquid (E.C.) (4a, b, and c)	PHED V1.1	80 acres groundboom, 800 acres aerial, and 10 acres rights-of-way	**Baseline:** "Best Available" grades: Hands, dermal acceptable grades. Hands = 53 replicates; Dermal = 25 to 122 replicates. **High confidence in dermal data**. **PPE:** "Best Available" grades: Hands and dermal acceptable grades. Hands = 59 replicates; Dermal = 25 to 122 replicates. **High confidence in dermal data**. PHED data used for baseline and PPE, no PFs were necessary.
Applicator Exposure			
Aerial equipment--enclosed cockpit (liquids) (5)	PHED V1.1	800 acres for fixed-wing	**Baseline:** "Best Available" grades: Hands acceptable grades, dermal grades A,B,C. Hands = 34 replicates; Dermal = 24 to 48 replicates. **Medium confidence in dermal data**. PHED data used for baseline, no PFs were necessary.
Rights-of-Way (6)	PHED V1.1	10 acres	**Baseline:** "Best Available" grades: Hands, dermal, acceptable grades. Hands = 16 replicates; Dermal = 16 (no head data) replicates. **Low (only because of no head data) confidence in dermal data.** PHED data used for baseline, no PFs were necessary.
Groundboom (7)	PHED V1.1	80 acres	**Baseline:** "Best Available" grades: Hands, dermal acceptable grades. Hands = 29 replicates; Dermal = 32 to 42 replicates. **High confidence in dermal data**. PHED data used for baseline, no PFs were necessary.
Solid Broadcast Spreader (tractor drawn) (8)	PHED V1.1	80 acres	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 5 replicates; Dermal = 4 to 5 replicates; Inhalation = 5 replicates. **Low confidence in dermal and inhalation data**. PHED data used for baseline, no PFs were necessary.
Flagger			
Liquids (9)	PHED V1.1	800 acres	**Baseline:** "Best Available" grades: Hands, dermal acceptable grades. Hands = 16 replicates; Dermal = 16 to 18 replicates. **High confidence in dermal data**. PHED data used for baseline, no PFs were necessary.
Mixer/Loader Applicator			
Backpack Sprayer (spot treatment) (10)	PHED V1.1	Homeowner: 1,000ft^2; Occupational: 1 acre	**Baseline:** "Best Available" grades: Hands and dermal grades A,B,C. Hands = 11 replicates; Dermal = 9 to 11 replicates. **Low confidence in dermal data**. PHED data used for baseline was derived from single layer clothing and chemical resistant gloves; a 90% PF was used to remove the chemical resistant gloves to simulate a no glove scenario.
Low Pressure Handwand (11)	PHED V1.1	Homeowner: 1,000ft^2; Occupational: 1 acre	**Baseline:** "Best Available" grades: Hands, dermal all grades. Hands = 70 replicates; Dermal = 25 to 96 replicates. **Low confidence in both dermal data**. **PPE:** "Best Available" grades: Hands acceptable grades, dermal all grades. Hands = 15 replicates; Dermal = 25 to 96 replicates. **Low confidence in dermal data**. PHED data used for baseline and PPE values, no PFs were necessary.

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Residential Broadcast Spreader (12)	PHED V1.1	1 acre	**Baseline:** "Best Available" grades: Hands and dermal grades A,B,C. Hands = 15 replicates; Dermal = 15 (no head data) replicates. **Low (no head data) confidence in dermal data.** PHED data used for baseline, no PF were necessary.
High Volume Turf Sprayer (13)	PHED V1.1	8 acres	**Baseline:** "Best Available" grades: Hands and dermal all grades. Hands = 14 replicates; Dermal = 14 (no head data) replicates. **Low confidence in dermal data.** PHED data used for baseline was derived from single layer clothing and chemical resistant gloves; a 90% PF was used to remove the chemical resistant gloves to simulate a no glove scenario.

a Standard Assumptions based on an 8-hour work day as estimated by The Agency. BEAD data were not available.

b "Best Available" grades are defined by The Agency SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

Table 5 below shows the estimated exposure for individuals handling pendimethalin in both residential and occupational settings. Estimated dermal exposure values (mg/kg/lb ai) for each task were obtained from the Pesticide Handler's Exposure Database (PHED), Version 1.1.

Table 5: Short-Term and Intermediate-Term Exposure of Pendimethalin

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Application rate[b] lbai/acre)	Daily Acres Treated[c]	Daily Dermal Exposure[d] (mg/day)
Mixer/Loader Exposure				
Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Rights-of-Way Spraying (1a)	0.07	3.96	10	2.8
Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Groundboom Applications (1b)		3.96	80	22.2
Mixing/Loading Wettable Powders (water soluble packets) for Groundboom Applications and for Impregnating Dry Bulk Fertilizer (2)	0.02 (wtr. sol. pk.)	3.0	80	4.8
Loading Granulars for Solid Broadcast Applications (3)	0.008	3.0	80	1.9
Mixing/Loading Liquid for Aerial Applications and Irrigation Systems (4a)	2.9	1.98	800	4,594
Mixing/Loading Liquid for Rights-of-Way Spraying (4b)		4.0	10	116
Mixing/Loading Liquid for Groundboom Applications (4c)		1.98	80	459
Applicator Exposure				
Aerial-Fixed Wing - enclosed cockpit (liquid) (5)	0.005	1.98	800	7.9
Rights-of-Way (6)	1.2	4.0	10	48
Groundboom Tractor (7)	0.015	3.96	80	4.8
Solid Broadcast Spreader (tractor drawn) (8)	0.01	3.0	80	2.4
Flagger				
Flagging (liquid) (9)	0.01	1.98	800	15.8
Mixer/Loader/Applicator				
Backpack (spot treatment) (10)	2.6	3.96	(H) 1,000ft^2 (O) 1.0	(H) 0.24 (O) 10.3
Low Pressure Handwand (spot treatment) (11)	103.8	3.96	(H) 1,000ft^2 (O) 1.0	(H) 9.4 (O) 411
Residential Broadcast Spreader (12)	2.9	3.0	1.0	8.7
High Volume Turf Sprayer (13)	0.77	3.0	8	18.5

[a] Baseline dermal unit exposures represent long pants, long sleeve shirts, no gloves, open mixing/loading, enclosed cockpit (open cockpit data are not available), and open cab tractor.
[b] Application rates derived from labels for EPA Reg. Nos.: E.C. 241-337 and 241-305, Granular 538-188, WDG 10404-52, 241-340 and 241-268 (CA), WP 538-195 (water soluble packets)
[c] Values represent the area [(H) = homeowner, (O) = occupational] which can be used in a single day to complete treatments for each exposure scenario of concern.
[d] Daily dermal exposure (mg/day) = Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre) * Max. Treated (acres).

Postapplication Exposures and Assumptions

The Agency has determined that there is potential exposure to persons entering treated sites after application is complete. Post-application exposures may occur to:

- Agricultural workers following applications to commercial or research food, feed, fiber, ornamental, forestry, and turf crops during routine crop-production tasks, such as planting, transplanting, incorporation, cultivation, hoeing, scouting, thinning, and harvesting;

- Mowers and other golf-course maintenance workers following applications to turfgrass on golf courses;

- Landscape and grounds maintenance workers following applications to commercial landscape plantings;

- Workers following applications in rights-of-way and other noncrop areas; and

- Persons, including children, following applications to residential and recreation area turf or ornamental plantings.

No chemical-specific post-application studies have been conducted by the Registrant for pendimethalin. In lieu of such studies, EPA has used a registrant-submitted published study as surrogate data. This study (Hurto and Prinster, 1992) compared foliar dislodgeable residues (FDRs) for five different chemicals. The study does not meet guideline requirements, and the Agency therefore has low confidence in the exposure and risk estimates using this data. However, it is the best available source of data with which to evaluate post-application exposure and risk pending development of chemical specific post-application data which meets guideline requirements. Based on the FDR data from the study, EPA has developed reasonable worst-case estimates to assess the post-application exposure and risk for three representative post-application scenarios: (1) toddler exposure to residential turf, (2) maintenance worker exposure to golf course turf, and (3) harvesting turfgrass from a sod farm. However, it should be noted that the registrant is a member of the Agricultural Reentry Task Force which is developing agricultural and residential post-application/reentry exposure data. These post-application risk assessments follow in section b (Occupational and Residential) portion of Risk Characterization.

3. Risk Characterization

a. Dietary

Food uses evaluated in the Dietary Risk Evaluation System (DRES) analysis were the published uses of pendimethalin listed in 40 CFR § 180.361 and the Tolerance Index System (TIS). The analysis used tolerance level residues for registered commodities.

Reassessed Tolerances:

Based on the Product and Residue Chemistry Assessment of the Reregistration Eligibility Decision Document (B. Cropp-Kohlligian, 12/12/95), the Agency recommended that tolerances for residues of pendimethalin on rice be increased from 0.05 ppm to 0.1 ppm due to the analytical method's limit of quantification for the combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite. Additionally, the Agency recommended that the tolerance for onions (dry bulb) be applied to shallots (dry bulb only).

In the DRES analysis, both rice and dry bulb shallots were included at these recommended tolerance levels. See Table 1 within Attachment 3, Dietary Risk Assessment, for all the commodities and tolerances included in this analysis.

Dietary Exposure and Risk from Food: The following DRES chronic dietary exposure estimates are based on a Theoretical Maximum Residue Contribution (TMRC). TMRC assumes residues on foods are at tolerance levels and that 100 percent of each crop registered for pendimethalin is treated. Food consumption estimates are averages taken from the 1977-78 USDA Food Consumption Survey. TMRC exposure estimates for the overall U.S. population and various population sub-groups were then compared to the pendimethalin RfD (0.1 mg/kg/day) with chronic risk expressed as a percent of the RfD.

Based on the above assumptions and including all registered pendimethalin food uses, DRES estimates chronic exposure to pendimethalin to be 0.00042 mg/kg/day (< 1% RfD) for the Overall U.S. population. The estimated most highly exposed DRES sub-group for pendimethalin is non-nursing infants at a level of 0.00140 mg/kg/day (< 2% RfD).

Dietary Exposure and Risk from Drinking Water:

Pendimethalin is not regulated under the Safe Drinking Water Act (SDWA) and does not have an established Maximum Contaminant Level (MCL).

Ground Water: Pendimethalin has a history of high use over a wide geographic area on several major crops. However, there are few reports of detections in ground water. Specifically, residues of pendimethalin have been found in ground water in limited areas of two states at concentrations of 0.2 to 0.9 ppb.

Surface Water: Pendimethalin may contaminate surface water from spray drift associated with aerial and ground spray applications, or in runoff from rainfall and through irrigation waters (chemigation). Transport of pendimethalin during runoff events which occur soon after application can be considerable due to its persistence and extensive use.

Pendimethalin has been detected in surface water samples taken from lower Great Lakes tributaries (Baker, 1988) and in surface water samples from 13 States as reported in the STORET database. However, a study by Coupe et al. (1993) of the Mississippi River and its tributaries did not detect dissolved pendimethalin above the reporting limit of 0.018 ug/L (which indicates pendimethalin would not be present in public drinking water).

The maximum reported concentration of pendimethalin is 17.6 ug/L (ppb) from a surface water sample collected in Ohio (STORET data).

Drinking Water Risk: Exposure and risk estimates for pendimethalin in drinking water will be based on the following assumptions:

" A 10 kilogram child will consume 1 litre (L) of drinking water per day (making children the most highly exposed group, as demonstrated in exposure estimates for food sources).

" Drinking water is contaminated with pendimethalin at a level as high as 18 ppb based on the highest reported measured sample in the STORET database (this level will be used for the purpose of risk assessment only and does not imply this value is considered typical).

" Contamination at a level of 18 ppb is constant (although actual durations of maximum levels are not known).

At a level of 18 ppb pendimethalin in water, a 10 kg child will be exposed at the rate of 0.0018 mg/kg body weight/day. The endpoint for pendimethalin risk assessment (all exposure durations except 1-day) is 10 mg/kg/day, based on the 14-day thyroid function study. Therefore, a Margin of Exposure is estimated at > 5,000. A chronic exposure from dietary intake of 0.0018 mg/kg/day is < 2% of the pendimethalin RfD.

b. Occupational and Residential

Table 6 below shows the estimated risks for individuals handling pendimethalin in both residential and occupational settings. Estimated unit dermal exposure values (mg/kg/lb ai) for each task were obtained from the Pesticide Handler's Exposure Database (PHED), Version 1.1. The unit exposure value was used to find the daily dose and a corresponding margin

of exposure (MOE) for each use, based on the short- and intermediate-term (10 mg/kg/day) endpoint of concern (equations used to find daily exposures are presented in the previous section on occupational and residential exposure assessment). Risks are presented in terms of the Margin of Exposure (MOE), described below. The Toxicology Endpoint Selection Document for pendimethalin (dated July 25, 1996) specified that **NO** risk assessment was required for inhalation exposure unless the inhalation exposure represents more than five percent of the dermal exposure. In these cases the inhalation exposures, adjusted by a 50 percent absorption factor, were added to the absorbed dermal dose and footnoted. The inhalation exposure was greater than five percent of the dermal exposure for only two scenarios -- Scenarios 3 and 8.

MOEs from short- and intermediate-term exposures were calculated using the following formula:

MOE = NOEL / Absorbed Daily Dermal Dose

For pendimethalin, an MOE value of at least 100 is considered adequate.

Table 6: Short-Term and Intermediate-Term Risk of Pendimethalin

Exposure Scenario (Scen. #)	Baseline Daily Dermal Dose (mg/kg/day)[a]	Baseline Daily Absorbed Dermal Dose (mg/kg/day)[b]	Baseline Dermal MOE[c]	Risk Mitigation Measure				
				Additional PPE[d]				
				Dermal Unit Exposure (mg/lb ai)	Daily Dermal Exposure (mg/day)	Daily Dermal Dose (mg/kg/day)[a]	Daily Dermal Absorbed Dose (mg/kg/day)[b]	Dermal MOE[c]
Mixer/Loader Risk								
Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Rights-of-Way Spraying (1a)	0.040	0.004	2,500	NA	NA	NA	NA	NA
Mixing/Loading Water Dispersible Granulars (Dry Flowables) for Groundboom Application (1b)	0.32	0.032	313		NA	NA	NA	NA
Mixing/Loading Wettable Powders (Water Soluble Packets) for Groundboom Applications and for Impregnating Dry Bulk Fertilizer (2)	0.069	0.007	1,429		NA	NA	NA	NA
Loading Granulars for Solid Broadcast Applications (3)	0.027	0.003	667 (e)		NA	NA	NA	NA
Mixing/Loading Liquid for Aerial Applications and Irrigation Systems (4a)	65.6	6.56	1.5	0.04	63.4	0.91	0.091	110
Mixing/Loading Liquid for Rights-of-Way Spraying (4b)	1.7	0.17	59		1.6	0.023	0.0003	33333
Mixing/Loading Liquid for Groundboom Applications (4c)	6.6	0.66	15		6.3	0.09	0.009	1,111
Applicator Risk								
Aerial-Fixed Wing - enclosed cockpit (liquid) (5)	0.11	0.011	909	NA	NA	NA	NA	NA
Rights-of-Way (6)	0.69	0.069	145	NA	NA	NA	NA	NA
Groundboom Tractor (7)	0.069	0.007	1,429	NA	NA	NA	NA	NA
Solid Broadcast Spreader (tractor drawn) (8)	0.034	0.003	909 (e)	NA	NA	NA	NA	NA

Exposure Scenario (Scen. #)	Baseline Daily Dermal Dose (mg/kg/day)[a]	Baseline Daily Absorbed Dermal Dose (mg/kg/day)[b]	Baseline Dermal MOE[c]	Risk Mitigation Measure				
				Additional PPE[d]				
				Dermal Unit Exposure (mg/lb ai)	Daily Dermal Exposure (mg/day)	Daily Dermal Dose (mg/kg/day)[a]	Daily Dermal Absorbed Dose (mg/kg/day)[b]	Dermal MOE[c]
Flagger Risk								
Flagging (liquid) (9)	0.23	0.023	435	NA	NA	NA	NA	NA
Mixer/Loader/Applicator								
Backpack Sprayer (10)	(H) 0.003 (O) 0.15	(H) 0.0003 (O) 0.015	(H) 33,333 (O) 667	NA	NA	NA	NA	NA
Low Pressure Handwand (11)	(H) 0.13 (O) 5.9	(H) 0.013 (O) 0.59	(H) 769 (O) 17	(O) 4.1	(O) 16.2	(O) 0.23	(O) 0.023	(O) 435
Residential Broadcast Spreader (12)	0.12	0.012	833	NA	NA	NA	NA	NA
High Volume Turf Sprayer (13)	0.26	0.026	385	NA	NA	NA	NA	NA

NA Not applicable since previous MOE was over 100.

[a] Daily dermal dose = daily dermal exposure/70 kg.

[b] Absorbed dermal dose = daily dermal dose * dermal absorption rate (10.0 percent).

[c] Short-term and intermediate-term dermal MOE = NOEL (10.0 mg/kg/day) / daily absorbed dermal dose.

[d] Additional PPE = for Scenario 4a, b, c = Single layer of clothing and chemical resistant gloves.
for Scenario 11 = Single layer of clothing and chemical resistant gloves.

[e] Inhalation dose is combined with absorbed dermal dose in scenerios 3 and 8 because inhalation exposurre for these two scenerios exceeded 5% of the dermal exposure (see TESC document). For scenerio 3, inhalation unit exposure value is 3.4 ug/lb. ai; for scenerio 8, inhalation exposure value is 2.4 ug/lb. ai. Inhalation absorption is assumed tobe 100%.

Handler Risk - Short- and Intermediate-term Risk

Exposure and risk for the short- and intermediate-term uses of pendimethalin are summarized in Tables 5 and 6. Short- and intermediate-term risk was calculated using the 10 mg/kg/day toxic effect. Exposure estimates are based on the best available exposure data derived from the Pesticide Handlers Exposure Database (PHED V1.1), which varied in quality from high confidence data to low confidence data (see Table 4 for a description of the confidence level associated with exposure data).

The calculations indicate that the MOEs for short- and intermediate-term exposures for handlers wearing baseline attire (long-sleeve shirt, long pants, shoes, and socks) are over 100 for all but the following use scenarios: (scenarios 4a, b, c) mixing/loading liquid formulations for aerial application and irrigation systems (baseline MOE is 1.5), mixing/loading liquids for rights-of-way application (baseline MOE is 59), mixing/loading liquids for groundboom application (baseline MOE is 15); and occupational mixing, loading, and applying using low-pressure handwand equipment (spot treatment) (scenario 11) (baseline MOE is 17). The risks to these handlers in these scenarios are reduced to an adequate level (MOEs are all above 100) when handlers wear chemical-resistant gloves in addition to baseline attire.

