REREGISTRATION ELIGIBILITY DECISION

PRONAMIDE

LIST A

CASE 0082

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

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

JUN 13 1994

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 **pronamide** which includes the active ingredient **[N-(1,1-Dimethylpropynyl)-3,5-dichlorobenzamide] or 3,5-dichloro-N (1,1-dimethyl-2-propynyl) benzamide**. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical[s], 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 ingredient to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Karen Jones at (703) 308-8047.

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. Complete the two response forms provided with each DCI letter by following the instructions contained in each DCI. **You must submit the response forms for each product and for each DCI within 90 days of the date you receive the RED; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

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

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

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

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

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

e. **Certification With Respect to Citation of Data**. Complete and sign this form (EPA form 8570-29) for each product. **Cite-all is not a valid option for reregistration.**

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

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

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB-0082)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB-0082)**
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.

TABLE OF CONTENTS

PRONAMIDE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Steve Jarboe	Biological Analysis Branch
James Saulmon	Biological Analysis Branch
Eric Maurer	Economic Analysis Branch

Environmental Fate and Effects Division

Mike Davy	Ecological Effects Branch
Larry Liu	Environmental Fate and Groundwater Branch
Kathy Monk	Science Analysis and Coordination Staff

Health Effects Division

Laura Morris	Occupational and Residential Exposure Branch
Leung Cheng	Reregistration Support Chemistry Branch
Nguyen Thoa	Toxicology Branch I and Chemical Coordination Branch
John Baziun	Science Analysis Branch

Registration Division

Wesley Allen	Fungicide-Herbicide Branch
Joanne Hayes	Registration Support Branch

Special Review and Reregistration Division

Karen Jones	Reregistration Branch
Carol Stangel	Policy, Planning and Operations Branch

Policy and Special Projects Section

Jean Frane	Special Review and Reregistration Section

Office of General Counsel

Philip Ross

Office of Compliance Monitoring

Beverly Updike	Pesticides Enforcement Policy Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GRAS	Generally Recognized As Safe as designated by FDA
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
LOEL	Lowest Observed Effect Level
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

MOE	Margin Of Exposure (PAD)
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The dose at which a substance produces a toxic effect.
TGAI	Technical Grade Active Ingredient.
TMRC	Theoretical Maximum Residue Contribution.

EXECUTIVE SUMMARY

Reregistration Decision

The Agency has determined that all of the uses of pronamide, as currently registered, with the exception of the late season use (1-day PHI) on artichokes and residential lawn and turf uses, will not cause unreasonable risk to humans. However, pronamide may pose adverse effects to terrestrial plants and aquatic plants may also be at risk. All of the uses of pronamide, except for the broadcast application on residential lawns and turf and the late season use on artichokes, are eligible for reregistration. Due to a lack of exposure information, a reregistration eligibility decision on the granular and wettable powder formulations applied by broadcast application for use on residential lawn and turf cannot be made at this time. Postapplication/reentry data on foliar dislodgeable dissipation and dermal passive dosimetry studies are required before a regulatory decision can be made on the residential lawn and turf uses. Similarly, due to a lack of residue data, a regulatory decision cannot be made at this time on the late season use on artichokes. The amendment of product labels deleting the late season use on artichokes or submission of replacement cropfield trial data is required.

Background

Pronamide is a selective, preemergence and/or postemergence herbicide registered for the control of grassy and broadleaf weeds on terrestrial food crops [artichoke, blackberry, blueberry, boysenberry, cherry, endive (escarole), lettuce, nectarine, peach, pear, plum, prune, raspberry (black,red), rhubarb]; terrestrial food and feed crops (agricultural fallow/idleland, apple, grapes, peas, sugar beet); terrestrial feed crops (alfalfa, clover, sainfoin, trefoil, vetch); terrestrial non-food crop (christmas tree plantations, golf course turf, ornamental herbaceous plants, recreation area lawns, pyrethrum) and terrestrial non-food crop and outdoor residential (ornamental and/or shade trees, ornamental woody shrubs and vines). The registered formulations of pronamide include a wettable powder (50% a.i.) and a granular (0.57-1% a.i.). There is a registered formulation intermediate (50% a.i.) product and technical grade (92% a.i.) product. Maximum application rates range from 0.25 to 4 lb a.i./A. Pronamide may be applied using conventional ground spray equipment, soil incorporation, or aircraft.