Risk From Postapplication Exposures

EPA has determined that the following post-application exposure and risk scenarios, based on the surrogate FDR data, are representative worst-case exposure and risk assessments for other pendimethalin post-application scenarios:

- post-application exposure to workers harvesting turfgrass from sod farms is representative of worst-case post-application exposures to other agricultural workers following pendimethalin applications to commercial or research food, feed, fiber, ornamental, forestry, and turf crops.

- post-application exposure to golf-course maintenance workers is representative of worst-case post-application exposures to landscape and grounds maintenance workers in commercial landscape plantings and in rights-of way and other non-crop areas.

- post-application exposures to toddlers on residential turf is representative of worst-case post-application exposures to other persons following pendimethalin applications on turf at residential sites and at parks and recreation areas.

Surrogate Postapplication Data and Derived REIs

RESIDENTIAL TURF

Table 7 presents the MOEs for toddlers on residential turf ranging from the day of application (two hours after treatment) to two days after application when the MOE exceeded 100 for the maximum application rate. The transfer coefficient (Tc) was estimated by the

Occupational and Residential Branch (OREB) based on the reasonable worst-case activity of children (3-6 yrs, 17 kg--Exposure Factors Handbook, U.S. EPA, 1990) playing on turf 4 hours per day. The surrogate pendimethalin FDR data from Hurto and Prinster 1992 were chosen by EPA as the best available surrogate data for residential turf. The surrogate FDR data in the published study are assumed to represent an application rate of 2.0 lb ai/A. The minimum and maximum rates for the residential turf are 1.0 and 3.0 lb ai/A respectively (EPA Reg. No. 241-340). An adjustment (i.e., normalization to the maximum application rate of 3.0 lb ai/A) was made to the surrogate FDR data in these calculations.

Table 7: Postapplication Risk Estimates for Residential Turf[a]

Crop	HAT/DAT (hrs or days after treatment)	FDR ($\mu g/cm^2$)[b]		Daily Absorbed Dose (mg/kg/day)[c]		MOE[d]	
		2 lbs ai/ acre rate	3 lbs ai/acre rate	2 lbs per acre	3 lbs per acre	2 lbs per acre	3 lbs per acre
Residential Turf	2 HAT	0.4	0.6	0.09	0.14	111	71
	1 DAT	0.28	0.42	0.07	0.10	142	100
	2 DAT	0.24	0.36	0.06	0.09	167	111
	3 DAT	0.12	0.18	0.03	0.04	333	250

[a] Tc of 10,000 (cm^2/hr) is based on OREB's best estimate.

[b] Published pendimethalin-specific FDR data (monitored at 2.0 lb ai/acre) for turf where 2 HAT and 1 and 2 DAT the FDRs are 0.4, 0.28, and 0.24 $\mu g/cm^2$, respectively (Hurto and Prinster 1992).

[c] Daily Absorbed Dose (mg/kg/day) = [(normalized FDR ($\mu g/cm^2$) x T_c(cm^2/hr))/1,000 unit conv.) x 4 hrs/day]/17 kg] x 0.1 (dermal absorption).

[d] MOE = NOEL (10 mg/kg/day)/Daily Absorbed Dose (mg/kg/day).

GOLF COURSE TURF

Table 8 presents the MOEs for golf course workers at the day of application (2-hrs after treatment). The transfer coefficient (Tc) was estimated by the Agency based on the reasonable worse-case tasks of routine golf-course turf maintenance. The surrogate pendimethalin FDR data from Hurto and Prinster 1992 were chosen by EPA as the best available surrogate data for the golf course turf. The surrogate FDR data in the published study represent an application rate of 2.0 lb ai/A. The maximum rate for the golf course turf (EPA Reg. No. 241-340) is 3.0 lb ai/A. An adjustment (i.e., normalization to the 3.0 lb ai/A application rate) was made to the surrogate FDR data in these REI calculations.

Table 8: Risk Estimates and Restricted-Entry Interval for Golf Course Turf[a]

Crop	HAT (Hours After Treatment)	FDR ($\mu g/cm^2$)[b]	Daily Absorbed Dose (mg/kg/day)[c]	MOE[d]
Golf Course (Turf)	2-hrs	0.60	0.003	2,917

[a] Tc of 500 (cm^2/hr) is based on Occupational and Residential Exposure Branch's (OREB 's) best estimate.

[b] Published pendimethalin-specific FDR data (monitored at 2.0 lb ai/acre) for turf where 2 HAT, and 1, 2, and 3 DAT the FDRs are 0.4, 0.28, 0.24, and 0.12 $\mu g/cm^2$ respectively. (Hurto and Prinster 1992).

[c] Daily Absorbed Dose (mg/kg/day) = [(normalized FDR ($\mu g/cm^2$) x T_c(cm^2/hr))/1,000 unit conv.) x 8 hrs/day]/70 kg] x 0.1 (dermal absorption).

[d] MOE = NOEL (10 mg/kg/day)/Daily Absorbed Dose (mg/kg/day).

SOD FARM TURF:

Table 9 presents the MOEs for sod farm workers ranging from the day of application (two hours after treatment) to three days after application. The transfer coefficient (Tc) was estimated by the Agency based on the reasonable worse-case tasks of harvesting sod. The surrogate pendimethalin FDR data from Hurto and Prinster 1992 were chosen by EPA as the best available surrogate data for the sod farm turf. The surrogate FDR data in the published study represent an application rate of 2.0 lb ai/A. The maximum rate for the sod farm turf is 3.0 lb ai/A (EPA Reg. No. 241-340). An adjustment (i.e., normalization to the 3.0 lb ai/A application rate) was made to the surrogate FDR data in these REI calculations.

EPA notes that the maximum application rate for certain ornamental-crop uses (EPA Reg. No. 241-340) is 3.96 lb ai/A. However, the post-application exposures to workers harvesting or transplanting ornamentals are likely to be lower than the estimated post-application exposures to workers harvesting turf from sod farms. In the absence of chemical-specific data, EPA estimates that harvesting sod represents the reasonable worse-case estimate for post-application exposures to ornamental crops, as well as other food, feed, fiber, and turf crops.

Table 9: Risk Estimates and Restricted-Entry Interval for Sod Farm Turf[a]

Crops	HAT/ DAT(Days After Treatment)	FDR ($\mu g/cm^2$)[b]	Daily Absorbed Dose (mg/kg/day)[c]	MOE[d]
Sod Farm (Turf)	2-hrs	0.6	0.069	144
	1 DAT	0.42	0.048	208
	2 DAT	0.36	0.041	244
	3 DAT	0.18	0.021	476

[a] Tc of 10,000 (cm^2/hr) is based on OREB's best estimate.

[b] Published pendimethalin-specific FDR data (monitored at 2.0 lb ai/acre) for turf where 2 HAT, and 1, 2, and 3 DAT the FDRs are 0.4, 0.28, 0.24, and 0.12 $\mu g/cm^2$ respectively. (Hurto and Prinster 1992).

[c] Daily Absorbed Dose (mg/kg/day) = [[(((normalized FDR ($\mu g/cm^2$) x T_c(cm^2/hr))/1,000 unit conv.) x 8 hrs/day]/70 kg] x 0.1 (dermal absorption).

[d] MOE = NOEL (10 mg/kg/day)/Daily Absorbed Dose (mg/kg/day).

Exposures following applications to commercial or research food, feed, fiber, turf, and ornamental crops may be mitigated by restricted-entry intervals (REIs). REIs allow sufficient time to pass for residues to dissipate to levels that result in adequate MOEs for entering workers who contact treated surfaces. However, restricted-entry intervals are not feasible as a mitigation measure for post-application residential exposures and occupational exposures in noncrop areas (such as rights-of-ways), or in turf- and ornamental-plant settings such as parks and landscape plantings.

The Agency has concluded that the following pendimethalin uses indicate an **increased level of concern** for post-application exposures in certain settings, and therefore demand mitigation. For specific mitigtion measures and the rationales, refer to section IV of this document.

- **!** Most applications to ornamentals and turf are to established plants and are often broadcast over the entire ornamental and turf foliage, thus increasing potential exposure risk from foliar contact with such treated foliage;

- **!** Workers entering turf and ornamental production (commercial or research) areas following pendimethalin applications may perform hand-labor tasks such as transplanting, harvesting, weeding, or pruning. For these crops, the timing of applications make hand labor activities likely following pendimethalin applications.

- **!** Persons, including children, may be exposed to treated turfgrass (lawns) at residential sites frequently and for relatively long periods of time.

- **!** This assessment is based on surrogate, non-guideline data which indicates an increased level of concern.

4. Food Quality Act Considerations Regarding Pendimethalin

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by setting a new safety standard for the establishment of tolerances. In determining whether a tolerance meets the new safety standard, section 408(b)(2)(C) directs EPA to consider information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have a common mechanism of toxicity.

The FQPA amendments to section 408(b)(2)(C) require EPA to apply an additional 10-fold uncertainty factor (safety) unless reliable data demonstrate that the additional factor is unnecessary to protect infants and children.

Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources including drinking water as well as non-occupational exposures such as those derived from pesticides used in and around the home. The Agency must also consider the potential cumulative effects of the pesticide for which a tolerance is being sought as well as other substances that have a common mechanism of toxicity.

Because pendimethalin has food uses, specific consideration of the risks to infants and children, as well as aggregate exposures and potential cumulative effects is warranted.

a. Potential Risks to Infants and Children

In determining whether an additional uncertainty factor is or is not appropriate for assessing risks to infants and children, EPA considers all reliable data and makes a decision using a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

For the purposes of assessing the pre- and post-natal toxicity of pendimethalin, EPA has evaluated developmental studies in two species (rat and rabbit), and two- and three-generation rat studies. However, as EPA fully implements the requirements of FQPA, additional data related to the special sensitivity of young organisms may be required.

Developmental and Reproductive Effects

In a developmental toxicity study, pendimethalin was administered to groups of 20 artificially inseminated rabbits by gavage at dose levels of 0, 15, 30, or 60 mg/kg/day from gestation day 6 through 18. No maternal toxicity was reported at doses equal to or greater than 60 mg/kg/day (highest dose

tested). Therefore the maternal LOEL is greater than 60 mg/kg/day and the maternal NOEL is equal or greater than 60 mg/kg/day. This dose was considered adequate since maternal mortality was observed in a range-finding study at 125 mg/kg/day. There was no increase in developmental effects at any dose. The developmental LOEL greater than 60 mg/kg/day and the developmental NOEL equal to or greater than 60 mg/kg/day.

In a developmental toxicity study, pendimethalin was administered to groups of 30 mated rats by gavage at daily dose levels of 0, 125, 250, or 500 mg/kg/day from gestation day 6 through 15. There were no maternal or developmental effects noted at any dose level tested, and based on those results, the NOELs for developmental and maternal toxicity are equal to or greater than 500 mg/kg/day (highest dose tested). This dose is considered adequate because: 1) This dose is about one-half of the acute LD_{50} for rats (albeit a different strain). 2) This is one-half of the limit dose of 1000 mg/kg/day. 3) Although not statistically significant, there was about a two-fold increase in litters with delayed ossification in the extremities that suggests that the high dose may have approached an effect level. 4) From a regulatory consideration, this study would not be used for risk calculations since there is a rabbit study where maternal mortality occurred at lower dose levels (125 mg/kg/day).

In a two-generation reproduction study, pendimethalin was administered in the diet to groups of 25 male and 25 female rats at dose levels of 0, 500, 2500 or 5000 ppm (corresponding to 0, 34, 172 or 346 mg/kg/day in males and 0, 43, 216 or 436 mg/kg/day in females). There were no clinical signs or changes in organ weight data. There was a minimal (5%) decrease in body weight gain and food consumption (possibly due to palatability) at 2500 ppm. At 5000 ppm the decrease in body weight gain was as much as 20%. Therefore, the parental systemic NOEL could not be unambiguously determined. There were decreased pup weights during much of the lactation period at 5000 ppm. Based upon this finding, the LOEL for reproductive effects is 5000 ppm (346 and 436 mg/kg/day for males and females, respectively). The NOEL for reproductive effects is 2500 ppm (172 and 216 mg/kg/day, in males and females, respectively).

Uncertainty Factor

In general, the data base for pendimethalin does not indicate a potential for increased toxicological sensitivity from pre- and post-natal exposures. No developmental toxicity was observed in either the rat or rabbit developmental toxicity studies, nor was there any evidence in the two generation study that there was developmental or reproductive toxicity at dose levels below those in which parental toxicity was observed. It is known that pendimethalin affects the pituatary-thyroid axis; the basis for the RfD (0.10 mg/kg/day) is based on combined subchronic studies (14 days, and 28 days) in which thyroid hormonal

and histologic thyroid changes were observed. Based on the thyroid effects, pendimethalin by definition is an endocrine disrupter.

The Act further directs EPA to consider potential for increased susceptibility of infants and children to the toxic effects of pesticide residue. The Agency considered the appropriateness of an additional uncertainty factor, which can be applied in situations where available data indicate infants and children may have an increased sensitivity to the pesticide. In general, the data base for pendimethalin does not indicate a potential for increased toxicological sensitivity from either pre- or post-natal exposures. No developmental toxicity was observed in either the rat or rabbit developmental toxicity studies, nor was there evidence in the two-generation reproduction study of developmental or reproductive toxicity at dose levels below those in which parental toxicity was observed. Therefore, the Agency has determined that an additional uncertainty factor is not warranted.

b. Aggregate Exposure/Risk

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from pesticide residues in food and other exposures for which there is reliable information. These other exposures may include drinking water and non-occupational exposures, e.g., to pesticides used in and around the home.

Pendimethalin has both food and non-occupational uses; therefore, the considerations for aggregate exposure are those from food, drinking water, and residential (non-occupational) sources.

The following exposure scenarios pertinent to aggregate risk are associated with pendimethalin uses: chronic dietary, chronic water, and short-term residential.

Chronic dietary risk

Chronic dietary risks utilizing tolerance level residues and 100% crop treated (TMRC) are <1% RfD for the general U.S. population, and <2% RfD for non-nursing infants, the population subgroup with the highest estimated risk. These risk estimates are extremely conservative; actual risks utilizing anticipated residue information would be considerably <1% RfD for all population subgroups.

Chronic water risk

Limited ground water monitoring data are available for pendimethalin (Pesticides in Ground Water Data Base, EPA, 1992). In the data from 8 states, detectable residues were found in only 2 states, with <1% of wells monitored having detectable residues. The maximum level found was 0.9 ppb. The maximum level of pendimethalin found in surface water is 17.6 ppb. Based on this information, risks from water are estimated to be <2% RfD for all population subgroups, including those most highly exposed to pendimethalin residues.

Short-term residential risk

MOEs for exposures to residential applicators and for post-application exposures (children) are 833 and 111 respectively. The post-application risk estimates are based on 2.0 lbs. ai/acre for residential and sod farm uses as discussed in the residential risk section of this document. Although the risk assesssment for children exposed to pendimethalin-treated lawns showed an acceptable MOE (111), the Agency has low confidence in the data used for these exposure calculations and these estimates do not include ingested or inhaled quantities. Therefore, the Agency has concerns for post-application exposure to children in residential settings, and has strongly recommended that the maximum application rate for residential (and sod farms) uses be reduced from 3.0 lbs. ai/acre to 2.0 lbs. ai/acre. (The registrant has already agreed to this reduction in the maximum application rate.)

Aggregate risk estimates

Aggregate risks which must be considered include those from:

(a) chronic food plus chronic water exposure;

(b) (a) plus residential applicator exposure;

(c) (a) plus residential post-application exposure.

The estimated aggregate risks from (a), (b) and (c) are <4% RfD, MOE = 680, and MOE = 107, respectively. These aggregate risk estimates do not exceed the Agency's levels of concern.

c. Cumulative Effects

Section 408(b)(2)(d)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanism increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether pendimethalin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pendimethalin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pendimethalin has a common mechanism of toxicity with other substances.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

An oral (LD_{50}) study (preferably mallard duck or bobwhite quail) and two subacute dietary (LC_{50}) studies (one species of waterfowl, preferably the mallard duck and one species of upland game bird, preferably bobwhite quail) are required to establish the acute and subacute toxicity of a pesticide to birds. Results of these tests are tabulated below.

Table 10: Avian Acute Oral Toxicity Findings (LD_{50})

Species	% A.I.	LD_{50} (mg/kg)	Accession No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Mallard Duck	Technical	1,421	00059739 Fink/1976	Slightly toxic	Yes

Table 11: Avian Subacute Dietary Toxicity Findings (LC_{50})

Species	% A.I.	LC_{50} (ppm)	Accession No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Northern Bobwhite Quail	Technical	4,187	00026675 Fink/1973	Slightly toxic	Yes
Mallard Duck	Technical	4,640	00026674 Fink/1973	Slightly toxic	Yes

These results indicate that pendimethalin is slightly toxic to avian species on an acute oral and subacute dietary basis. The guideline requirements (71-1(a) and 71-2(a) & (b)) are fulfilled (Accession No. 00059739, 00026675, 00026674).

(2) Birds, Chronic

Avian reproduction studies using the technical grade of the active ingredient are required because pendimethalin has been shown to have a half-life of 4 days in both field and laboratory studies. It has a high potential to bioaccumulate in fish. Pendimethalin is a widely used agrochemical with up to 25 million pounds per year applied nationwide and may be applied several times per use season on various crops. Therefore, avian reproduction studies are required for all use sites. An avian chronic hazard assessment cannot be completed without these studies. The guideline (71-4) is not fulfilled.

(3) Mammals

Data from available mammalian studies which are used for human health risk assessment will be used to estimate toxicity to wild mammalian species. A rat acute oral LD_{50} study (81-1, MRID 00026657) resulted in an LD_{50} of 1050 mg/kg for female rats and 1250 mg/kg for male rates. These results indicate that pendimethalin is slightly toxic to small mammals on an acute oral basis.

A two-generation rat reproduction study (83-4, MRID # 41725203) reported a reproductive NOEL of 2500 ppm and an LOEL of 5000 ppm.

(4) Insects

A honey bee acute contact LD_{50} study using the technical grade of the active ingredient is required for pendimethalin because of the extensive agricultural use patterns. The result of this test is provided below.

Table 12: Nontarget Insect Acute Contact Toxicity Findings

Species	% A.I.	LD_{50} (μg/bee)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Honey Bee	Tech	>49.7	00099890 Atkins/1974	Practically nontoxic	Yes

The results indicate that pendimethalin is practically nontoxic to bees on an acute contact basis. The guideline requirement (141-1) is fulfilled (MRID 00099890).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

Acute

Two freshwater fish toxicity studies using the technical grade of the active ingredient are required to establish the toxicity of a pesticide to freshwater fish. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish). Results of these tests are tabulated below.

Table 13: Freshwater Fish Acute Toxicity Findings for Technical Pendimethalin

Species	% A.I.	LC_{50} (ppm)	Accession No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Rainbow trout	93.2	0.138	106764 Sleight/1973	Highly toxic	Yes
Bluegill sunfish	93.2	0.199	106764 Sleight/1973	Highly toxic	Yes
Channel catfish	93.2	0.418	106764 Sleight/1973	Highly toxic	Yes

The results indicate that technical pendimethalin is highly toxic to fish on an acute basis. The guideline requirement (72-1(a) & (c) is fulfilled (Accession No. 106764).

Freshwater fish toxicity studies using a typical end use product were conducted. Results of these tests are tabulated below.

Table 14: Freshwater Fish Acute Toxicity Findings for the Formulated product

Species	% A.I.	LC_{50} (ppm)	Accession No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Rainbow trout	45	0.52	00037927 Bentley/1974	Highly toxic	Yes, for formulation
Bluegill sunfish	45	0.92	00037927 Bentley/1974	Highly toxic	Yes, for formulation
Channel catfish	45	1.9	000251601 Sousa/1983	Moderately toxic	Yes, for formulation

The results indicate that this formulated product of pendimethalin is highly to moderately toxic to fish on an acute basis. The guideline requirement (72-1(b) & (d)) is fulfilled (Accession No. 00037927, 000251601).

Chronic

A fish life-cycle test using the technical grade of the active ingredient is required for pendimethalin because it can be aerially applied, it has extensive use sites, many of which may occur near water bodies, and has a halflife of greater than 4 days. The preferred test species is the fathead minnow. Results of this test are tabulated below.

Table 15: Fish Life-Cycle Toxicity Findings

Species	% A.I.	NOEC/LOEC (ppb)	MATC (ppb)	Accession No. Author/Year	Endpoints Affected	Fulfills Guideline Requirement?
Fathead minnow	98.3	6.3/9.8	7.85	00096342 EG&G Bionomics/1975	Egg production reduced at 9.8 ppb; reduced hatch at 22 and 43 ppb.	Yes

The results indicate that reproductive effects to freshwater fish may occur at levels greater than 6.3 ppb (μg/L). The guideline requirement (72-5) is fulfilled (Accession No. 00096342).

(2) Freshwater Invertebrates

Acute

A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is required to assess the toxicity of a pesticide to freshwater invertebrates. The preferred test organism is *Daphnia magna*, but early instar amphipods, stoneflies, mayflies, or midges may also be used. Results of this test are tabulated below.

Table 16: Freshwater Invertebrate Toxicity for Technical Pendimethalin and the Formulated Product

Species	% A.I.	LC_{50}/EC_{50} (ppm)	Accession No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Daphnia magna	Technical	0.28	FAOPEN05 EG&G Bionomics/1976	Highly toxic	Yes
Daphnia magna	45.6	5.1	260404 Forbis/1985	Moderately toxic	Yes for formulated product
Procambarus simulans Crayfish	94.2	1.0	00099889 ABC Inc./ 1980	Highly toxic	No - supplemental

The results indicate that technical pendimethalin is highly toxic to aquatic invertebrates on an acute basis and a formulated product of pendimethalin is moderately toxic to aquatic invertebrates on an acute basis. The guideline requirement (72-2(a) & (b)) is fulfilled (Accession No. FAOPEN05 & 260404).

Chronic

Data from an aquatic invertebrate life-cycle test using *Daphnia magna* are required because pendimethalin is toxic to *Daphnia magna* (EC_{50} of 0.28 ppm), is registered for uses that involve multiple applications, and has a halflife of greater than 4 days. Results of this test are tabulated below.

Table 17: Aquatic Invertebrate Life-Cycle Toxicity Findings

Species	% A.I.	NOEC/LOEC(ppb)	MATC (ppb)	Accession No. Author/Year	Endpoints Affected	Fulfills Guideline Requirement?
Daphnia magna	92.2	14.5/35.8	22.78	247299 Gramey/1981	Mean brood size	Yes

The results indicate that aquatic invertebrate reproductive impairment may occur at levels greater than 14.5 ppb (μg/L). The guideline requirement (72-4(b)) is fulfilled (Accession No. 247299).

(3) Estuarine and Marine Animals, Acute

Acute toxicity testing with estuarine and marine organisms (fish, shrimp and oyster embryo-larvae or shell deposition) using the technical grade of the active ingredient is required for pendimethalin because of the extensive agricultural use patterns near estuarine and marine habitats and labeling permits aerial application. Results of these tests are tabulated below.

Table 18: Estuarine/Marine Acute Toxicity Findings for Technical Pendimethalin

Species	% A.I.	LC_{50}/EC_{50} (ppm)	Acc. No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Eastern oyster (embryo-larvae)	92.2	0.210	251601 Ward/1983	Highly toxic	Yes
Sheepshead minnow	92.2	0.707	251601 Ward/1983	Highly toxic	Yes
Pink shrimp	92.2	1.6	251601 Ward/1983	Moderately toxic	Yes

The results indicate that technical pendimethalin is moderately to highly toxic to estuarine/marine organisms on an acute basis. The guideline requirement (Gdln 72-3 (a), (b), & (c)) is fulfilled (Accession No. 251601).

Estuarine/marine toxicity studies using the typical end use product were provided. Results of these tests are tabulated below.

Table 19: Estuarine/Marine Acute Toxicity Findings for Formulated Product

Species	% A.I.	LC_{50}/EC_{50} (ppm)	Acc. No. Author/Year	Toxicity Category	Fulfills Guideline Requirement?
Eastern oyster (embryo-larvae)	45	0.450	251601 Ward/1983	Highly toxic	Yes, for formulation
Sheepshead minnow	45	1.7	251601 Ward/1983	Moderately toxic	Yes, for formulation
Pink shrimp	45	11	251601 Ward/1983	Slightly toxic	Yes, for formulation

The results indicate that this formulated product of pendimethalin is slightly to highly toxic to estuarine/marine organisms on an acute basis. The guideline requirement (Gdln 72-3(d), (e), & (f)) is fulfilled (Accession No. 251601).

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for pendimethalin because it is volatile (vapor pressure $\geq$1.0 x 10^{-5}mm Hg at 25°C), it can be aerially applied, and because it may affect endangered plant species which are located near the use areas.

For the seedling emergence and vegetative vigor testing the following plant species and groups should be tested: (1) six species of at least four dicotyledonous families, one species of which is soybean (Glycine max), and the second of which is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (Zea mays).

Results of Tier II seedling emergence toxicity testing on the technical material are tabulated below.

Table 20: Nontarget Terrestrial Plant Seedling Emergence Toxicity Findings (Tier II)

Most Sensitive Species	% A.I.	Parameter Affected	NOEC (lbs a.i./A)	EC_{25} (lbs a.i./A)	MRID No. Author/Year	Fulfills Guideline Requirement?
Ryegrass	92.98	Percent emergence	0.02	0.03	42372201 Chetram & Gagne/1992	Yes
		Percent survival	0.02	0.06		
		Phytotoxicity rating	0.02	N/A		
		Plant height	0.01	0.05		
		Plant weight	0.01	0.02		

These results indicate that exposure levels of greater than 0.01 lbs a.i./A may cause significant detrimental effects on certain terrestrial plants. The guideline requirement (123-2) is fulfilled (MRID 42372201).

Results of Tier II seedling germination toxicity testing on the technical material are tabulated below.

Table 21: Nontarget Terrestrial Plant Seedling Germination Toxicity Findings (Tier II)

Most Sensitive Species	% A.I.	NOEC (lbs a.i./A)	EC_{25} (lbs a.i./A)	MRID No. Author/Year	Fulfills Guideline Requirement?
Ryegrass	92.98	0.25	0.82	42372202 White & Gagne/1992	Yes

These results indicate that exposure levels of greater than 0.25 lbs a.i./A may cause significant detrimental effects on the germination of certain terrestrial plants. The guideline requirement (123-2) is fulfilled (MRID 42372202).

Results of Tier II vegetative vigor toxicity testing on the technical material are tabulated below.

Table 22: Nontarget Terrestrial Plant Vegetative Vigor Toxicity Findings (Tier II)

Most Sensitive Species	% A.I.	Parameter Affected	NOEC (lbs a.i./A)	EC_{25} (lbs a.i./A)	MRID No. Author/Year	Fulfills Guideline Requirement?
Ryegrass and lettuce	92.98	Phytotoxicity rating	0.063	N/A	42372203 Canez & Gagne/1992	Yes - classified as supplemental but fulfills guideline requirement
Onion		Percent survival	1.0	1.4		
Ryegrass		Plant height	0.063	0.10		
Ryegrass		Plant dry weight	<.035	0.035		

These results indicate that exposure levels of greater than 0.063 lbs a.i./A may cause significant detrimental effects on the vigor of certain terrestrial plants. The guideline requirement (123-2) is fulfilled (MRID 42372203).

(2) Aquatic

Aquatic plant testing is required for pendimethalin. Results of Tier II toxicity testing on the technical material are tabulated below.

Table 23: Nontarget Aquatic Plant Toxicity Findings (Tier II)

Species	% A.I.	EC_{50} (ppb)	NOEC (ppb)	MRID No. Author/Year	Fulfills Guideline Requirement?
Freshwater diatom *Navicula pelliculosa*	92.98	5.8	3.2	42372206 Hughes et al/1992	Yes
Duckweed *Lemna gibba*	92.98	12.5	5.6	42137101 Hughes et al/1991	Yes
Green algae *Selenastrum capricornutum*	92.98	5.4	3.0	42372204 Hughes et al/1992	Yes
Marine diatom- *Skeletonema costatum*	92.98	5.2	0.7	42372205 Hughes et al/1992	Yes
Blue-green algae *Anabaena flos-aquae*	92.98	> 174	98	42372207 Hughes et al/1992	Yes

These results indicate that exposure levels of greater than 0.7 ppb (μg/L) of pendimethalin may cause detrimental effects to the growth and reproduction of certain aquatic plant species. The guideline requirement (123-2) is fulfilled (MRID 42372206, 42137101, 42372204, 42372205,

42372207).

2. Environmental Fate

a. Environmental Fate Assessment

Pendimethalin dissipates in the environment by binding to soil, microbially-mediated metabolism, and volatilization. Persistence decreases with increased temperature, increased moisture and decreased soil organic carbon. Pendimethalin residues are tightly bound to soil and sediment particles. Field dissipation information on the major use sites (cotton and soybeans) that would more clearly describe the environmental fate of pendimethalin has not been submitted.

Pendimethalin is stable to sterile hydrolysis, soil photolysis, and anaerobic soil metabolism, but degrades slowly under aqueous photolysis conditions with a calculated half-life of 21 days. Aerobic soil metabolism half-lives range from 42-1322 days with 172 days used for the purpose of exposure assessment. Pendimethalin forms many minor (<10% of applied) degradates that are primarily an intact benzene ring with rearranged alkyl groups. Anaerobic aquatic metabolism half-lives ranged from 6 to 105 days. Aqueous residues of parent pendimethalin and its degradates bind to sediment in anaerobic aquatic metabolism and soil mobility studies. This is consistent with mobility studies indicating that pendimethalin is essentially immobile in all soils studied.

The calculated half-life of pendimethalin in a field study (almond orchard in California) was 34 days. Although the orchard site is not a major use site for pendimethalin, the resulting half-life is consistent with the results from the soil metabolism studies.

Pendimethalin accumulated readily in bluegill sunfish with biological concentration factors of 1400X in edible, 5800X in non-edible and 5100X in whole fish, however, depuration was rapid.

Pendimethalin may contaminate surface water from spray drift associated with aerial and ground spray application, or in runoff from rainfall events and through irrigation waters (chemigation). However, the high affinity for pendimethalin to sorb to soil and sediment particles should limit concentrations of pendimethalin in surface waters. Pendimethalin was detected in surface water samples at a maximum of 3.66 μg/L in selected Lower Great Lake Tributaries during 1982-1985. In a study of the spatial and temporal distributions of pesticides and nutrients in the Mississippi River and its tributaries, dissolved pendimethalin was not detected in surface water samples above the reporting limit of 0.018 μg/l. Surface water monitoring results found in the Storage and Retrieval of Water Quality Data (STORET) database

are a compilation of various states' monitoring data. The maximum concentration of pendimethalin was 17.6 μg/L (ppb) for a surface water sample collected in Ohio; the next highest reported concentration was 10 μg/L with a range of 1-10 μg/L. From the (STORET) data (excluding the highest Ohio sampling results), the maximum concentrations of pendimethalin in surface water samples range from 0.01 to 3.2 μg/L.

Pendimethalin has a low potential to leach to ground water in most soils. Pendimethalin has a history of high use over a wide geographic area on several major crops, however, there are few reports of detections in ground water. Specifically, residues of pendimethalin have been found in ground water in limited areas in two states. The concentrations found in ground water were relatively low, ranging from 0.2 to 0.9 ppb.

b. Environmental Fate and Transport

(1) Degradation

Abiotic Hydrolysis

Pendimethalin did not degrade in sterile aqueous buffer solutions (pH 5, 7, and 9) that were incubated in darkness at 25°C for 30 days. The guideline requirement is fulfilled (Guideline 161-1, MRID 00106777)

Abiotic and Biotic Hydrolysis

Calculated half-lives were 10-11 days (average of 10.6 days) in water containing different soil fungi and 354 days in sterile water. Three degradates were formed, which were ring rearrangements and ring additions. Zimdahl et al., 1990.

Photodegradation in Water

The calculated half-lives were 16.5 days at pH 5, 7, and 9 (MRID 43808201), and 21 days at pH 7 (MRID 00153763). The artificial light intensity for the new study was for September 13, 1990 at Princeton, New Jersey and Chicago, Illinois on June 30 and the temperature was set at 25°C. Up to 37 minor degradates were isolated, but only one degradate was identified, 2,6-dinitro-3,4-dimethyl aniline (a ring-rearrangement of parent pendimethalin with an ethylpropyl group removed from an amine group). However, the degradate did not exceed 9.3% of applied, and no other degradate reached this amount. Pendimethalin was stable in the dark controls which is consistent with the hydrolysis study. The guideline requirement is fulfilled Guideline 161-2, MRIDs 00153763;43808201)

Photodegradation on Soil

Pendimethalin did not degrade on sandy loam exposed to artificial light at 25ºC. The guideline requirement is fulfilled (Guideline 161-3, MRID 00153764).

Photolysis in Air

This study is not required because pendimethalin is tightly bound to soil and its toxicity is in Class 3. Guideline 161-4, waived on 6/27/91.

Aerobic Soil Metabolism

Pendimethalin degraded with a calculated half-life of 1322 days in sandy loam soil in a study submitted for registration. This half-life was considered an outlier and was not used in assessing the environmental fate of pendimethalin. The identified minor degradates were 2,6-dinitro-3,4-xylidine, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitro benzyl alcohol, and 4-[(1-ethylpropyl)amino]-3,5-dinitro-o-toluic acid. All of these degradates were ring rearrangements of parent pendimethalin.

The half-lives for aerobic soil metabolism ranged from 42-563 days in the literature studies referenced below with a guideline study reporting a half-life of 1322 days for a total of 27 total observations. Because of the range of values, statistical analyses of the available data were performed. The mean, median, and modal half-lives are 126, 122, and 122 days, respectively, with a standard deviation of 66 days (n=24). The half-life values of 409, 563, and 1322 days were not included in the final statistical analyses because they were greater than three standard deviations from the mean. Based on soils and crops that are normally treated with pendimethalin, the reviewer assumed that temperatures would likely range from 20-30ºC and soil moisture contents from 50-75% Field Capacity (FC). The range of observed half-lives in the above experimental conditions were 72-172 days. The 172-day half-life was used for GENeric Expected Environmental Concentration Program (GENEEC) calculations since it was the longest half-life for the observed range. Although some of the studies were conducted using foreign soils, the half-lives for foreign soils fall within the range of values seen in studies using U.S. soils. Guideline. 162-1, MRID 40185104.

Half lives were affected by study conditions. Walker and Bond (1977) evaluated the effect of moisture, temperature and different soils on soil persistence.

As indicated in Table 24, persistence decreased about 5 days for every one percent increase in moisture.

Table 24. Calculated Half-Lives of Parent Pendimethalin in Sheeps Pen Loam Soil (1.2% OC, 18.3% clay) at 25ºC (Walker and Bond, 1977).

% Moisture (Field Capacity, **FC**)	Half-Life (days)
12.5	563
25	261
37.5	225
50	239
62.5	166
75	122

As indicated in Table 25 below, persistence decreased about 15 days for every degree of temperature increase.

Table 25. Calculated Half-Lives of Parent Pendimethalin in Sheeps Pen Loam Soil (1.2 % OC, 18.3 % clay) at 75 % Field Capacity (Walker and Bond, 1977).

Temperature (ºC)	Half-life (days)
30	98
25	122
20	168
15	265
10	409

As indicated in Table 26 below, the persistence of pendimethalin generally increased with increasing soil organic carbon and clay content.

Table 26. Half-Lives of Parent Pendimethalin in Different Soils at 25ºC and 75% FC (Walker and Bond, 1977).

Soil *	% OC	% clay	Half-life (days)
Soakwaters	0.87%	27.6%	72
Gravel Pits	1.08%	20.4%	87
Gallas Leys	1.12%	37.8%	132
Sheeps Pen	1.2%	18%	129
Big Cherry	1.33%	20%	139
Pump Ground	1.75%	20.5%	127
Water Meadows	6.8%	60.4%	172

* Incomplete soil characterization information was provided.

Table 27 below reports aerobic soil metabolism half-lives.

Table 27. Calculated Half-Lives of Parent Pendimethalin in Different Soils (Zimdahl, et al., 1984).

Soil	% OC	% FC	Temperature (ºC)	Half-Life (days)
Clay loam	0.76%	50%	30	73
Clay loam	0.76%	75%	35	61
Clay loam	0.76%	75%	30	54
Clay loam	0.76%	75%	20	77
Clay loam	0.76%	75%	10	101
Clay loam	0.76%	100%	30	56
Clay	1.0%	75%	30	42
Sandy loam	0.76%	75%	30	45

As szhowsn in Table 27, persistence generally increased with increasing clay and organic carbon content. The calculated half-lives were 42-101 days in a range of soils with 0.76 and 1.0% Organic Content (OC) at 50-100% Field Capacity (FC) and 10-35ºC. Persistence decreased with increasing moisture and temperature.

Anaerobic Soil Metabolism

Pendimethalin is stable to anaerobic soil metabolism. Ninety-eight percent of parent remained after 60 days of anaerobic conditions. The identified minor degradates were 2,6-dinitro-3,4-xylidine, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitro benzyl alcohol, and 4-[(1-ethylpropyl)amino]-3,5-dinitro-o-toluic acid. The guideline requirement is fulfilled (Guideline 162-2, MRID 40185105).

Anaerobic Aquatic Metabolism

The calculated half-lives were 6, 30, 33, 45, 52, 59, 62, 63, and 105 days.

A half-life of 105 days was calculated in silt loam soil (1.2% OC) that was incubated for one week under aerobic conditions and for 8 weeks under anaerobic conditions. Only minor degradates (<2.5%) were isolated; none were identified. Less than 3% was associated with the flood water at any time in the study. (Guideline 162-3 MRID 40813501, reviewed on 6/27/91).