Pronamide was initially registered as a pesticide in 1972. In 1977 the Agency initiated a Special Review of pronamide based on a Medical College of Virginia (MCV) 18-month mouse carcinogenicity study which indicated that mice given diets containing 0, 1000, or 2000 ppm pronamide showed a treatment-related increase in hepatocellular carcinomas. The incidence of tumors was observed at 18 months in male mice only. At that time, this study provided the only evidence that pronamide might possess human carcinogenic potential. The Special Review was completed in 1979, and the final decision included the following: 1) restricted use classification for 50% wettable powder end-use products; 2) use of protective clothing during mixing and application of wettable powder formulations; 3) implementation

of water-soluble packaging for wettable powder formulations; and 4) tolerance on lettuce lowered from 2 ppm to 1 ppm to reduce dietary exposure. In April 1986, a Registration Standard was issued for pronamide (NTIS #PB87-103735). The Registration Standard summarized available data supporting the reregistration of products containing pronamide used for control of grassy and broadleaf weeds on lettuce, endive, alfalfa, rhubarb, pome and stone fruits, artichokes, berries, legumes, lawns and turf (commercial and residential), fallow land, woody ornamentals, nursery stock, and Christmas tree plantations. The Registration Standard also required additional product chemistry, toxicology, environmental fate, and residue chemistry data. The Agency has now completed its review of the pronamide target data base including data submitted in response to the 1986 Registration Standard.

Supporting Rationales for Reregistration Decision

Pronamide is in Category III for acute dermal toxicity. The Agency has classified Pronamide as a Group B2 (Probable Human) Carcinogen based on uncommon benign testicular interstitial cell and thyroid tumors in rats and liver carcinomas in mice. The Agency has also determined that dietary exposure to pronamide may be associated with an excess carcinogenic risk of 5×10^{-7} to the general population.

Based on the known toxicological concerns for pronamide, including its Group B2 classification, the Agency is requiring Personal Protective Equipment (PPE) for applicators and other handlers, as well as early entry workers, in accordance with the PPE level required in the Worker Protection Standard (WPS). The Agency is also requiring a Restricted Entry Interval (REI) of 24 hours for all WPS sites as a conservative measure to mitigate risk to workers entering treated areas after application.

The Reference Dose (RfD) is 0.08 mg/kg/day based on the chronic/carcinogenicity feeding study in rat, with respective male and female NOELs of 8.46 and 10.69 mg/kg/day and an uncertainty factor of 100. The percent of RfD utilized is 0.039%. A reassessment of tolerances is also included in this document.

There is a potential for postapplication dermal exposure to foliar dislodgeable residues and soil residues from use of both granular and wettable powder formulations. The Agency has determined that a reregistration decision on the broadcast use of pronamide on residential lawns cannot be made at this time. It was not feasible for the Agency to estimate the risk to homeowners and children from the broadcast treatment of pronamide granular and wettable powder formulations on residential lawns because of the numerous uncertainties in potential exposure levels. Regulatory decisions relating to postapplication reentry will be developed after the foliar dislodgeable dissipation and dermal passive dosimetry studies required to support the residential lawn uses of pronamide are submitted and reviewed. However, the broadcast treatment of pronamide for commercial turf is eligible for reregistration. Foliar dislodgeable dissipation and dermal passive dosimetry studies are required to confirm the postapplication reentry assessment for commercial turf uses. The Agency has imposed a restricted entry interval for commercial turf. The foliar dislodgeable dissipation and dermal

passive dosimetry studies will confirm this interval. Similarly, postapplication reentry data are required for pronamide use on lettuce because there is the potential for significant hand contact following the treatment of lettuce. These data are considered confirmatory for the lettuce use.