A half-life of 6 days was calculated for non-sterilized sandy loam pond sediment from Ontario, Canada (1.8% organic carbon) at 25ºC incubated for 39 days under anaerobic aquatic conditions. In all conditions (5ºC non-sterile, 5ºC sterile, 25ºC non-sterile, and 25ºC

sterile), aqueous residues decreased rapidly to form soil-extractable residues, followed by a rapid increase in soil-bound residues. At 5ºC and 25ºC under non-sterile conditions, aqueous residues declined to about 11.8% by 16 days and remained constant until the end of the study at 39 days. Extractable residues decreased from 60.8-70.9% at 5ºC (non-sterile) to 27% by 39 days. Many minor (<10%) degradates were isolated, and none were identified. Guideline. 162-3, MRID 43154702, reviewed for reregistration.

The calculated half-lives for 30 kilo pascals (kPa) (100% field capacity), continuous flood, and alternate wet/dry treatments were 59, 63, and 30 days, respectively, in Crowley silt loam soil (5% sand, 74% silt, 21% clay, pH 5.5, 1% OC). Soil persistence decreased with increasing soil moisture content. Alternating wet/dry conditions decreased persistence presumably by increasing the volatility during the wet cycle. Barrett and Lavy, 1983.

The calculated half-lives were 62, 52, 45, and 33 days in sterile, non-flooded; non-sterile, non-flooded; sterile, flooded; and non-sterile, flooded sandy loam soil with 60% sand, 21% silt, 19% clay, 0.35% OC, and pH 8.2. Persistence decreased with flooded conditions regardless of sterility. Three minor degradates with ring rearrangements were formed. Kulshrestha and Singh, 1992.

As reported in another study, between 45-59% of pendimethalin was bound to sediment (Matapeake silt loam, pH 5.3, 0.87% organic matter, 38.4% sand, 49.4% silt, and 12.2% clay) by 30 days. Only 11-13% of residues were associated with the aqueous phase throughout the study. Polar residues reached 54% by 2 days and >90% by 9-30 days. A total of 32% of soil residues was extractable. Isensee and Dubey, 1983.

The guideline requirement is fulfilled (Guideline-162-3, MRIDs 40813501,43154702).

(2) Mobility

Unaged Mobility (Batch Equilibrium)

Parent pendimethalin was essentially immobile in loamy sandy (0.46% OC), sandy loam (0.93% OC), silt loam (2.73% OC), loam (2.21% OC), and silty clay loam (2.91% OC), and sandy clay loam (1.5% OC) soils from the U.S. with Freundlich K_{ads} values of 30, 110, 380, 301, and 854, respectively. Desorption coefficients were not provided. K_{ocads} values were 15000, 13000, 14100, 13700, and 29400, respectively. The N values were 1.05, 1.08, 0.89, 1.20, and 0.83, respectively. The guideline requirement (Guideline 163-1) is fulfilled. MRID 00153765

Parent pendimethalin was essentially immobile in loamy sandy (0.87% OC), sandy loam (0.44% OC), sandy clay loam (0.67% OC), and sandy clay loam (1.5% OC) soils from Japan with Freundlich K_{ads} values of 61, 193, 153, and 285, respectively. Freundlich K_{des} values were 124, 284, 323, and 556, respectively. K_{ocads} values were 7011, 43863, 22835, and 19000 and K_{ocdes} values were 14252, 64545, 48208, and 37066, respectively. The N values ranged from 1.03-1.13. Guideline 163-1, MRID 43041901

Aged Mobility

Waived for reregistration since there are no significant transformation products of pendimethalin. Guideline 163-1.

Laboratory Volatility

Volatility can be significant under warm, moist conditions. The maximum volatility rate for air-dried sandy loam soil (0.8% OC) was 5.4 x 10^{-5} $\mu g/cm^2/hr$ and the maximum air concentration was 0.54 ug/m^3. The maximum volatility rate for moist (80% FC) sandy loam soil was 2.1 x 10^{-3} cm^2/hr and the maximum air concentration was 31 ug/m^3. The moist soil volatility rate and air concentration were approximately 38 times and 57 times that of the dry soil (respectively). The guideline requirement (Guideline 163-2) is fulfilled. MRID 00153766

Table 28. Volatility Half-lives (Walker and Bond, 1977).

Surface*	Half-life (days)
Bare Metal (aluminum)	6
Dry Sheeps Pen (1.2% OC, 18% clay)	96
Moist Sheeps Pen (1.2% OC, 18% clay)	37

* Incomplete soil characterization information was provided.

Volatilization of pendimethalin may be responsible for some of the accelerated rate of loss as the soil moisture increases.

(3) Accumulation

Bioaccumulation in Fish

Pendimethalin residues accumulated in bluegill sunfish exposed to 3 ppb of pendimethalin, with BCFs of 1400X for edible, 5800X for non-edible, and 5100X for whole fish. Pendimethalin comprised 68-81% of the recovered radioactivity, and the degradate 4-[(1-ethylpropyl-amino]-2-methyl-3,5-dinitro-benzyl alcohol (CL 202,347) was 2-3.1% of the recovered radioactivity. Many other minor degradates were formed, and totaled 32% of the applied radioactivity. Depuration was rapid, with 87-91% of the ^{14}C-residues eliminated from the fish tissues by 14 days of depuration. The guideline requirement is fulfilled (Guideline 165-4, MRIDs 00158235,00156726).

(4) Field Dissipation

Terrestrial Field Dissipation

No acceptable field dissipation studies were submitted for the major crops treated with pendimethalin (cotton and soybeans). The registrant should provide studies for these crops, since the orchard study in CA is not necessarily representative of soybeans and cotton. These studies can be modified to include volatility information.

The calculated half-life of pendimethalin in sandy loam soil in an almond orchard in California was 34 days. No leaching was observed below 6 inches of depth. Guideline 164-1, MRID 41722504

Walker and Bond (1977) observed that volatilization occurred more rapidly with warmer soil temperatures in English Sheeps Pen and Big Ground soils. In the field, up to 50% volatilized in 30-40 days from the first surface application, and in 12-14 days from the second surface application. Pendimethalin was lost more rapidly from surface treatments than in incorporated treatments. When incorporated, between 65-80% remained in field soil 20-23 weeks after application. Walker and Bond, 1977.

The guideline requirement (164-1) is not fulfilled. Additional studies are needed.

Aquatic Field Dissipation

Aquatic field dissipation is unsatisfied at this time since no acceptable study has been submitted to the agency. However, the registrant has conducted an aquatic field dissipation study in dry-seeded rice in Arkansas that has not yet been submitted. The guideline requirement 164-2 is not fulfilled.

(5) Spray Drift

No pendimethalin specific studies were reviewed. Droplet size spectrum (Guideline 201-1) and drift field evaluation (Guideline 202-1) studies are required for pendimethalin, since the different formulations may be applied by aircraft and it is estimated that there will be detrimental effects to non-target terrestrial and semi-aquatic plants due to drift. However, to satisfy these requirements the registrant, in conjunction with other registrants of other pesticide active ingredients, formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. During 1997 the Agency plans to evaluate these studies. In the interim, and for this assessment of pendimethalin, the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The estimated drift rates at 100 feet downwind of the treated sites are 1% at the applied spray volume from ground applications and 5% from aerial applications. After review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks of the application of pendimethalin products.

c. Water Resources

(1) Ground Water

The Agency concludes that pendimethalin has a low potential to leach to ground water in most soils. Pendimethalin exceeds all of the ground water persistence triggers, however, the high K_d and K_{oc} values demonstrate that pendimethalin will bind strongly to soil organic matter and is not mobile. There is no indication that pendimethalin would exceed any ground water LOC. Residues of pendimethalin have been found in ground water in limited areas in two states. The concentrations were relatively low, ranging from 0.2 to 0.9 ppb (μg/L). However, considering its history of high use over a wide geographic area on several major crops, there are relatively few detections in ground water.

(2) Surface Water

Pendimethalin may contaminate surface water from spray drift associated with aerial and ground spray application, or in runoff from rainfall events and through irrigation waters (chemigation). Transport of pendimethalin during runoff events which occur soon after application could be considerable due to its persistence and extensive use. The intermediate to high soil/water partitioning coefficients for pendimethalin (Freundlich K_{ad}s of 30-854 ml/g; K_{oc}s of 7011-64545) indicate pendimethalin would be transported in runoff adsorbed onto eroding soil or entrained sediment. The anaerobic aquatic metabolism and soil mobility studies both reported partitioning of pendimethalin primarily with the soil or sediment phase, and it is not partitioned into the aqueous phase.

Surface waters may be contaminated through drift from aerial and ground spray applications. Pendimethalin is aerially applied to 50% of the treated rice fields, <15% of the treated cotton acres, and <5% for all other treated crops. Based on the environmental fate assessment, volatilization losses of pendimethalin following aerial applications may also be important. At this time, spray drift information is unavailable; however, the registrant is a participating member of the SDTF and data from the SDTF have been submitted and are under review.

In receiving surface water bodies, pendimethalin is moderately persistent (anaerobic aquatic metabolism half-life of 60 days). Pendimethalin is stable to hydrolysis; however, it degrades by aqueous photolysis (half-lives of 17-21 days) and should dissipate fairly rapidly in shallow water exposed to sunlight. Volatilization of pendimethalin from well-mixed surface waters may be an important transport process because greater volatilization was observed under moist field conditions

(maximum of 50% volatilized from moist soils in field studies) than for dry soils. The reported vapor pressure of 2.9×10^{-6} Torr at 20°C and estimated Henry's Law Constant of 2.2×10^{-5} atm-m^3-mol^{-1} support the conclusion of volatility as a significant transport mechanism.

Pendimethalin is not regulated under the Safe Drinking Water Act (SDWA); therefore, a Maximum Contaminant Level (MCL) has not been established for it. Pendimethalin is classified in Toxicity Category III based on the Oral LD_{50} from a rat study and has been classified as a Group C nonquantifiable carcinogen by the HED Carcinogenicity Peer Review Committee.

Monitoring Data

Baker (1988) studied sediment, nutrient, and pesticide transport in selected Lower Great Lake Tributaries during 1982-1985. Pendimethalin was detected in surface water samples from numerous river transport stations. Maximum concentrations of pendimethalin were 3.66 μg/L (Upper Honey Creek) for 1983; 1.25 μg/L (Honey Creek) for 1984, and 0.31 μg/L (Lost Creek) for 1985. The maximum concentrations for pendimethalin in stream water samples for selected Lower Great Lakes Tributaries are summarized in Table 29 (Baker, 1988).

Table 29. Maximum Concentrations of Pendimethalin for 1982-1985 (Baker, 1988)

SAMPLING LOCATION	1982	1983 (μg/L)	1984 (μg/L)	1985 (μg/L)
Maumee River	n/a	0.269	0.666	0.0
Sandusky River	n/a	0.371	0.570	0.130
Honey Creek	n/a	0.623	1.248	0.230
Rock Creek	n/a	0.470	0.276	0.0
U. Honey Creek	n/a	3.660	0.055	0.0
Lost Creek	n/a	3.455	0.346	0.310
River Raisin	n/a	0.333	0.080	0.0
Cuyahoga River	n/a	1.057	0.139	0.0

Note: data for 1984 and 1985 were corrected for recoveries less than 100%.

In a study of the spatial and temporal distributions of pesticides and nutrients in the Mississippi River and its tributaries, Coupe et al. (1993) did not detect dissolved pendimethalin in surface water samples above the reporting limit of 0.018 μg/L. These study results suggest pendimethalin would not be present in public drinking water. The sampling period was April, 1991 to September, 1992 for eight sampling

stations (three on the Mississippi, and one each on the Ohio, Illinois, Missouri, Platte, and White Rivers). The USGS study focused on selected pesticides associated with agriculture row crop production and employed extensive field and laboratory quality assurance procedures to generate high-quality monitoring data.

A summary of the pendimethalin detections in the STORET database are shown in Table 30. The surface water monitoring results found in the STORET database are a compilation of various states' monitoring data. The STORET data does not have strict quality assurance criteria. The maximum concentration of pendimethalin was 17.6 μg/L (ppb) for a surface water sample collected in Ohio; the next highest reported concentration was 10 μg/L with a range of 1-10 μg/L. From the STORET data (excluding the highest Ohio sampling results), the maximum concentrations of pendimethalin in surface water samples range from 0.01 to 3.2 μg/L.

Table 30. Summary of Pendimethalin Detections in STORET database

STATE	MONITORING PERIOD	DETECTIONS/ SAMPLES	MAXIMUM CONCENTRATION -- μg/L --
AR	1995	12/35	0.08
CA	1992-94	20/291	0.30
CO	1993-94	32/92	3.2
CT	1993-94	2/2	0.12
KS	1993	1/1	0.01
LA	1995	2/2	0.06
NE	1992-93	17/71	0.07
OH	1981-87	650/2436	17.6
OR	1992-95	8/64	0.25
PA	1993-95	56/207	0.24
TX	1995	1/1	0.04
WA	1993-94	26/81	0.19
WI	1993-94	16/122	0.05

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 LOCs. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, e.g. the LC_{50}. The acute effect levels typically are:

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

The chronic test results are the:

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

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

Levels of Concern (LOC) and associated Risk Presumption

Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	Potentially 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	Chronic risk, endangered species maybe affected chronically

Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	Potentially 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	Chronic risk, endangered species may be affected chronically

Plants

IF THE	LOC	PRESUMPTION
RQ>	1	Potentially high risk
RQ (using the NOEC or EC05) >	1	Endangered plants may be affected

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

Pendimethalin use patterns addressed in risk assessment: Pendimethalin is used on a wide variety of agricultural crops as well as many non-agricultural use sites. The following application rates and use patterns were assessed. These were based on labels and registrant information:

Terrestrial Animals and Terrestrial and Semi-aquatic Plants: The majority of use sites have a maximum use rate of 2.0 lbs ai/A or less. This includes such sites as corn, cotton, beans, grain sorghum, peanuts (1 lb ai/A), soybeans, rice (1 lb ai/A) and some others. These use sites make up over 90% of pendimethalin usage based on pounds applied annually. Risk based on this rate is considered to be typical for pendimethalin. However, there are some use sites that have higher single application rates and higher maximum seasonal rates. Although these make up less than 10% of pendimethalin usage, they still represent several million pounds of ai applied annually. These include:

Turf (max. single = 3 lb ai/A, max. seasonal = 5 lbs ai/A),
Onions (max. single = 2 lbs ai/A, max. seasonal = 6 lbs ai/A),
Sugarcane (max. single = 4 lbs ai/A, max. seasonal = 6 lbs ai/A) and
Ornamentals, landscape sites, non-cropland and alfalfa grown for seed (max. single = 4 lbs ai/A, max. seasonal = 4 lbs ai/A).

Aquatic Animals and Plants: Aquatic EECs were calculated using GENEEC for the following use rates and patterns

1) 1.0 lb ai/A - typical application rate applied once on a variety of agricultural crops including cotton, corn, and soybeans, both ground and aerial,

2) 2.0 lbs ai/A - maximum single application rate for cotton, soybeans, corn and other use patterns having a maximum application rate of 2 lbs ai/A, both ground and aerial,

3) 1.0 lbs ai/A - typical application rate for cotton, applied twice, with a two week application interval, both ground and aerial application,

4) 4 lbs ai/A for alfalfa grown for seed and sugarcane, applied once per season, both ground and aerial application, and

5) 2 lbs ai/A for onions applied 3 times per season at two week intervals, both ground and aerial application.

Aquatic EECs were not estimated for rice (1.0 lb ai/A), turf, ornamental, landscape & grounds maintenance, non-cropland, and nonbearing nuts and vines (use rates of 3 and 4 lbs ai/A, ground application only). GENEEC is a model designed specifically to model runoff from certain agricultural fields and the risk assessment team did not consider it appropriate for sites such as these. It is assumed, for assessment purposes, that exposure from these use patterns would not be higher than exposure from other uses where GENEEC was used to estimate exposure. Exposure from the rice use is not expected to be greater than from the cotton use at 1.0 lb ai/A. Rationale for this is provided in Section (4) Environmental Risk Characterization.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Residues found on dietary food items following application are compared to LC_{50} values to predict hazard to birds. Day 0 residues on vegetation were estimated based on the work of Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994) for application rates of 4.0 lbs, 3.0 lbs and 2.0 lbs ai/A. For cotton (1.0 lb ai/A), the highest (peak) residues after the second application were estimated using a computerized dissipation program that calculates daily estimated residues after repeated applications and first-order dissipation kinetics at an assumed rate. The use rate per application is 1.0 lb ai/A with a between application interval of two weeks (14 days), during which time the residues from the first application would partially degrade. The aqueous photolysis half-life of 21 days was used to estimate the degradation of pendimethalin on vegetation.

The predicted 0 day maximum of pendimethalin that may be expected to occur on different avian food items following various applications of pendimethalin, and their corresponding risk quotients, are presented in the table below:

Table 31: Estimated Environmental Concentrations and Dietary Risk Quotients for Birds (Based on an LC_{50} = 4,187 ppm)

Avian Food items	EEC - ppm 4.0 lbs ai/A	RQ Acute	EEC - ppm 3.0 lbs ai/A	RQ Acute	EEC - ppm 2.0 lbs ai/A	RQ Acute	EEC - ppm 1.0 lbs ai/A	RQ Acute
Short Grasses	960	**0.2**	720	**0.2**	480	0.1	391	<0.1
Long Grasses	440	0.1	330	0.08	220	<0.1	180	<0.1
Broadleaf Plants and insects	540	0.1	405	0.1	270	<0.1	220	<0.1
Fruits and pods	60	<0.1	45	<0.1	30	<0.1	24	<0.1

Pendimethalin has low acute toxicity to birds, therefore, the risk quotients are small. The LOC for endangered species (0.1) has been slightly exceeded for the turf use (3.0 application rate) and smaller acreage use sites (4.0 lbs ai/A). Therefore, there is the potential that endangered species may be affected, specifically grazers. The risk quotients at 3.0 and 4.0 lbs ai/A are approximate to the restricted use LOC (0.2). However, the use of pendimethalin is expected to pose minimal overall acute risk to avian species, as further described in Section 4 Environmental Risk Characterization.

Chronic risk to avian species cannot be determined at this time due to lack of data.

(b) Mammals

Mammals are assumed to be exposed to dietary residues similar to birds. The EEC's calculated in Table 22 will be used to estimate exposure to mammals.

Small mammal acute risk is usually addressed using acute oral LD_{50} values converted to estimate an LC_{50} value for comparison with dietary exposure. However, in the case of pendimethalin, it was determined that the 2-generation reproductive toxicity study with rats which reported no mortality at 2500 ppm (NOEL for acute and subacute effects) was a better indicator of potential for acute toxicity from dietary exposure. The maximum estimated concentration on mammalian food items is 960 ppm. Because the maximum EEC is much less than the NOEL, where no effects, either sublethal or lethal, occurred, it is unlikely that mammals, including endangered mammal species, would be exposed to enough pendimethalin to cause adverse effects.