Because there is also a potential for mixer/loader/applicator (handlers) exposure to pronamide sprays and dusts through dermal and inhalation routes, following ground boom, aerial, and hand-spray applications for the wettable powder formulation and no adequate mixer/loader/applicator exposure data for the granular formulation of pronamide are currently available. Potential exposure from granular formulation is expected to be less than that from wettable powder formulations according to the exposure assessment in the 1986 Pronamide Registration Standard. The Agency is requiring confirmatory mixer/loader/applicator data for the granular formulation of pronamide. Data relating to estimation of dermal and inhalation exposure at outdoor sites are required to confirm the mixer/loader/applicator exposure for the granular formulation use on commercial and residential turf.

Pronamide is practically non-toxic to birds and mammals. It is moderately toxic to freshwater invertebrates and slightly toxic to freshwater fish. Currently, there are no data available for estuarine organisms. Based on the low toxicity of pronamide to freshwater fish and moderate toxicity to freshwater invertebrates, the Agency anticipates that additional data will confirm that pronamide does not represent a major problem to aquatic organisms. Estuarine data are required to confirm this assessment. The Agency believes that given the persistence of pronamide in water, a potential chronic exposure to aquatic invertebrates is possible. Therefore, the Agency is requiring the aquatic invertebrate life cycle study to assess this potential risk. Potential risks to endangered terrestrial plants will be addressed through the evaluation of additional data. When the Agency completes its Endangered Species program, additional precautionary labeling may be required to mitigate the risk to terrestrial plants. Also, aquatic plants may be at risk, but there are insufficient phytotoxicity data to ascertain the risk. Based on the data for algae, the risks to aquatic plants are not likely to be unreasonable; however, these risks will be further assessed when additional phytotoxicity data (which are not part of the target database for this reregistration review) on aquatic plants are submitted and evaluated.

Pronamide is stable to hydrolysis, to photolysis in water and on soil, and to aerobic/anaerobic microbial degradation in soil. This chemical has a relatively low vapor pressure and it is relatively mobile in soil. Therefore, pronamide is expected to be relatively persistent and mobile in the field and leaching appears to be the major route of dissipation. Although results from an unacceptable field dissipation study indicate that pronamide is neither persistent or mobile under field conditions, the Agency cannot rely on this data since it was generated by Craven Laboratories. The Agency is requiring a new field dissipation study to confirm the findings from this study. The new study will provide useful information for a better understanding of pronamide dissipation through the combined fate processes (i.e., degradation, metabolism, adsorption, leaching, volatilization, runoff) in the field. The

Agency is also requiring field rotational crop and spray drift studies which will provide additional information for the understanding of the fate of pronamide in the environment.

A Confidential Statement of Formula for the 92% technical pronamide is required for product identity. Similarly, a confirmatory independent lab validation for the residue analytical method (plant/animal) study is required. For FDA enforcement monitoring purposes, the Agency is requiring that representative plant and animal tissue samples bearing metabolites of pronamide be subjected to analysis by FDA multi-residue protocols C, D, and E from PAM Vol. I.

In addition, some of the existing residue data were generated by Craven Laboratories. The Agency does not consider Craven-generated data to be reliable or adequate to support continued registration or tolerance levels for the pesticide uses founded upon these data. Therefore, the Agency has determined that some of these data must be replaced. Storage stability data on alfalfa, apples, and lettuce were generated by Craven Laboratories and no other storage stability data for other crops are available. The Agency will extrapolate and apply storage stability data on poultry liver to ruminants and plants; based on the storage stability data on poultry, residues of pronamide and its metabolites are assumed to be stable in plant and animal commodities for up to 34 months. Storage stability data on milk, lettuce, apples, plums, grapes, and alfalfa, and the processed commodities of apples, grapes, and plums are required to confirm this assessment.

Furthermore, based on the available data, the Agency concluded that residues of pronamide are not likely to concentrate significantly in processed commodities of these crops, and no food or feed additive tolerances are currently required. The Agency is requiring data on the processed commodities of apples, grapes, plums to confirm this assessment.

Because the late season use of pronamide on artichokes is based on data generated by Craven Laboratories, a reregistration eligibility decision for this use cannot be made at this time. Registrants are required to amend their labels by deleting the late season use on artichokes or submit the required replacement cropfield trial data. Residue data on alfalfa seed were generated by Craven Laboratories; therefore, confirmatory residue data are required. However, tolerances which exist on alfalfa forage will support the alfalfa seed use until these data are generated. Likewise, the tolerance for dried winter peas was established using data generated by Craven Laboratories and confirmatory residue data are required. Alternate data from Europe are available to support the tolerance on dried winter peas until the required data are generated.