Based on the same 2-generation reproductive toxicity study in rats, minimal chronic risk to mammalian species, including endangered species, is expected. The NOEL of 2500 ppm is much higher than the maximum EEC of 960 ppm.

(c) Insects

Pendimethalin is practically non-toxic to honeybees. Honeybees are not likely to be adversely affected by the use of pendimethalin.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations: The Agency calculated Generic Estimated Environmental Concentrations (GEECs) for pendimethalin application to a variety of crops at several different rates and application patterns. These GEECs are designed as a coarse screen and depend on basic chemical parameters and pesticide label application information. The GENeric Expected Environmental Concentration Program (GENEEC) which was used to calculate the GEECs is a Tier I model which uses a chemical's soil/water partition coefficient and degradation half-life values to estimate runoff from a ten hectare field into a one hectare by two meter deep pond. GENEEC was designed to specifically model runoff from agricultural fields.

GENEEC calculates both acute and chronic generic EEC values. It considers reduction in dissolved pesticide concentration due to adsorption of pesticide to soil or sediment, incorporation, degradation in soil before washoff to a water body, direct deposition of spray drift into the water body, and degradation of the pesticide within the water body. Review of the Spray Drift Task Force data has not been completed, so spray drift is assumed to be 1% of the application rate for ground applications and 5% of the application rate for aerial applications.

The following values were used for input into the GENEEC program:

Soil organic carbon partitioning coefficient:	7011
Soil aerobic metabolic half-life	172 days
Hydrolysis half-life:	Stable
Photolysis half-life:	Stable
Aquatic aerobic metabolic half-life	Stable
Water solubility:	375 ppb

Table 32: Generic EECs for Pendimethalin

Crop	Application Method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	4-day EEC (ppb)	21-day EEC (ppb)	56-day EEC (ppb)
Soybeans, Cotton, Corn	Broadcast - ground	1.0 (1) typical rate	3	3	2	1
Soybeans, Cotton, Corn	Aerial	1.0 (1) typical rate	5	4	2	1
Soybeans, Cotton, Corn	Broadcast - ground	2.0 (1) maximum rate	7	6	3	2
Soybeans, Cotton, Corn	Aerial	2.0 (1) maximum rate	10	8	4	3
Cotton	Broadcast - ground	1.0 (2) typical rate - 2 week application interval	7	6	3	2
Cotton	Aerial	1.0 (2) typical rate - 2 week application interval	10	9	5	3
Sugarcane, Alfalfa (grown for seed)	Broadcast- ground	4.0 (1) maximum rate	13	12	6	4
Sugarcane, Alfalfa (grown for seed)	Aerial	4.0 (1) maximum rate	19	17	9	5
Onions	Broadcast - ground	2.0 (3) maximum rate - 2 week application interval	20	17	9	6
Onions	Aerial	2.0 (3) maximum rate - 2 week application interval	31	27	14	9

Peak exposure levels range from 3 to 31 ppb (μg/L), with 56-day average values ranging from 1 to 9 ppb (μg/L).

Since one application at 2.0 lbs ai/A yielded essentially the same GEEC as that from two applications at 1.0 lb ai/A, both of these scenarios will be combined in the risk quotient tables.

(a) Freshwater Fish

Table 33: Acute Risk Quotients (RQ) for Freshwater Fish based on Testing with Technical Pendimethalin

Crop and application method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Species	96 hour LC_{50} (ppb)	Acute RQ
Soybeans, Cotton and Corn - ground	1.0 (1) - typical	3	Rainbow trout	138	0.02
Soybeans, Cotton and Corn - aerial	1.0 (1) - typical	5			0.04
Soybeans, Cotton and Corn - ground	2.0 (1) - maximum rate	7			0.05
Soybeans, Cotton and Corn - aerial	2.0 (1) - maximum rate	10			**0.07**
Sugarcane, Alfalfa - ground	4.0 (1) - maximum rate	13			**0.09**
Sugarcane, Alfalfa - aerial	4.0 (1) - maximum rate	19			**0.14**
Onions - ground	2.0 (3) - maximum rate 14 day appl. interval	20			**0.14**
Onions - aerial	2.0 (3) - maximum rate 14 day appl. interval	31			**0.22**

Acute

The majority of pendimethalin use is represented by the 1.0 and 2.0 lb ai/A application rates. At the typical rate of 1.0 lb ai/A, no LOCs are exceeded. This suggests fish are not typically at acute risk from pendimethalin.

When using maximum application rates, all use patterns except 2.0 lbs ai/A, ground application, result in acute risk quotients for fish that exceed the endangered species LOC (0.05). Thus, pendimethalin may affect endangered fish species under these conditions.

Use patterns involving higher application rates such as sugarcane and alfalfa and onions result in acute risk quotients for fish that exceed the restricted use LOC (0.1) by a small margin.

The Agency assumes that aquatic risk from turf (1.5 to 3.0 lbs ai/A, label indicates ground application only) and landscaping, ornamentals and non-cropland (2.0 to 4.0 lbs ai/A, label indicates ground application only) are not higher that risk from other "ground application" use patterns with similar application rates. Therefore, it is assumed turf, landscaping, ornamentals and noncropland could affect endangered fish species but would not exceed the restricted use LOC.

Aquatic EECs were not estimated for rice since GENEEC was not designed to estimate aquatic exposure from this use pattern. Aquatic risk from rice (1.0 lb ai/A) is expected to be less than from the cotton use at 1.0 lb ai/acre as discussed in the Environmental Risk Characterization Section.

None of the use patterns for pendimethalin result in acute risk quotients for fish that exceed 0.5. Thus, high acute risk to fish is unlikely.

Chronic

Based on the MATC from the fathead minnow full life-cycle study 7.85 ppb (μg/L) and the 56-day average GEECs, most use sites represent minimal chronic risk to fish.

The 56-day average GEEC for *Onions* (4.0 lbs ai/acre, aerial), 9 ppb (μg/L), exceeds the MATC by a small margin indicating potential for chronic risk to fish.

Turf, landscape, ornamental, non-cropland and rice uses are expected to result in minimal chronic risk to fish.

(b) Freshwater Invertebrates

Table 34: Acute Risk Quotients (RQ) for Freshwater Aquatic Invertebrates based on Testing with Technical Pendimethalin

Crop and application method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Species	96 hour LC_{50} (ppb)	Acute RQ
Soybeans, Cotton and Corn - ground	1.0 (1) - typical rate	3	*Daphnia magna*	280	0.01
Soybeans, Cotton and Corn - aerial	1.0 (1) - typical rate	5			0.02
Soybeans, Cotton and Corn - ground	2.0 (1) - maximum rate	7			0.02
Soybeans, Cotton and Corn - aerial	2.0 (1) - maximum rate	10			0.04
Sugarcane, Alfalfa - ground	4.0 (1) - maximum rate	13			0.05
Sugarcane, Alfalfa - aerial	4.0 (1) - maximum rate	19			**0.07**
Onions - ground	2.0 (3) - maximum rate 14 day appl. interval	20			**0.07**
Onions - aerial	2.0 (3) - maximum rate 14 day appl. interval	31			**0.11**

Acute

Use patterns such as cotton, corn and soybeans involving an application rate of 1.0 to 2.0 lbs ai/A (aerial or ground) do not result in acute risk quotients for aquatic invertebrates that exceed any LOCs. These use patterns represent minimal acute risk to aquatic invertebrates.

Sugarcane and alfalfa, when treated by aerial equipment at 4 lbs ai/A and onions when treated three times at 2.0 lbs ai/A result in acute risk quotients for aquatic invertebrates that exceed the endangered species LOC (0.05) by a small margin.

Aerial application to onions (three times at 2.0 lbs ai/A) results in acute risk that exceeds the restricted use LOC (0.1) by a small margin.

The Agency assumes that aquatic risk from turf (1.5 to 3.0 lbs ai/A, label indicates ground application only) and ornamentals and non-cropland (2.0 to 4.0 lbs ai/A, label indicates ground application only) are not greater than risk from other use patterns with similar application rates. Therefore, it is assumed these use patterns may affect endangered aquatic invertebrates but would not be expected to exceed the restricted use LOC.

Aquatic EECs were not estimated for rice since GENEEC was not designed to estimate aquatic exposure from this use pattern. Aquatic risk from rice (1.0 lb ai/A) is expected to be less than from the cotton use at 1.0 lb ai/A as discussed in the Environmental Risk Characterization Section. The rice use does not exceed the aquatic invertebrate endangered species LOC.

None of the use patterns for pendimethalin result in acute risk quotients that exceed 0.5. Thus, high acute risk to aquatic invertebrates is unlikely.

Chronic

Based on the aquatic invertebrate MATC from the *Daphnia magna* life-cycle study 23 ppb (μg/L) and 21-day average Generic EECs, the use of pendimethalin represents minimal chronic risk to aquatic invertebrates.

Turf, landscape, ornamental, non-cropland, and rice uses are expected to result in minimal chronic risk to aquatic invertebrates.

(c) Estuarine and Marine Animals

Table 35: Acute Risk Quotients (RQ) for Eastern Oyster based on Testing with Technical Pendimethalin

Crop and application method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Species	48-hour EC_{50} (ppb)	Acute RQ
Soybeans, Cotton and Corn - ground	1.0 (1) - typical rate	3	Eastern oyster	210	0.01
Soybeans, Cotton and Corn - aerial	1.0 (1) - typical rate	4			0.02
Soybeans, Cotton and Corn - ground	2.0 (1) - maximum rate	7			0.03
Soybeans, Cotton and Corn - aerial	2.0 (1) - maximum rate	10			0.05
Sugarcane, Alfalfa - ground	4.0 (1) - maximum rate	13			**0.06**
Sugarcane, Alfalfa - aerial	4.0 (1) - maximum rate	19			**0.09**
Onions - ground	2.0 (3) - maximum rate 14 day appl. interval	20			**0.09**
Onions - aerial	2.0 (3) - maximum rate 14 day appl. interval	31			**0.14**

Acute

Risk quotients shown are only for the eastern oyster, which had the lowest EC50 of the three estuarine species tested. Risk quotients using the acute toxicity for shrimp and fish would not have exceeded any LOCs. Minimal acute risk to **shrimp** and **estuarine fish** is expected from all pendimethalin uses.

Use patterns such as cotton, corn and soybeans involving an application rate of 1.0 to 2.0 lbs ai/A (aerial or ground) do not result in risk quotients for oysters that exceed any LOCs. These use patterns represent minimal acute risk to estuarine species.

Sugarcane and alfalfa, when treated by air at 4 lbs ai/A and onions when treated three times at 2.0 lbs ai/A result in acute risk quotients for oysters that exceed the endangered species LOC (0.05) by a small margin.

Aerial application to onions (three times at 2.0 lbs ai/A) results in acute risk quotients that exceed the restricted use LOC (0.1) by a small margin.

The Agency assumes that aquatic risk from turf (1.5 to 3.0 lbs ai/A, label indicates ground application only) and ornamentals and non-cropland (2.0 to 4.0 lbs ai/A, label indicates ground application only) are not greater than risk

from other use patterns with similar application rates. Therefore, these use patterns may effect endangered mollusk species but would not be expected to exceed the restricted use LOC.

Aquatic EECs were not estimated for rice since GENEEC was not designed to estimate aquatic exposure from this use pattern. Aquatic risk from rice (1.0 lb ai/A) is expected to be less than from the cotton use at 1.0 lb ai/A as discussed in the Environmental Risk Characterization Section.

None of the use patterns for pendimethalin result in acute risk quotients that exceed 0.5. Thus, high acute risk to estuarine fish or invertebrates is unlikely.

Chronic

No chronic data with estuarine species were reviewed.

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-Aquatic

The Agency does separate risk assessments for nontarget terrestrial and semi-aquatic plants. Nontarget terrestrial plants inhabit non-aquatic areas which are generally well drained. Nontarget semi-aquatic plants inhabit low-lying areas that are usually wet, although they may be dry during certain times of the year. Semi-aquatic plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. Both the terrestrial and semi-aquatic plants are exposed to pesticides from runoff and drift. They differ, however, in that terrestrial plants are assumed to be exposed via sheet runoff, whereas semi-aquatic plants are assumed to be exposed via channelized runoff. Calculating runoff exposure is done using a simple model which assumes that a certain percent of that which is applied transports with run off. The percent is based on solubility. Since the solubility is 0.375 ppm, it is assumed no more than 1% of the applied pendimethalin would runoff. Drift from aerial applications is assumed to be 5%, while drift from ground applications would not be expected to exceed 1% of the applied.

Volatilization is also a potential route of exposure, however ecological risk assessment techniques are not currently available to determine risk from such exposure.

Nonendangered Terrestrial and Semi-aquatic Plants

Risk quotients for terrestrial and semi-aquatic plants are derived by dividing an exposure estimate, in lb ai/A, by an EC_{25}, also expressed in lb ai/A. The total loading rate (runoff plus spray drift) is used with the EC_{25} of the

most sensitive species in the seedling emergence study to determine the risk quotient for exposure to emerging seedlings. The loading from spray drift alone is used with the EC_{25} value of the most sensitive species in the vegetative vigor study to determine the risk to adult plants from foliar exposure.

The following table outlines the acute risk quotients to terrestrial and semi-aquatic plants using results from toxicity testing with technical pendimethalin.

Table 36: Exposure and Risk Quotients for Terrestrial and Semi-aquatic Plants

Application scenario & rate	**Plant type**	**Exposure scenario**	**Exposure (lb ai/A)**	**EC_{25} (lb ai/A)**	**Risk Quotient**
Ground, 2.0 lb ai/A (corn, soybeans and cotton, onions*)	Terrestrial	Sheet runoff + spray drift (1%)	0.04	0.02 (seedling emergence)	2
	Semi-aquatic	Channelized runoff + spray drift (1 %)	0.22	0.02 (seedling emergence)	11
	Terrestrial & semi-aquatic	Spray drift (1%)	0.02	0.035 (veg. vigor)	<1
Aerial, 2.0 lb ai/A (corn, soybeans and cotton, onions*)	Terrestrial	Sheet runoff + spray drift (5%)	0.12	0.02 (seedling emergence)	6
	Semi-aquatic	Channelized runoff + spray drift (5 %)	0.30	0.02 (seedling emergence)	15
	Terrestrial & semi-aquatic	Spray drift (5%)	0.10	0.035 (veg. vigor)	2.8
Ground, 3 lb ai/A (turf)	Terrestrial	Sheet runoff + spray drift (1%)	0.06	0.02 (seedling emergence)	3
	Semi-aquatic	Channelized runoff + spray drift (1 %)	0.33	0.02 (seedling emergence)	16.5
	Terrestrial & semi-aquatic	Spray drift (1%)	0.03	0.035 (veg. vigor)	<1
Ground, 4 lb ai/A (Ornamentals, landscape sites, non-cropland, nonbearing nuts and vines, alfalfa grown for seed, sugarcane)	Terrestrial	Sheet runoff + spray drift (1%)	0.08	0.02 (seedling emergence)	4
	Semi-aquatic	Channelized runoff + spray drift (1 %)	0.44	0.02 (seedling emergence)	22
	Terrestrial & semi-aquatic	Spray drift (1%)	0.04	0.035 (veg. vigor)	1

Application scenario & rate	Plant type	Exposure scenario	Exposure (lb ai/A)	EC_{25} (lb ai/A)	Risk Quotient
Aerial, 4 lb ai/A (alfalfa grown for seed, sugarcane)	Terrestrial	Sheet runoff + spray drift (5%)	0.24	0.02 (seedling emergence)	12
	Semi-aquatic	Channelized runoff + spray drift (5 %)	0.60	0.02 (seedling emergence)	30
	Terrestrial & semi-aquatic	Spray drift (5%)	0.20	0.035 (veg. vigor)	6

*Cotton and onion use involves multiple applications, however, the model used to estimate exposure does not handle multiple applications well. It is expected that the risk numbers could be higher with more applications at 2 lbs ai/A.

The LOC (1) for risk to terrestrial and semi-aquatic plant species has been exceeded for both ground and aerial application. This indicates that pendimethalin poses a risk to the vegetative vigor and emergence of nontarget terrestrial and semi-aquatic plants.

Endangered Terrestrial and Semi-aquatic Plants

Risk quotients for endangered terrestrial and semi-aquatic plants are derived by dividing an exposure estimate, in lb ai/A, by an NOEC, also expressed in lb ai/A. The lowest NOEC for terrestrial plants is 0.01 lb ai/A (ryegrass, seedling emergence). The risk quotients for endangered plants based on this NOEC compared to the range of exposures predicted would be from 4 to 60. This indicates that pendimethalin may affect threatened and endangered terrestrial and semi-aquatic plants.

(b) Aquatic

The same aquatic exposure values used to estimate risk to fish and invertebrates will be used to estimate risk to aquatic plants.

Nonendangered Aquatic Plants

Risk quotients for nonendangered plants are calculated for aquatic plants by dividing the GEEC by the aquatic plant EC_{50} values. A risk quotient for aquatic vascular plants is based on the EC_{50} of 12.5 ppb (μg/L) for duckweed (*Lemna gibba*). A risk quotient for nonvascular aquatic plants is based on the most sensitive algal or diatom species tested. For pendimethalin, the most sensitive nonvascular plant tested was the marine diatom *Skeletonema costatum* with an EC50 of 5.2 ppb (μg/L).

The following table outlines the risk quotients for nonendangered aquatic plants using results from toxicity testing with technical pendimethalin.

Table 37: Risk Quotients (RQ) for Vascular Aquatic Plants

Crop and application method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Species	EC_{50} (ppb) [NOEC]	RQs [End Spec]
Soybeans, Cotton and Corn - ground	1.0 (1) - typical rate	3	*Lemna gibba*	12.5 [5.6]	0.2 [0.5]
Soybeans, Cotton and Corn - aerial	1.0 (1) - typical rate	5			0.4 [0.9]
Soybeans, Cotton and Corn - ground	2.0 (1) - maximum rate	7			0.6 **[1.2]**
Soybeans, Cotton and Corn - aerial	2.0 (1) - maximum rate	10			0.8 **[1.8]**
Sugarcane, Alfalfa - ground	4.0 (1) - maximum rate	13			1.0 **[2.3]**
Sugarcane, Alfalfa - aerial	4.0 (1) - maximum rate	19			**1.5 [3.4]**
Onions - ground	2.0 (3) - maximum rate 14 day appl. interval	20			**1.5 [3.6]**
Onions - aerial	2.0 (3) - maximum rate 14 day appl. interval	31			**2.5 [5.5]**

Table 38: Risk Quotients (RQ) for non-vascular plants (representing algae and diatoms)

Crop and application method	Application Rate in lbs a.i./A (number of apps.)	Peak EEC (ppb)	Species	EC_{50} (ppb) [NOEC]	RQs [End Spec]
Soybeans, Cotton and Corn - ground	1.0 (1) - typical rate	3	*Skele-tonema costatum*	5.2 [0.7]	0.6 **[4.3]**
Soybeans, Cotton and Corn - aerial	1.0 (1) - typical rate	5			0.1 **[7.1]**
Soybeans, Cotton and Corn - ground	2.0 (1) - maximum rate	7			**1.3 [10.0]**
Soybeans, Cotton and Corn - aerial	2.0 (1) - maximum rate	10			**2.0 [14.3]**
Sugarcane, Alfalfa - ground	4.0 (1) - maximum rate	13			**2.5 [18.6]**
Sugarcane, Alfalfa - aerial	4.0 (1) - maximum rate	19			**3.6 [27.1]**
Onions - ground	2.0 (3) - maximum rate 14 day appl. interval	20			**3.8 [28.6]**
Onions - aerial	2.0 (3) - maximum rate 14 day appl. interval	31			**6.0 [44.3]**

Typical application rates for many of the large acreage crops for which pendimethalin is registered do not represent a risk to aquatic plants. However, uses of pendimethalin at maximum rates are expected to result in risk to aquatic plants for all sites.

Endangered Aquatic Plants

Risk quotients for endangered aquatic plants are calculated by dividing the GEEC by the aquatic plant NOEC or EC05 values. Risk quotients for endangered aquatic plants are based on the NOEC of 5.6 ppb (μg/L) for duckweed (*Lemna gibba*) and the NOEC of 0.7 for *Skeletonema costatum*. The risk quotients for endangered aquatic plants range from less than 1 (*L. gibba*, soybeans, cotton and corn, 1.0 lbs ai/A, ground) to a high of 44 (*S. costatum*, onions, three applications of 2 lbs ai/A, aerial). All uses of pendimethalin may affect endangered aquatic plants.

(4) Endangered Species

The use of pendimethalin may adversely effect endangered species of terrestrial and semi-aquatic plants, aquatic plants and invertebrates including mollusks, fish, and birds (specifically grazers).

When the Endangered Species Protection Program becomes final, limitations in the use of pendimethalin may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

b. Environmental Risk Characterization

Pendimethalin is a dinitroaniline herbicide registered for use on annual grasses and broadleaf weeds in terrestrial food crop and terrestrial non-food crop use groups. It is a cell growth inhibitor that prevents seedling development and is herbicidally active on the roots and coleoptiles of susceptible weeds. Pendimethalin does not control weeds postemergence and must be soil applied. Formulations include a 3.3 emulsifiable concentrate, a 4.0 emulsifiable concentrate, a 60DG water dispersible granule, and a fertilizer formulation. Application rates range from 1.0 to 4.0 lbs ai/A. Total pendimethalin use ranges from 14 to 25 million pounds active ingredient annually, with the largest usage occurring on soybeans, cotton, and corn.

(1) Environmental Fate and Water Resources

Pendimethalin dissipates in the environment by binding to soil, microbially-mediated metabolism, and volatilization. Persistence decreases with increased temperature, increased moisture and decreased soil organic carbon. Pendimethalin forms many minor (<10% of applied) degradates. Residues are

tightly bound to soil particles and in aquatic environments, pendimethalin and its degradates are primarily associated with the sediment and not the aqueous phase. Pendimethalin accumulates readily in bluegill sunfish, however, depuration is also rapid. Field dissipation studies on the major use sites (cotton and soybeans) that would more clearly describe the environmental fate of pendimethalin in the field have not been submitted and are requested. The purpose of these studies is to determine the dissipation routes of pendimethalin and the potential for off site effects from its use.

Pendimethalin may contaminate surface water from spray drift associated with aerial and ground spray application, or in runoff from rainfall events and through irrigation waters (chemigation). Pendimethalin is not regulated under the Safe Drinking Water Act (SDWA), therefore, an MCL has not been established for it. Pendimethalin has been classified as a Group C nonquantifiable carcinogen by the HED Carcinogenicity Peer Review Committee (RCAB risk assessment summary, 1/17/96). Pendimethalin has been detected in surface water samples at concentrations of <0.01 ppb (μg/L) to approximately 3 ppb (μg/L), and two additional higher values of 10 and 17.6 ppb (μg/L). The high affinity for pendimethalin to bind to soil and sediment particles, should limit concentrations of pendimethalin in surface waters.

The high K_d and K_{oc} values demonstrate that pendimethalin will bind strongly to soil organic matter and is not mobile. The Agency concludes that pendimethalin has a low potential to leach to ground water in most soils. Pendimethalin has a history of high use over a wide geographic area on several major crops, however the number of reported detections in ground water is small and the concentrations are relatively low. Pendimethalin residues in drinking water do not appear to be a human health concern. Pendimethalin residues originating from ground water also do not appear to be a concern to organisms such as aquatic plant, terrestrial plants, birds, fish and most aquatic invertebrates. The potential for ground water contamination from pendimethalin residues is low and the potential risk from residues in drinking water is low.

(2) Risk to Nontarget Species

According to the registrant, the typical application rate for the major uses of pendimethalin is 2 lbs ai/A. Except for the avian chronic risk which could not be determined, generally at this rate there is expected to be minimal acute risk to birds, minimal acute and chronic risk to fish and aquatic invertebrates, minimal acute risk to estuarine organisms and moderate risk to plants. Use rates higher than 2 lb ai/A are less than 10% or 2,000,000 lbs of pendimethalin total usage. These use rates did result in some LOC exceedances.

Birds: The *acute* risk to birds from pendimethalin is low. The risk

quotients (RQs) do not exceed the levels of concern (LOCs) for potentially high acute risk or restricted use. The avian endangered species LOC has been slightly exceeded for the turf and other uses with application rates of 3.0 lbs ai/A or higher. The slight exceedance (RQ of 0.2 compared to LOC of 0.1) was based on the maximum residues from the application rates of 3.0 and 4.0 lbs ai/A on short grasses. The species that may be affected would be primarily grazers (e.g. geese).

The avian acute RQs from the 2 lbs. ai/A rate do not exceed any LOCs. Thus the typical usage of pendimethalin is considered to represent minimal acute risk to birds.

Chronic risk to avian species cannot be determined because avian reproduction studies have not been submitted. Avian reproduction studies (preferably with the bobwhite quail and the mallard duck) are requested.

Mammals: Both the *acute* and *chronic* risk to mammals, including endangered species, is expected to be minimal. In a 2-generation reproductive toxicity study in rats a NOEL of 2500 ppm was reported. This NOEL is much higher than the maximum EEC of 960 ppm, therefore, it is unlikely that animals would be exposed to pendimethalin residues high enough to cause adverse effects.

Fish and Aquatic Invertebrates: The overall risk to nontarget aquatic animals from pendimethalin is low.

Fish: The LOC for *acute* effects to endangered freshwater fish species was equaled, or exceeded by small margins, by all use sites that are treated aerially at 2 lbs ai/A or higher (R.S. ranged from 0.05 to 0.22 compared to the LOC of 0.05), indicating a possibility of effects. All use sites with applications greater than 2.0 lbs ai/A would exceed the endangered fish LOC. A single ground application of pendimethalin at 2 lbs ai/A or lower would not exceed any loss and represents minimal acute risk to fish. Application to rice (1.0 lb ai/A) by either air or ground would not exceed any fish LOCs.

Application to onions (three times at 2 lbs ai/A) by air results in R.S. that exceeds the restricted use LOC for fish.

The *chronic* risk LOC for fish was exceeded by a small margin (RQ of 1.1 compared to the LOC of 1) by aerial use of pendimethalin on onions. This exceedance was based on the 56-day average GEEC of 9 ppb (μg/L). Pendimethalin use on onions is considered to represent a low chronic risk to fish. All other use patterns represent minimal chronic risk to fish.

Freshwater invertebrates: *Acute* risk to freshwater aquatic invertebrates tends to be lower than for fish since pendimethalin is less acutely toxic to these

organisms. Applications at 2 lbs ai/A, whether by air or ground, did not exceed any LOCs. Applications greater than 2 lbs ai/A, or multiple applications of 2 lbs ai/A yielded RQs that exceeded the endangered invertebrate LOC by a small margin indicating the possibility of effects to endangered invertebrates, including mollusks. Aerial treatment of onions (three applications at 2 lbs ai/A) resulted in an RQ that exceeded the restricted use LOC by a small margin (0.14 compared to an LOC of 0.1).

Chronic risk to freshwater aquatic invertebrates is expected to be minimal since the chronic RQs did not exceed the LOC for chronic effects for any uses.

Estuarine organisms: Pendimethalin represents minimal acute risk to estuarine fish and shrimp. Based on toxicity to the eastern oyster, the endangered species LOCs are exceeded by small margins (0.06 to 0.14 compared to and LOC of 0.05) from application rates greater than 2 lbs ai/A, or multiple applications at 2 lbs ai/A. Currently, there are no endangered estuarine species of mollusks.

Terrestrial and Semi-aquatic Plants: The risk to nontarget terrestrial and semi-aquatic plants is predicted to be moderate. The RQs are as high as 30 for emerging seedlings. The LOCs have been exceeded for both ground and aerial applications based on the application rate of 2.0 to 4.0 lbs ai/A. This indicates that exposure to pendimethalin from runoff and spray drift will pose risk to the emergence of nontarget plants. Spray drift from aerial applications above 2 lbs ai/A represent a risk to the vigor of mature plants (RQ of 2.8 to 6 compared to LOC of 1). Pendimethalin may also affect endangered terrestrial and semi-aquatic plant species.

Pendimethalin, because of its extensive usage, has the potential to exert impact on a large area of nontarget flora. The potential risk would be confined to areas around application sites, i.e. within the drift and runoff zone. Offsite movement from volatilization may also result in risk to plants, but the exposure levels could not be estimated.

It is also noteworthy that the magnitude of RQs, while exceeding the LOC by sizeable margins, are not as high as for other herbicides. Thus, it is presumed that pendimethalin represents a moderate risk to nontarget terrestrial and semi-aquatic plants. This is a balance of LOC exceedances that are not particularly high and extensive usage.

Aquatic Plants: The LOC for risk to nontarget aquatic plants has been exceeded. Risk may be a little higher for nonvascular aquatic plants (diatoms and algae; RQs from 1.3 to 6) than for vascular plants (*L. gibba*; RQs from 0.6 to 2.5). However, based on the magnitude of RQs, the overall risk to aquatic plants is considered to be moderate.

(3) Additional Discussion on Aquatic Risk of Pendimethalin

Additional information on pendimethalin that affects the determination of risk to aquatic organisms includes its tendency to bind to sediment and suspended particulates, monitoring results, and typical application rates. Because of its environmental fate characteristics, once pendimethalin reaches surface water habitats, it will tend to bind to sediment and suspended particulates. The strength of this binding increases with time as is evidenced by the methods required to extract pendimethalin from soil or sediment. This should limit long term concentrations in solution in surface waters.

The presumption that concentrations in surface water systems are limited is supported by monitoring results. In a study of the spatial and temporal distributions of pesticides and nutrients in the Mississippi River and its tributaries, Coupe et al. (1993) did not detect dissolved pendimethalin in surface water samples above the reporting limit of 0.018 μg/L. These study results suggest pendimethalin may not be present in the aqueous phase in concentrations above 0.018 ppb (μg/L). In monitoring reported by Baker (1988) from 1982 to 1985, the residues in Ohio creeks and rivers did not exceed 3.6 ppb (μg/L), and were typically less than 1 ppb (μg/L). The lowest toxicological endpoints for freshwater aquatic organisms are the fish full life cycle MATC of 7.85 ppb (μg/L) and the EC50 for Duckweed (*Lemna gibba*) of 12.5 ppb (μg/L). The reported levels from monitoring do not represent a high risk to aquatic organisms.

Finally, it is noted that while several use sites are labeled for use rates greater than 2 lbs ai/A, the typical application rate for most sites is 2 lbs ai/A, according to the registrant. The exceptions are ornamentals (3.0 lbs ai/A), landscape and grounds maintenance, non-cropland (4.0 lbs ai/A) and a few agricultural crops that have higher seasonal rates (e.g. onions; 6 lbs ai/A per season). According to the registrant information, less than 200,000 lbs of pendimethalin are applied to these "higher application rate" use sites annually. Thus, less than one percent of pendimethalin usage is typically at rates greater than 2 lbs ai/A.

Monitoring information indicates that pendimethalin residues are present in surface water. However, the Agency concludes that these concentrations do not represent a high risk to aquatic animals and plants, including estuarine organisms.

(4) Discussion of aquatic risk from other use sites for which GENEEC was not used.

Rice: Although pendimethalin is labelled for use on rice, EECs were not calculated for this use since GENEEC was not intended to model rice uses. The use rate for rice is 1.0 lbs ai/A, which is less than for cotton. Thus, the

EECs calculated for cotton would probably be greater than the maximum exposure expected from rice. Pendimethalin is applied directly to the soil of the rice fields; there is no application to water. Labeling specifically states that no floodwater should be on the field at time of application. Once it has been applied, the labeling recommends either rainfall or irrigation to occur within 7 days for pendimethalin to be most effective. The field is then flooded within 5-7 days after seeding and is flushed approximately 90 days later. Virtually all of the water is contained within the rice field, except that which is lost during storm/rainfall events. What is lost during these events constitutes mainly water, with little or no sediment. Based on the environmental fate characteristics, pendimethalin is expected to be sorbed to the sediment and soil particles, and would not be found in the water column. If any soil is lost during these events, the pendimethalin in the water column would tend to sorb to the sediment and soil with which it comes into contact. Therefore, there are reasons to conclude the EECs from rice would be less than those calculated for cotton.

Other use sites: Aquatic EECs were not estimated for turf, ornamental, landscape & grounds maintenance, non-cropland, and nonbearing nuts and vines (use rates of 3 and 4 lbs ai/A, ground application only). GENEEC is a model designed specifically to model runoff from certain agricultural fields and the risk assessment team did not consider it appropriate for sites such as these. It is assumed, for assessment purposes, that exposure from these use patterns would not be higher than exposure from other uses where GENEEC was used to estimate exposure. This is because these use sites are typically composed of uniformly treated areas much smaller than the 10 hectare watershed used for GENEEC. On turf, where treated sites could be larger than 10 hectares, soil erosion is expected to be minimal. When pendimethalin moves in runoff, it is primarily with suspended soil particles; therefore, surface water exposure from turf is predicted to be less than from agricultural fields. Aquatic risk from turf, ornamental, landscape & grounds maintenance, non-cropland, and nonbearing nuts and vines (use rates of 3 and 4 lbs ai/A, ground application only) is not expected to be greater than from agricultural use sites with similar application rates.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing pendimethalin active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing pendimethalin. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of pendimethalin, 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 pendimethalin and to determine that pendimethalin can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing pendimethalin as the active ingredients are eligible for reregistration as specified in this document. 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 pendimethalin 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 pendimethalin, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all uses of pendimethalin are eligible for reregistration.

C. Regulatory Position

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

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances with amendments and changes as specified in this document for pendimethalin meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food, and drinking water.

Pendimethalin has both food and non-occupational uses; therefore, the considerations for aggregate exposure are those from foods, drinking water, and residential non-occupational sources.

Chronic dietary risks utilizing tolerance level residues and 100% crop treated (TMRC) are <1% of the RfD for the general population.

Based on limited ground water monitoring data (data from 8 states with 2 states with detectable residues, the maximum level found was 0.9 ppb. The maximum level of pendimethalin found in surface water is 17.6 ppb. Based on this information, the estimated risks from water are <2% of the RfD for all population subgroups, including those most highly exposed to pendimethalin residues.

No acute endpoints of concern have been identified for pendimethalin.

In evaluating the potential for cumulative effects, EPA does not have, at this time, available data to determine whether pendimethalin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on common mechanism of toxicity, pendimethalin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pendimethalin has a common mechanism of toxicity with other substances.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for pendimethalin, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of pendimethalin residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from pendimethalin residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature and severity of the effects observed, and other information.

Based on current data requirements, pendimethalin has a complete data base for developmental and reproductive toxicity. The data base for pendimethalin does not indicate a potential for increased toxicological sensitivity from pre- and post-natal exposures. No developmental toxicity was observed in either the rat or rabbit developmental toxicity studies, nor was there any evidence in the two generation study that there was developmental or reproductive toxicity at dose levels below those in which parental toxicity was observed. Therefore, the Agency has determined that an additional uncertainty factor is not warranted.

The Agency estimates that pendimethalin residues in the diet of non-nursing infants (less than one year) account for <2% of the RfD.

Although the risk assessment for children exposed to pendimethalin-treatedx lawns showed an acceptable MOE (111), the Agency has low confidence in the data used for these exposure calculations and these estimates do not include ingested or inhaled quantities. Therefore, the Agency has concerns for post-application exposure to children in residential settings, and is requiring that the maximum application rate for residential (and sod farms) uses be reduced from 3.0 lbs. ai/acre to 2.0 lbs. ai/acre. (The registrant has agreed to this mitigation measure.)

In summary, an additional uncertainty factor is not required to protect for potential adverse developmental or reproductive effects. It is known that pendimethalin affects the pituitary-thyroid axis; the basis for the RfD (0.10 mg/kg/day) is based on combined subchronic studies (14 days and 28 days) in which thyroid changes were observed. Based on thyroid effects, pendimethalin by definition is an endocrine disrupter. Data cannot rule out the possibility that children may have special sensitivity to pendimethalin via effects on the thyroid. However, the data currently available indicate that humans are no more sensitive than the rodent model to thyroid perturbations.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementations, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

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

c. Effects to the Endocrine System

EPA is required to develop a screening program to determine whether certain substances (including all active ingredient pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end-use products.

2. Tolerance Reassessment

Tolerances for pendimethalin residues are currently expressed in terms of the combined residues of pendimethalin and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol [§180.361(a and c)] and, for peanut hulls only, in terms of the parent and aforementioned metabolite plus the metabolite 3-[(1-ethylpropyl)amino]-6-methyl-2,4-dinitrobenzyl alcohol [40 CFR §180.361(b)].

A summary of the pendimethalin tolerance reassessment and recommended modifications in commodity definitions are presented in Table 30.

Tolerances Listed Under 40 CFR §180.361(a)

Adequate data are available to reassess the established tolerances for pendimethalin residues in/on beans; bean forage; bean fodder; corn fodder; corn forage; corn grain; sweet corn; cottonseed; onions (dry bulb); peanuts; peanut hay; potatoes; sorghum fodder; sorghum forage; grain sorghum; soybeans; soybean forage; soybean hay; sugarcane; and sunflower seeds. [Note: Some commodity definitions must be corrected. See Table 39 for details.]

The tolerance for pendimethalin residues in/on peanut forage should be revoked since peanut forage is no longer considered to be a significant feed item according to the Livestock Feeds Table (Table II (September 1995)).

Available rice field trial data are deemed adequate to support the reregistration of pendimethalin for use on rice. The currently established tolerance on rice grain should be increased from 0.05 ppm to 0.1 ppm. A processing study on rice grain is outstanding.

Tolerances Needed Under 40 CFR §180.361(a)

Available rice field trial data are deemed adequate to support the reregistration of pendimethalin for use on rice. A tolerance for pendimethalin residues of concern in/on rice straw must be established. Available data indicate that a tolerance of 0.1 ppm would be appropriate.