In summary, the Agency is requiring that additional confirmatory data be submitted. These data include the following:

Product Identity - Confidential Statement of Formula for 92% Technical
Aquatic Invertebrate Life Cycle - required for use on turf, hay, clover, alfalfa, and pasture use sites

Estuarine and Marine Organisms (Mollusc and Shrimp) - required for use on turf, hay, clover, alfalfa, and pasture use sites
Terrestrial Field Dissipation - required for all use sites
Field Rotational Crop - required for lettuce and fallowland use sites
Droplet Size Spectrum and Drift Field Evaluation - required because of aerial application to lettuce, artichoke, endive, Xmas tree plantations and fallowland
Foliar Dislodgeable Dissipation - required for commercial turf and lettuce
Dermal Passive Dosimetry - required for commercial turf and lettuce
Estimation of Dermal/Inhalation Exposure at Outdoor Sites - required for granular formulation use on commercial and residential turf
Residue Analytical Method - plant/animal (Independent Lab Validation)
Storage Stability - required for milk, lettuce, apples, plums, grapes, and alfalfa and the processed commodities of apples, grapes, and plums
Magnitude of Residue - Plants (Alfalfa Seed and Dried Winter Peas)
Processed Food - required for apples, grapes, plums

Certain data, which are not part of the target database for pronamide, are required. These data include:

Seed Germination/Seedling Emergence
Aquatic Plant Growth

Accordingly, the Agency has determined that only the products containing pronamide as the sole active ingredient for the uses declared eligible for reregistration will be reregistered when acceptable labeling and product specific data are submitted and/or cited. Before reregistering each product, the Agency is requiring that product specific data be submitted by the registrants within eight months of the issuance of this document. Additionally, in order to remain in compliance with FIFRA, it is the Agency's position that revised labeling be submitted by the registrants within that same time period. After reviewing these data and revised labels, the Agency will determine whether the conditions and requirements of FIFRA 3(c)(5) have been met for the reregistration of these products.

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of pronamide as of (insert date). The document consists of six sections. Section I is the introduction. Section II describes pronamide, 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 pronamide . Section V discusses the reregistration requirements for pronamide. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision document. Additional details concerning the Agency's review of applicable data are available on request.[1]

[1]EPA's reviews of data on the set of registered uses considered for EPA's analysis may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, DC 20460.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Pronamide
- **Chemical Name:** [N-(1,1-Dimethylpropynyl)-3,5-dichlorobenzamide] or 3,5-dichloro-N-(1,1-dimethyl-2-propynyl) benzamide
- **CAS Registry Number:** 23950-58-5
- **OPP Chemical Code:** 101701
- **Empirical Formula:** $C_{12}H_{11}NOCl_2$
- **Trade and Other Names:** Kerb®
- **Basic Manufacturer:** Rohm and Haas Company

B. Use Profile

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

For Pronamide:

Type of Pesticide: Preemergence herbicide

Mechanism of Action: Inhibits mitosis

Use Sites: Terrestrial Food Crop: artichoke, blackberry, blueberry, boysenberry, cherry, endive (escarole), lettuce, nectarine, peach, pear, plum, prune, raspberry (black,red), rhubarb.

Terrestrial Food + Feed Crop: agricultural fallow/idleland, apple, grapes, peas.

Terrestrial Feed Crop: alfalfa, clover, sainfoin, trefoil, vetch.

Terrestrial Non-Food Crop: christmas tree plantations, golf course turf, ornamental herbaceous plants, recreation area lawns, pyrethrum, sugar beet grown for seed.

Terrestrial Non-Food Crop + Outdoor Residential: ornamental and/or shade trees, ornamental woody shrubs and vines.

Target Pests:

Grasses: barley, foxtail barley, barnyardgrass*, marsh bentgrass, annual bluegrass, Kentucky bluegrass, [perennial bluegrass], downy brome, cheatgrass, canarygrass, large crabgrass, oat, wild oat, foxtail, yellow foxtail, goosegrass, lovegrass, orchardgrass, fall panicum, quackgrass, rye, italian ryegrass, perennial ryegrass, wheat.