As a result of changes in the Livestock Feeds Table (Table II (September 1995)), the Agency currently considers cotton gin byproducts a raw agricultural commodity (RAC). Data depicting pendimethalin residues of concern in/on cotton gin byproducts resulting from the maximum registered use of pendimethalin to cotton are hereby required. On receipt of the required cotton gin byproducts data, the need for tolerances for pendimethalin residues of concern will be determined.

Tolerances Listed Under 40 CFR §180.361(b)

The tolerance for residues in/on peanut hulls should be revoked since peanut hulls is no longer considered a significant feed item according to the Livestock Feeds Table (Table II (September 1995)).

Tolerances Listed Under 40 CFR §180.361(c)

The Agency concludes that available garlic magnitude of the residue data from field trials conducted in CA and OR are adequate to support a national registration for the use of pendimethalin on garlic and recommends that the currently established tolerance with regional registrations for pendimethalin residue of concern in/on garlic should be changed to a tolerance without regional registrations at the same level (0.1 ppm) and listed under 40 CFR §180.361(a).

Table 39. Tolerance Reassessment Summary for Pendimethalin.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.361(a):			
Beans, lima (dry,snap)	0.1	0.1	*Beans, succulent and dry*
Beans, forage	0.1	0.1	
Beans, hay	0.1	0.1	
Corn, fodder	0.1	0.1	*Corn, stover*
Corn, forage	0.1	0.1	
Corn, grain	0.1	0.1	*Corn, field* and *Corn, pop*
Corn, fresh (including sweet, K+CWHR)	0.1	0.1	*Corn, sweet (K+CWHR)*
Cottonseed	0.1	0.1	*Cotton, undelinted seed*
Onions, dry bulb	0.1	0.1	
Peanuts	0.1	0.1	
Peanut, hay	0.1	0.1	
Peanut, forage	0.1	Revoke	No longer listed as a significant feed item
Potatoes	0.1	0.1	
Rice, grain	0.05	0.1	The tolerance level must be increased to the analytical method's limit of quantitation (LOQ) for the combined residues of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite
Sorghum, fodder	0.1	0.1	*Sorghum, stover*
Sorghum, forage	0.1	0.1	
Sorghum, grain	0.1	0.1	
Soybeans	0.1	0.1	
Soybeans, forage	0.1	0.1	
Soybeans, hay	0.1	0.1	
Sugarcane	0.1	0.1	
Sunflower, seeds	0.1	0.1	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances needed under 40 CFR §180.361(a):			
Cotton, gin byproducts	None	TBD[a]	Residue data are required.
Rice, straw	None	0.1	
Tolerances listed under 40 CFR §180.361(b):			
Peanut, hulls	0.25	Revoke	No longer listed as a significant feed item
Tolerances listed under 40 CFR §180.361(c):			
Garlic	0.1	0.1	Agency hereby recommends that this tolerance should be listed under 40 CFR §180.361(a)

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

3. Codex Harmonization

There are no established or proposed Codex MRLs for pendimethalin residues. Therefore, there are no questions of compatibility with respect to Codex MRLs and U.S. tolerances.

4. Summary of Risk Management Decisions

a. Human Health

(1) Acute Dietary

The Agency has concluded that there are no toxicologic endpoints for acute (one day) dietary exposure to pendimethalin.

(2) Chronic Dietary

The DRES dietary risk assessment for published and reassessed tolerances of pendimethalin indicate that the overall U.S. population and the estimated most highly exposed subgroup non-nursing infants receive less than 4 percent of the pendimethalin Reference Dose (with food and water sources combined). Since this is a relatively low estimate and is based on worst-case assumptions, the Agency concludes that chronic dietary risk to pendimethalin is not a concern for reregistration.

(3) Short and Intermediate Term Occupational and Residential

The Agency has determined that there is potential exposure to persons handling pendimethalin. Exposure may occur to: occupational handlers involved in food, feed, fiber, ornamental, turf, rights-of-way and other noncrop treatments; and homeowner handlers making applications to residential turf.

Occupational/Short and Intermediate Term:

Agency calculations indicate that MOEs for handlers wearing baseline attire (long-sleeve short, long pants, shoes and socks) are over 100 for all but three scenarios. For three scenarios (mixing/loading liquid for aerial applications and irrigation systems, mixing/loading liquid for rights-of-way spraying, and mixing/loading liquid for groundboom applications), the MOEs range from 1.5 to 59. The risks to these handlers in these three scenarios are reduced to an adequate level (MOEs range from 110 to 33,333) when chemical-resistant gloves are added to the baseline attire.

Occupational/Post Application:

The Agency has determined that there are risks following applications to commercial or research food, feed, fiber, turf, and ornamental crops. REIs allow sufficient time to pass for residues to dissipate to levels that result in adequate MOEs. Pending the development of pendimethalin-specific post application exposure data (foliar and soil residue dissipation studies-guidelines 132(a) and 132(b)), the Agency is requiring that the 12-hour interim REI be increased to 24 hours for all pendimethalin uses within the WPS.

However, REIs are generally not feasible as a mitigation measure for occupational exposures in noncrop areas (such as rights-of-way). As represented in Tables 7, 8, and 9 (post application risk estimates for residential turf, golf course turf and sod farm turf) the MOE‘s are unacceptable at the 3 lb. ai/acre rate. Therefore, as a risk mitigation measure, the Agency is requiring a reduction in the maximum use rate from 3 lbs ai/acre to 2 lbs. ai/acre. The registrant has agreed to reduce the maximum application rate from 3.0 lbs. ai/acre to 2 lbs.ai/acre on residential and recreation area turf grass.

Residential/Post Application:

Again, REIs are not practical or feasible for residential or recreational turf, consequently, the Agency is requiring a reduction in the maximum use rate to 2 lbs. ai/acre.

b. Environmental

(1) Avian

Acute/Chronic

Pendimethalin does not represent a high acute risk to birds. The chronic risk to birds could not be determined because avian reproduction studies have not been submitted

.

(2) Mammals

Pendimethalin does not represent a high acute or chronic risk to mammals.

(3) Fish

Chronic risk LOCs for fish were exceeded by a small margin. But it is presumed that overall, pendimethalin does not represent a high risk to aquatic animals and plants, including estuarine organisms.

(4) Nontarget Plants (Terrestrial and Semi-Aquatic)

The risk to nontarget terrestrial and semi-aquatic plants is expected to be moderate.

(5) Endangered Species

The use of pendimethalin may adversely affect endangered species of terrestrial and semi-aquatic plants, aquatic plants and invertebrates including mollusks, fish and birds (specifically grazers).

Currently, the Agency is developing a program ("The Endangered Species 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 from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

5. Labeling Rationale

Occupational/Residential

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 in which the plants are (or will be) grown.

At this time some of the registered uses of pendimethalin are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Uses that are outside the scope of the WPS include use:

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

- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other noncrop areas.

Compliance with the WPS

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

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

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

Personal Protective Equipment/Engineering Controls for Handlers

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

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

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

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

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

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

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

Occupational-Use Products

The Agency has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for pendimethalin for certain handler use-situations. The MOEs were less than 100 for certain occupational handler (mixers, loaders, and applicators) use-scenarios, unless chemical-resistant gloves were used in addition to the baseline protection of long-sleeve shirt, long pants, shoes, and socks. The Agency is requiring active-ingredient-based protections for handlers of pendimethalin in these exposure situations: (1) mixing and loading emulsifiable concentrate formulations and (2) mixing, loading, and applying using low-pressure handwand equipment. In addition, since wettable powder formulations are currently contained in water-soluble packaging and the Agency's exposure and risk assessments were based on that assumption, the Agency will require wettable powder formulations of pendimethalin to be contained in water-soluble packaging. If the Registrant intends to register any wettable powder product not contained in water-soluble packaging, the Agency must first conduct an exposure risk assessment to determine if mitigation measures such as PPE would be necessary.

WPS and NonWPS Uses: Since potential handler exposure is similar for WPS and nonWPS uses, there is only one set of active-ingredient-based minimum (baseline) PPE requirements for occupational uses of pendimethalin (specified in Section V). These requirements must be followed in the labeling of all pendimethalin end-use products intended primarily for occupational use.

Homeowner-Use Products

The Agency is not establishing minimum (baseline) handler PPE for pendimethalin end-use products that are intended primarily for homeowner use, because the Agency has determined that the frequency, duration, and degree of exposure by such handlers do not warrant such risk mitigation measures.

Postapplication/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval:

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

established at 12 hours. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REIs established on the basis of adequate data, and (2) interim REIs that are longer than those that would be established under the WPS.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to shorten or lengthen the previously established REI.

By default, PR Notice 93-7 specifies a 12 hour interim REI currently in effect. EPA notes that the 12-hour interim WPS REI was established because data indicated that pendimethalin was in toxicity category III/IV for acute dermal toxicity, skin irritation potential, and eye irritation potential.

During the reregistration process, the Agency has determined that the REI established under the WPS should be changed for some uses due to:

-the identification of short and intermediate term toxicity endpoints of concern,
-the potential for significant postapplication worker exposure in certain crops,
-a number of reported incidents for pendimethalin,
-an absence of acceptable pendimethalin-specific post application exposure data for all use sites and scenarios, and
-the findings of the Agency's analysis of potential post-application exposure risk using surrogate data and reasonable worst-case assumptions.

Thus, the Agency is establishing a 24-hour restricted-entry of all occupational-use products that contain pendimethalin and have use-directions for commercial or research food, feed, fiber, ornamental, forestry, and turfgrass crops grown for commercial or research purposes.

Early-Entry PPE:

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry PPE are set in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

   The PPE for dermal protection required for early entry based on the acute toxicity categories, non-acute toxicity endpoints, and the potential for post-application dermal exposure are coveralls, chemical-resistant gloves, and shoes plus socks.

WPS Notification Statement:

Under the WPS, the labels of some pesticide products must require employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The reregistration process also may decide that a product requires this type of "double notification."

The Agency has determined that double notification is not required for pendimethalin end-use products.

Occupational-Use Products (NonWPS Uses)

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

Homeowner-Use Products

Since the Agency has concerns about post-application exposures to persons after homeowner applications of pendimethalin, the Agency is establishing entry restrictions for all homeowner uses of pendimethalin end-use products. For specific requirements, refer to Section V of this document.

(Note: The registrant has agreed to a reduction in the maximum application rate from 3 lbs. active ingredient per acre to 2 lbs. active ingredient per acre on residential and recreation area turf grass.)

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing pendimethalin. 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, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

7. Environmental Hazards Statement

All pesticides with outdoor, terrestrial uses are required to have an environmental hazard statement. Specific language is found in section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

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

Required Handler Studies:

No chemical-specific handler exposure data for pendimethalin exists and the Agency has low confidence in the data available for several pendimethalin use scenarios. Additional handler exposure studies are required. Requirements for such studies are addressed in Subdivision U of the Pesticide Assessment Guidelines. The required studies are for dermal exposure (Guideline 231) and are necessary to provide data on mixers, loaders, and applicators for:

- high volume turf sprayer applications with WP/WDG/liquid formulations;
- low pressure handwand applications with WDG/liquid formulations;
- backpack sprayer applications with WDG/liquid formulations; and

" rights-of-way applications with WDG/liquid formulations.

EPA notes that the registrant is a member of the Outdoor Residential Exposure Task Force (ORETF) and that some of the required data for applications to turf is being developed by the task force. Guideline 231 studies may be reserved at this time pending the completion of the ORETF studies.

Required Postapplication Studies

There are no pendimethalin-specific post-application exposure data available at this time. These chemical-specific data are necessary for EPA to establish permanent restricted-entry intervals since a short and intermediate-term endpoint of concern has been identified. The registrant must submit postapplication exposure studies. Requirements for such postapplication exposure studies are addressed by subdivision K of the Pesticide Assessment Guidelines. Data are required to support the use of pendimethalin on the following crop groups/use sites:

" food, feed, and fiber crops (transplanting and weeding tobacco);

" ornamental crops (harvesting/transplanting woody ornamentals);

" residential turfgrass; and

" sod farm turfgrass (harvesting).

Requirements for post-application/reentry exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. The required data include:

" foliar residue dissipation (Guideline 132-1(a);

" soil residue dissipation (Guideline 132-1(b); and

" postapplication dermal passive dosimetry exposure (Guideline 133-3) may be reserved at this time pending completion of the databases on agricultural and residential post-application/reentry exposure currently being developed by the Agricultural Reentry Task Force and the ORETF since the Registrant is a member of both task forces.

Product chemistry

Additional physical/chemical properties for the 86.8% and 60% FIs.

Residue Chemistry

Magnitude of residue studies for tobacco and cotton gin byproducts - Guideline 171-4(k)

Rice processing study - Guideline 171-4(l)

Ecological Effects

Avian Chronic - Guideline 71-4

Environmental Fate

Field Dissipation - Guideline 164-1 - cotton and soybeans

Aquatic Dissipation - Guideline 164-2 - rice

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):..."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

"Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

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

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

a. Occupational/Residential

PPE/Engineering Control Requirements for Pesticide Handlers

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

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

Products Intended Primarily for Occupational Use (WPS and nonWPS)

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

The Agency is establishing minimum (baseline) engineering controls for occupational uses of pendimethalin end-use products formulated as wettable powders. All wettable powder formulations must be contained in water-soluble packaging.

The Agency is establishing minimum (baseline) personal protective equipment (PPE) requirements for some occupational uses of pendimethalin end-use products. The minimum (baseline) PPE for occupational uses of pendimethalin

end-use products are:

For emulsifiable concentrate formulations:
"Mixers and loaders must wear:
-- long-sleeved shirt and long pants,
-- chemical-resistant gloves*, and
-- shoes plus socks."

* For the glove statement, use the statement established for pendimethalin through the instructions in Supplement Three of PR Notice 93-7.

For water-dispersible granule, wettable powder, and emulsifiable concentrate formulations whose use directions reasonably permit application using hand-held sprayers:

"Commercial Handlers (mixers, loaders, and applicators) who apply this product using hand-held equipment or hoses (not including hoses attached to truck-mounted equipment) must wear:
-- long-sleeved shirt and long pants,
-- chemical-resistant gloves*, and
-- shoes plus socks."

* For the glove statement, use the statement established for pendimethalin through the instructions in Supplement Three of PR Notice 93-7.

Determining PPE Requirements for End-use Product Labels

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

Placement in Labeling

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

Products Intended Primarily for Homeowner Use

Minimum (baseline) PPE Requirements

The Agency is not establishing active-ingredient-based minimum (baseline) handler PPE for pendimethalin end-use products that are intended primarily for homeowner use.

Determining PPE Requirements for End-Use Product Labels

Any necessary PPE for each pendimethalin end-use product intended primarily for homeowner use will be established on the basis of the end-use product's acute toxicity category.

Placement in Labeling

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

Entry Restrictions

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

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

Products Intended Primarily for Occupational Use

WPS Uses

Restricted-entry interval:

A 24-hour restricted-entry interval (REI) is required for uses on food, feed, fiber, ornamental, forestry, and turf crops within the scope of the WPS on all pendimethalin end-use products.

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

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:
-- coveralls,
-- chemical-resistant gloves, and
-- shoes plus socks,

Placement in labeling:

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

NonWPS uses

Entry restrictions:

The Agency is establishing the following entry restrictions for nonWPS occupational uses of pendimethalin end-use products: (NOTE: This presumes the registrant reduces the maximum application rate for turf at residential sites and parks and recreation areas to two pounds active ingredient per acre.)

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

For dry applications:
"Do not enter or allow others to enter the treated area until dusts have settled."

Placement in labeling:

If WPS uses are also on label -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

If no WPS uses are on the label -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Products Intended Primarily for Homeowner Use

Entry restrictions:

The Agency is establishing the following entry restrictions for all homeowner uses of pendimethalin end-use products (NOTE: This presumes the registrant reduces the maximum application rate for turf at residential sites and parks and recreation areas to two pounds active ingredient per acre.):

For liquid applications:
"Do not allow people or pets to touch treated plants until the sprays have dried."

For dry applications:
"Do not allow people or pets to enter the treated area until dusts have settled."

Placement in labeling:

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

Other Labeling Requirements

Products Intended Primarily for Occupational Use

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

Application Restrictions

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

Engineering Controls

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

User Safety Requirements

1. {Registrant: add the following statements if coveralls are required for pesticide handlers on the end-use product label:}

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

2. {Registrant: add the following statement always:}

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

User Safety Recommendations

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

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

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

Products Intended Primarily for Home Use

Application Restrictions

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."

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."

b. Environmental Hazards Statement

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

c. Application Rates

The labels of all pendimethalin end-use products must be revised to bear the following application rate for the respective uses:

For residential lawn and sod farm uses:

"Maximum application rate of 2.0 lbs. active ingredient per acre."

C. 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.
>
> The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.
>
> 1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.
>
> 2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.
>
> Where states have more stringent regulations, they should be observed.
>
> The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.
>
> 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 altitudes 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).

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 pendimethalin 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 preexisting Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

Appendix A is 69 pages long and is not being included. Copies of Appendix A are available upon request per the instructions in Appendix E

GUIDE TO APPENDIX B

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

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
EPA REG. #241-245			
61-1	**Chemical Identity**	**ALL**	**00106751**
61-2A	**Start. Mat. & Mnfg. Process**	**ALL**	**00153762,00158623**
61-2B	**Formation of Impurities**	**ALL**	**00152847,00153762**
62-1	**Preliminary Analysis**	**ALL**	**00153762,41111301**
62-2	**Certification of limits**	**ALL**	**00153762,41111301, 1725201**
62-3	**Analytical Method**	**ALL**	**00153762,41111301, 41725201**
63-2	**Color**	**ALL**	**00153762**
63-3	**Physical State**	**ALL**	**00153762**
63-4	**Odor**	**ALL**	**00153762**
63-5	**Melting Point**	**ALL**	**00153762**
63-6	**Boiling Point**		**N/A**
63-7	**Density**	**ALL**	**00153762**
63-8	**Solubility**	**ALL**	**00153762**
63-9	**Vapor Pressure**	**ALL**	**00153762**
63-10	**Dissociation Constant**	**ALL**	**00153762**
63-11	**Octanol/Water Partition**	**ALL**	**00153762**

REQUIREMENT		USE PATTERN	CITATION(S)
63-12	pH	ALL	00153762
63-13	Stability	ALL	00153762
63-14	Oxidizing/Reducing Action	ALL	00153762
63-15	Flammability	ALL	00153762
63-16	Explodability	ALL	00153762
63-17	Storage stability	ALL	00161758
63-18	Viscosity		N/A
63-19	Miscibility		N/A
63-20	Corrosion characteristics	ALL	00153762
63-21	Dielectric breakdown volt		N/A
64-1	Submittal of Samples		N/A
EPA REG. #241-291			
61-1	Chemical Identity	ALL	40392101
61-2A	Start. Mat. & Mnfg. Process	ALL	40392101
61-2B	Formation of Impurities	ALL	SAME AS 241-245
62-1	Preliminary Analysis	ALL	N/A
62-2	Certification of limits	ALL	40392101
62-3	Analytical Method	ALL	SAME AS 241-245
63-2	Color	ALL	DATA GAP
63-3	Physical State	ALL	DATA GAP
63-4	Odor	ALL	DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
63-5	**Melting Point**	**ALL**	**N/A**
63-6	**Boiling Point**		**N/A**
63-7	**Density**	**ALL**	**DATA GAP**
63-8	**Solubility**	**ALL**	**N/A**
63-9	**Vapor Pressure**	**ALL**	**N/A**
63-10	**Dissociation Constant**	**ALL**	**N/A**
63-11	**Octanol/Water Partition**	**ALL**	**N/A**
63-12	**pH**	**ALL**	**DATA GAP**
63-13	**Stability**	**ALL**	**N/A**
63-14	**Oxidizing/Reducing Action**	**ALL**	**DATA GAP**
63-15	**Flammability**	**ALL**	**DATA GAP**
63-16	**Explodability**	**ALL**	**DATA GAP**
63-17	**Storage stability**	**ALL**	**DATA GAP**
63-18	**Viscosity**	**ALL**	**DATA GAP**
63-19	**Miscibility**	**ALL**	**DATA GAP**
63-20	**Corrosion characteristics**	**ALL**	**DATA GAP**
63-21	**Dielectric breakdown volt**		**N/A**
64-1	**Submittal of Samples**		**N/A**
EPA REG. #241-281			
61-1	**Chemical Identity**	**ALL**	**00154789**
61-2A	**Start. Mat. & Mnfg. Process**	**ALL**	**00154789**

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
61-2B	**Formation of Impurities**	**ALL**	**SAME AS 241-245**
62-1	**Preliminary Analysis**	**ALL**	**N/A**
62-2	**Certification of limits**	**ALL**	**00154789**
62-3	**Analytical Method**	**ALL**	**00154789**
63-2	**Color**	**ALL**	**00154789**
63-3	**Physical State**	**ALL**	**00154789**
63-4	**Odor**	**ALL**	**00154789**
63-5	**Melting Point**	**ALL**	**N/A**
63-6	**Boiling Point**		**N/A**
63-7	**Density**	**ALL**	**00154789**
63-8	**Solubility**	**ALL**	**N/A**
63-9	**Vapor Pressure**	**ALL**	**N/A**
63-10	**Dissociation Constant**	**ALL**	**N/A**
63-11	**Octanol/Water Partition**	**ALL**	**N/A**
63-12	**pH**	**ALL**	**DATA GAP**
63-13	**Stability**	**ALL**	**N/A**
63-14	**Oxidizing/Reducing Action**	**ALL**	**00154789**
63-15	**Flammability**	**ALL**	**00154789**
63-16	**Explodability**	**ALL**	**DATA GAP**
63-17	**Storage stability**	**ALL**	**DATA GAP**
63-18	**Viscosity**	**ALL**	**00154789**

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
63-19	Miscibility	ALL	DATA GAP
63-20	Corrosion characteristics	ALL	DATA GAP
63-21	Dielectric breakdown volt		N/A
64-1	Submittal of Samples		N/A
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral-Quail/Duck	ALL	00059739
71-1B	Acute Avian Oral - Quail/Duck TEP		N/A
71-2A	Avian Dietary - Quail	ALL	00026675
71-2B	Avian Dietary - Duck	ALL	00026674
71-3	Wild Mammal Toxicity		N/A
71-4A	Avian Reproduction - Quail	ALL	DATA GAP
71-4B	Avian Reproduction - Duck	ALL	DATA GAP
71-5A	Simulated Field Study		N/A
71-5B	Actual Field Study		N/A
72-1A	Fish Toxicity Bluegill	ALL	00106764
72-1B	Fish Toxicity Bluegill - TEP	ALL	00037927,00131773
72-1C	Fish Toxicity Rainbow Trout	ALL	00106764
72-1D	Fish Toxicity Rainbow Trout- TEP	ALL	00251601,00037927

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
72-2A	Invertebrate Toxicity	ALL	FAOPEN05,00071123, 00059738
72-2B	Invertebrate Toxicity - TEP	ALL	00153772
72-3A	Estuarine/Marine Toxicity - Fish	ALL	00131774
72-3B	Estuarine/Marine Toxicity - Mollusk	ALL	00131772
72-3C	Estuarine/Marine Toxicity - Shrimp	ALL	00131775
72-3D	Estuarine/Marine Toxicity Fish- TEP	ALL	00131774
72-3E	Estuarine/Marine Toxicity Mollusk - TEP	ALL	00131772
72-3F	Estuarine/Marine Toxicity Shrimp - TEP	ALL	00131775
72-4A	Early Life Stage Fish	ALL	N/A
72-4B	Life Cycle Invertebrate	ALL	00100504,00247299
72-5	Life Cycle Fish	ALL	00037940,00096342
72-6	Aquatic Organism Accumulation		RESERVED
72-7A	Simulated Field - Aquatic Organisms		N/A
72-7B	Actual Field - Aquatic Organisms		WAIVED

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
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**	**ALL**	**42372201,42372202**
123-1B	**Vegetative Vigor**	**ALL**	**42372203**
123-2	**Aquatic Plant Growth**	**ALL**	**42137101,42372204,42137205,42372206, 42372207**
124-1	**Terrestrial Field**		**N/A**
124-2	**Aquatic Field**		**N/A**
141-1	**Honey Bee Acute Contact**	**ALL**	**00099890**
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**	**00026657,00072802**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	**ALL**	**00026657,00072802**
81-3	**Acute Inhalation Toxicity - Rat**	**ALL**	**00073342**
81-4	**Primary Eye Irritation - Rabbit**	**ALL**	**00026657,00072802**

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
81-5	Primary Dermal Irritation - Rabbit	ALL	00026663,00026657
81-6	Dermal Sensitization - Guinea Pig	ALL	00153767
81-7	Acute Delayed Neurotoxicity - Hen		N/A
82-1A	90-Day Feeding - Rodent	ALL	00156081,00106754
	Special study-92-day thyroid function		42065601
	Special study-56-day thyroid function		43135001
			43135003
	Special study-14-day thyroid function		
82-1B	90-Day Feeding - Non-rodent	ALL	00058657,00059468 00059469
82-2	21-Day Dermal - Rabbit/Rat	ALL	00026663
82-3	90-Day Dermal - Rodent		N/A
82-4	90-Day Inhalation - Rat		N/A
82-5A	90-Day Neurotoxicity - Hen		N/A
82-5B	90-Day Neurotoxicity - Mammal		N/A
83-1A	Chronic Feeding Toxicity - Rodent	ALL	00156081,40174401,4090990 1,42027802

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	**ALL**	**00058657,44106801**
83-2A	**Oncogenicity - Rat**	**ALL**	**40909901,41909701**
83-2B	**Oncogenicity - Mouse**	**ALL**	**40909901,41909701**
83-3A	**Developmental Toxicity - Rat**	**ALL**	**00025752,41725202**
83-3B	**Developmental Toxicity - Rabbit**	**ALL**	**44106803,44106804**
83-4	**2-Generation Reproduction - Rat**	**ALL**	**41725203**
84-2A	**Gene Mutation (Ames Test)**	**ALL**	**00067519,00153771 00153770 43135006,43177802 00153769, 00153768**
84-2B	**Structural Chromosomal Aberration**	**ALL**	**00026673,00153771 00153770,00153769, 431777802,00153768**
84-4	**Other Genotoxic Effects**	**ALL**	**42027801,43135007 00153768**
85-1	**General Metabolism**	**ALL**	**00046275**
85-2	**Dermal Penetration**		**N/A**
86-1	**Domestic Animal Safety**		**N/A**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	ALL	**DATA GAP**
132-1B	**Soil Residue Dissipation**	ALL	**DATA GAP**

REQUIREMENT		USE PATTERN	CITATION(S)
133-3	**Dermal Passive Dosimetry Exposure**	ALL	**RESERVED**
133-4	**Inhalation Passive Dosimetry Exposure**		**N/A**
231	**Estimation of Dermal Exposure at Outdoor Sites**		**RESERVED**
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			
160-5	**Chemical Identity**		N/A
161-1	**Hydrolysis**	**ALL**	**0010677**
161-2	**Photodegradation - Water**	**A,B,C,D**	**00153763,438008201**
161-3	**Photodegradation - Soil**	**A,B,C**	**00153764**
161-4	**Photodegradation - Air**		**WAIVED**
162-1	**Aerobic Soil Metabolism**	**ALL**	**40185104**
162-2	**Anaerobic Soil Metabolism**	**A,B,C,D**	**40185105,431544701**
162-3	**Anaerobic Aquatic Metabolism**	**A,B,C,D**	**40813501,43154702**
162-4	**Aerobic Aquatic Metabolism**		**WAIVED**

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
163-1	Leaching/Adsorption/Desorption	ALL	43041901
163-2	Volatility - Lab	A,B	00153766
163-3	Volatility - Field		WAIVED
164-1	Terrestrial Field Dissipation	A,BC,K	41722504,DATA GAP
164-2	Aquatic Field Dissipation	D	DATA GAP
164-3	Forest Field Dissipation		N/A
164-5	Long Term Soil Dissipation		RESERVED
165-1	Confined Rotational Crop		DATA GAP
165-2	Field Rotational Crop		DATA GAP
165-3	Accumulation - Irrigated Crop		WAIVED
165-4	Bioaccumulation in Fish	A,B,C,D	00158235,00156726
165-5	Bioaccumulation - Aquatic NonTarget		RESERVED
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		TASK FORCE
202-1	Drift Field Evaluation		TASK FORCE

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	**A,B,D,K**	**00029803, 00031219, 00039535, 00039537 00046278 ,00046280, 00051963, 00051965 00058478, 00067293, 00071121, 00074621 00093698, 00106779, 00106795, 00108317 0010991,41469901,2467801, 2686401 43154705**
171-4B	**Nature of Residue - Livestock**	**A,B,D**	**00046275, 00046293, 00067288, 00067289, 00071124, 41713901, 42467802,**

REQUIREMENT		USE PATTERN	CITATION(S)
171-4C	Residue Analytical Method - Plants	A,B,D,K	00019004, 00023780, 00023781, 00023782, 00024823, 00025820, 00025821, 00025822, 00025827, 00025828, 00025831, 00025832, 00025833, 00025837, 00029018, 00029020, 00031212, 00031214, 00039519, 00039520, 00039521, 00039522, 00039526, 00039527, 00039528, 00039529, 00041898, 00041901, 00041904, 00051958, 00051959, 00051960, 00051961, 00051962, 00052558, 00070962, 00071120, 00072810, 00072822, 00072823,00072824, 00072825, 00106752, 00106791,00106808, 00106830, 41431001, 41845801,41982701, 42471901,42471902, 42471903,42266302, 42859202, 43068501,4315470, 43185901,
171-4D	Residue Analytical Method - Animal	A,B,D	00023796,00058835

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT		USE PATTERN	CITATION(S)
171-4E	Storage Stability	A,B,C,D,K	43147801,42266301 42471903
171-4F	Magnitude of Residues - Potable H2O		N/A
171-4G	Magnitude of Residues in Fish		WAIVED
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		WAIVED
171-4K	Crop Field Trials	A,B,D,K	
	- Tobacco		DATA GAP
	- Potatoes		00106797
	- Garlic		402325401
	-Onion		41827401
	-Beans(Succulent & Dry)		00039518,00039519,00039520,00039521, 00039522,00039523 00039524,00039534, 00081581
	-Soybeans		42471901,43154704, 00025818,00029801 00041897

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT	USE PATTERN	CITATION(S)
	-Bean forage & hay	00039518,00039519, 00039520,0009521, 00081581,00039523 00039524,00039534, 00039522
	-Soybean forage & hay	0002518,00029801,00161759 00161760, 00161761,40185101
	-Corn, grain	00023786,00023787, 000237788,00023789, 00023790,00023791 00023792,00023793, 00023794,00023795 00029029,00030697, 0016820,00093697
	-Corn, fresh	00074619,00093719
	-Rice, grain	00067283,00071120
	-Rice, straw	00067283,00071120
		00106791,00106807 00114313
	--Sorghum, grain	

REQUIREMENT		USE PATTERN	CITATION(S)
	-Corn, forage & fodder		00023786,00023787 00023788,00023789 00023790,00023791, 00023792,00023793, 00023794,00023795 00029028,00029029, 00030697,00093697 00106820
	-Sorghum, Forage & fodder		00106791,00106807 00114313
	-Cottonseed		00018997,00106752 00106829, 41881201,42858901
	-Peanuts		00106785
	-Peanut, hulls		00031215,00031216 00031217 00106785
	-Peanut, forage		00106785
	-Peanut, hay		00106785
	-Sugarcane		42859201
171-4L	Processed Food	A,B,D	
	-Cottonseed		00106752
	-Peanuts		00106785
	-Potatoes		00106797

Data Supporting Guideline Requirements for the Reregistration of Pendimethalin

REQUIREMENT	USE PATTERN	CITATION(S)
	-Rice grain	DATA GAP
	-Soybeans	00025818
	-Sugarcane	PP#3F2765
	-Sunflower seed	00134355
171-5	Reduction of Residues	N/A
171-6	Proposed Tolerance	N/A
171-7	Support for Tolerance	N/A
171-13	Analtyical 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.

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FAOPEN05 EG&G Bionomics. 1976. Acute toxicity of CL-92,553 to Daphnia magna. (Unpublihed study received under 241-243; submitted by American Cyanamid Co. Princeton, N. J

00018997 Smith, J.; Lignowski, E.; Coble, H.D.; et al. (1978) Summary: Prowl (CL 92,553) plus Cotoran (Fluometuron) Preemergence Tank Mixture--Soil and Cottonseed Residues. (Unpublished study received Sep 11, 1978 under 241-243; prepared in cooperation with North Carolina State Univ., Crop Science Dept., Upper Coastal Plain Research Station, submitted by American Cyanamid Co., Princeton, N.J.; CDL:235084-B)

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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 5).

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

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

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 Reqistrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Reqistrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

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

c. Generic Data Exemption -

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

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

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

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

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you

are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product

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

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

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

forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

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

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

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

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

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

Option 4. Submitting an Existing Study

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

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

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

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

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

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

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

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification,

the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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

Option 5. Upgrading a Study

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

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

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

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

Option 6. Citing Existing Studies

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

number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

2. Product Specific Data

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

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

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

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

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic

data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

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

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

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

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

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

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

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

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

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

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

information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

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

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

PENDIMETHALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 PENDIMETHALIN. 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 PENDIMETHALIN 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 PENDIMETHALIN are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on PENDIMETHALIN 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 PENDIMETHALIN 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 Jane Mitchell at (703) 308-8061.

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

Jane Mitchell
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: **PENDIMETHALIN**

PENDIMETHALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 PENDIMETHALIN. 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 PENDIMETHALIN 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 PENDIMETHALIN are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on PENDIMETHALIN are needed. These data are needed to fully complete the reregistration of all eligible PENDIMETHALIN 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 Jane Mitchell at (703) 308-8061.

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

Jane Mitchell, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: PENDIMETHALIN

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

INTRODUCTION

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

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

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

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

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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

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

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

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

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

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

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

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

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

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

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

FOR BOTH MUP and EUP products

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

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

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

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

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

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

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

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

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Using available information, batching has been accomplished by the process described in the preceding paragraph. Not with-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an

Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

56 products were found which contain pendimethalin as an active ingredient. The products have been placed into six batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each batch. Table 2 lists the products which have been placed in the "no batch" category. PRS advises the registrants to carefully review the following tables for accuracy. They may propose an alternative method of supporting their products (such as bridging data from another batch) which we will take into consideration.

TABLE 1

Batch	EPA Reg. No.	% active ingredient	Formulation Type
1	241-245	90.00	liquid
	241-291	86.00	liquid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
2	241-243	42.3	liquid
	241-305	42.3	liquid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
BATCH 3	241-341	37.4	liquid
	241-360	37.4	liquid
	241-337	37.4	liquid
	AZ92000700	37.4	liquid
	ID93001200	37.4	liquid
	ID96000700	37.4	liquid
	MT93000300	37.4	liquid
	NV92000400	37.4	liquid
	OR93000100	37.4	liquid
	UT92000400	37.4	liquid
	WA92001500	37.4	liquid
	WA92003400	37.4	liquid
	WA96001900	37.4	liquid
	WY92000500	37.4	liquid
	OR93000200	37.4	liquid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
4	241-340	60	solid
	241-338	60	solid
	241-268	60	solid

Batch	EPA Reg. No.	% active ingredient	Formulation Type
5	10404-52	60	solid
	10404-74	60	solid

Batch	EPA Reg. No.	% of active ingredient	Formulation Type
6	341-370	0.66	solid
	538-172	1.00	solid
	538-189	1.03	solid
	538-190	0.90	solid
	538-196	1.15	solid
	538-202	1.79	solid
	538-206	4.14	solid
	538-207	1.79	solid
	538-213	0.50	solid
	538-214	1.79	solid
	538-219	1.79	solid
	538-226	0.81	solid
	538-227	4.13	solid
	538-237	1.79	solid
	8378-45	1.79	solid
	10404-82	0.86	solid
	538-188	2.68	solid
	538-192	1.71	solid
	538-193	1.71	solid
	241-375	2.00	solid

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrants of these products are responsible for meeting the acute toxicity data requirements separately.

TABLE 2

No Batch	EPA Reg. No.	% active ingredient	Formulation Type
	241-281	60.00	liquid
NO	538-195	60.00	solid
BATCH	241-373	50.00	liquid
	241-244	34.40	liquid
	241-315	30.39	liquid
	241-331	30.24	liquid
	241-327	21.96	liquid
NO	241-376	25.40	liquid
BATCH	241-297	25.00	liquid
	5905-495	11.25	liquid
	538-251	0.25	solid

The technicals are listed in batch 1 and the acute toxicology data base, according to the HED chapter of the pendimethalin RED, is adequate and will support their reregistration eligibility.

NOTE: PRS advises that acute toxicology data from Batch 1 may be bridged to support product 241-281.

LIST OF REGISTRANTS RECEIVING THIS DCI
(Please remove this page and insert registrants mailing list)

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

m. The upper and lower certified limits for all 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	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

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

United States Environmental Protection Agency
Washington, D.C. 20460

Certification of Offer to Cost Share in the Development of Data

Form Approved
OMB No. 2070-0106, 2070-0057
Approval Expires 3-31-99

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-233, 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 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 firms 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 obselete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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-233, 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:

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 "Re 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 reregistrati

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 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 PENDIMETHALIN that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jane Mitchell at (703)-308-8061.

1. Appendix A.

2. PR Notice 86-5.

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

4. A full copy of this RED document.

5. A copy of the fact sheet for Pendimethalin.

The following documents are part of the Administrative Record for PENDIMETHALIN 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