Broadleaf weeds: carpetweed*, common chickweed, mouseear chickweed, nettleaf goosefoot, henbit, knotweed, common lambsquarters, cypressvine morningglory, tall morningglory, wild mustard*, nettle, burning nettle, stinging nettle, nightshade, black nightshade, hairy nightshade*, redroot pigweed*, common purslane, London rocket*, shepherdspurse*, smartweed, pale smartweed, red sorrel, tomato.
[* pest claimed to be suppressed on at least one of the labels for pronamide]

Formulation Types Registered:

Granular - 0.57 to 1.0 %
Wettable powder - 50.0 %
Formulation intermediate - 50.0%
Technical grade - 92.0%

Method and Rates of Application:

Granular - Rates for golf course turf include 1.5 lb AI/A applied (equipment not on label) in the fall or late winter. Use sites include: commercial areas (such as golf courses and athletic fields) and residential lawns.

Wettable Powder: Wettable powder formulation is registered for all pronamide use sites.

--One of three rates for lettuce is 6 lb AI/A allowed by SLNs (MI880004 and OH88001); remaining rates for lettuce are 1.5 lb AI/A and 2 lb AI/A.

--Rates for apples are from 2 to 4 lb AI/A applied by band at nonbearing or at postharvest via low pressure ground equipment; or by directed spray at nonbearing or postharvest via low pressure ground equipment.

--Rate for blackberries is 3 lb AI/A applied by band in the fall or winter via low pressure ground equipment; or applied as a low volume (concentrate) in the fall or winter via low pressure ground equipment.

--Rate for agricultural fallow/idleland is 0.5 lb AI/A applied as a broadcast in September via aircraft, ground, or low pressure ground equipment; or in December via aircraft, ground, or low pressure ground equipment.

Current Limitations on Use Practices:

For all formulations: Do not apply through any type of irrigation system. Moisture is required after application.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of pronamide. 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's use by site.

Percent of Various U.S. Crops Treated with Pronamide, 1989 - 1991

Site[1]	Acres Grown[2] (1,000)	Acres Treated (1,000)	Percent Crop Treated	Pounds AI Applied (1,000)
Apple	480.2	<1	<1	<1
Alfalfa	63,254.0	15 - 28	<1	10 - 20
Artichoke	11.8	1 - 2	8 - 17	2 - <5
Blackberry	6.7	<1 - 1	<1 - 15	<1 - 1

Site[1]	Acres Grown[2] (1,000)	Acres Treated (1,000)	Percent Crop Treated	Pounds AI Applied (1,000)
Blueberry[3]	59.2	<1	<1	<1
Boysenberry	1.1	<1	<1	<1
Cherry	97.6	<1	<1	<1
Clover[4]	145.8	3 - 4	2 - 3	3 - <5
Endive	2.7	1 - 2	37 - 74	<1 - 1
Grapes	740.8	<1 - 1	<1 - 1	<1 - 1
Lettuce	235.9	118 - 184	50 - 78	75 - 180
Nectarine	25.2	<1 - 1	<1 - 4	<1
Peaches[5]	185.6	<1 - 1	<1 - 1	<1
Pears	71.1	2 - 5	3 - 7	1 - 10
Raspberry	9.8	1	10	1
TOTALS	Not Applicable	143 - 233	Not Applicable	94 - 215

[1] Site identification based on REFS.

[2] Average acreage from 1989 - 1991 was the most consistent source used, (USDA/NASS) although it was not the only one used.

[3] Usage concentrated in Oregon which represents <5 percent of U.S. blueberry acreage.

[4] Usage reflective of CA data only which represents five percent of U.S. clover acreage.

[5] Usage concentrated in CA which represents 30 percent of U.S. peach acreage.

Data based on proprietary sources, USDA, and state statistics.

Percent of crop treated for woodland is <1% of 483,319 acres. All other registered sites had either no known usage or no available data. Those with no known usage include Peas and Plums/Prunes. Those with no available data include Birdsfoot Trefoil, Christmas tree plantations, Crown vetch, Sainfoin, Western wheatgrass, residential lawns and turf, and commercial turf.

D. Data Requirements

Data required by the 1986 Registration Standard for pronamide included studies on product chemistry, toxicology, environmental fate and residue chemistry. In 1990, a Data Call-In was issued for pronamide requiring data on plant protection, residue chemistry, and environmental fate studies. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Pronamide was registered in the United States in 1972 for use as a herbicide to control grassy and broadleaf weeds on field and vegetable, and orchard crops, forage and fodder, fallow land, woody ornamentals, nursery stock, and Christmas tree plantations. In 1977, a RPAR (Rebuttable Presumption Against Reregistration or Special Review) of pronamide was initiated on the basis of a Medical College of Virginia (MCV) 18-month mouse carcinogenicity study which indicated that mice given diets containing 0, 1000, or 2000 ppm pronamide showed a treatment-related increase in hepatocellular carcinomas. The incidence of tumors was observed at 18 months in male mice only. At that time, this study provided the only evidence that pronamide might possess human carcinogenic potential. After reviewing all the available information, the Agency determined that the cancer risk presumption had not been rebutted, and that the uses of pronamide posed unacceptable risks of cancer to certain exposed groups. The Agency also reviewed information relating to benefits of these uses, and after considering risks in relation to benefits, determined that these risks could be reduced by modifying the terms and conditions of registration for some uses. The RPAR review was completed in 1979, and the final decision included the following:

1) Restricted use classification for 50% wettable powder end-use products.

2) Use of protective clothing during mixing and application of wettable powder formulations.

3) Implementation of water-soluble packaging for wettable powder formulations.

4) Tolerance on lettuce lowered from 2 ppm to 1 ppm to reduce dietary exposure.

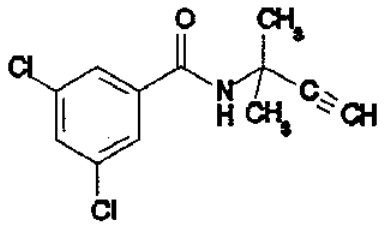
A Registration Standard for pronamide was issued in April 1986 in which the Agency required data to be submitted to support the existing uses of the pesticide and determined whether existing data were acceptable and sufficient to satisfy the requirements. Under the 1986 Registration Standard, registrants were required to generate data, supply missing data and to replace unacceptable data. A Data Call-In was issued in 1990 for pronamide requiring additional product chemistry, residue chemistry, plant protection, and environmental fate data. This Reregistration Eligibility Decision document reflects a reassessment of all data which were submitted in response to the Registration Standard and the Data Call-In.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Identification of the Active Ingredient

Pronamide [N-(1,1-dimethylpropynyl)-3,5-dichlorobenzamide], a restricted use pesticide (1979 Special Review), is a systemic herbicide which is registered for use on a variety of food and feed crops as well as for certain non-food/non-feed sites. The structural formula for pronamide is:



Empirical Formula: $C_{12}H_{11}NOCl_2$
Molecular Weight: 256.13
CAS Registry No.: 23950-58-5
Shaughnessy No.: 101701

Technical pronamide is a white crystalline solid with a melting point of 155-156° C and a specific gravity of 0.48 g/cc. The solubility of pronamide in water at 25° C is 15 ppm. Pronamide is soluble in dimethyl sulfoxide and dimethyl formamide at 33 ppm; in mesityl oxide, isophorone, methyl ethyl ketone, and cyclohexanone at 20 ppm; in methanol, isopropanol, and chlorobenzene at 12-15 ppm; in butyl cellosolve, xylene, acetonitrile, and kerosene at 10 ppm; and in nitrobenzene and ethylene dichloride at 5 ppm.

2. Other Product Chemistry Issues

Products registered for use include a 92% a.i. technical grade manufacturing product (TGAI; 92%T), a 50% a.i. formulation intermediate (FI), thirteen 50% a.i. wettable powder end-use products, and three granular end-use products ($\leq$1% a.i.). The wettable powder end-use products are registered for terrestrial food/feed use and non-food/non-feed outdoor residential use. The granular end-use products are registered only for terrestrial non-food residential uses (e.g., ornamental lawns/turf and recreation area lawns).

The following required product chemistry data, GL# 61-1 Product Identity (Confidential Statement of Formula (CSF, EPA Form 8570-4)) for the 92%T and GL# 61-2 Beginning Materials and Manufacturing Processes for the FI must be submitted.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base is adequate and will support reregistration.

a. Acute Toxicity

The acute toxicity data on pronamide technical (92% a.i.) are summarized below:

Acute Toxicity

Test	Results	Category
Oral LD_{50} in rats	> 5000 mg/kg (1)	IV
Dermal LD_{50} in rabbits	> 3160 mg/kg (1)*	III
Inhalation LC_{50} in rats	>3.2 mg/l (2)	III(2)

* Unacceptable (test material was administered as a powder on unmoistened skin) for 92% technical, however the study performed with the Kerb-50W is acceptable.

(1) Refer to MRID# 00085505.

(2) Refer to MRID# 00083663. The inhalation/rat study performed with Kerb-50W is acceptable and satisfies the inhalation rat requirement for the pronamide technical.

Acute toxicity studies with pronamide technical oral/rat (GL# 81-1), dermal/rabbit (GL#81-2), inhalation/rat (GL# 81-3), are considered adequate for regulatory purposes upon consideration of the acute toxicity studies performed with the Kerb-50W (MRID 00083663). The results of the dermal LD_{50} in rabbits for the Kerb-50W is a LD_{50} value greater than 10 g/kg. Also, the results of the inhalation LC_{50} in rats for the Kerb-50W is a LC_{50} value greater than 3.2 mg/l. The combined results observed with pronamide technical and Kerb-50W will satisfy the acute toxicity data requirement for pronamide technical. An acute delayed neurotoxicity study in the hen (GL# 81-7) is not required because pronamide is not an organophosphate. An acute neurotoxicity screening battery (GL# 81-8) is not required at this time because there was no evidence of neurotoxicity in any of the existing studies with pronamide.

b. Subchronic Toxicity

In a 90-day feeding study in rodents, pronamide was administered in the diet to Sprague Dawley CD rats (10/sex/group) for 13 consecutive weeks, at concentrations of 0, 50, 150, 450, 1350, or 4050 ppm (0, 2.5, 7.5, 22.5, 67.5, or 202.5 mg/kg/day). A systemic NOEL was established at 50 ppm (2.5 mg/kg/day). A systemic LOEL was established at 150 ppm (7.5 mg/kg/day), based on increases in liver weight (absolute and relative) in both sexes. The high dose (4050 ppm; 202.5 mg/kg/day) caused decreases in body weight and increases in liver weight in both sexes and increases in testes weight in males. This study was classified "core supplementary" because there were no individual data on many parameters (body weight, feed consumption, hematology, urinalysis, and organ weight), no clinical observations, and no analysis for test material concentration and stability. This study did not fully satisfy the toxicological data requirement for a subchronic feeding study (GL# 82-1) in rodents. (MRID 00085506).

In another 90-day feeding study in rodents, pronamide was administered in the diet to Crl:CD®BR rats (10/sex/group) for 13 consecutive weeks, at concentrations of 0, 40, 200, 1000, or 4000 ppm (0, 2.5, 12.3, 60.0, or 254.0 mg/kg in males; 0, 3.1, 15.0, 74.6, or 289.2 mg/kg in females). A systemic NOEL was established at 200 ppm (12.3 mg/kg/day/male; 15.0 mg/kg/day/female). A systemic LOEL was established at 1000 ppm (60.0 mg/kg/day/male; 74.6 mg/kg/day/female), based on increased liver relative weight and incidence of liver histopathology (centrilobular hypertrophy) in both sexes, decreased body weight/weight gain and feed consumption in females, and increased blood cholesterol level in males. At the high dose (4000 ppm; 254.0 mg/kg/day/male; 289.0 mg/kg/day/female) decreases in body weight/weight gain and feed consumption (without any alteration in feed efficiency) in both sexes, and increases in liver-related effects [increases in cholesterol (both sexes), transaminase and alkaline phosphatase (males), triglycerides (females), liver absolute/relative weights (both sexes), incidence/severity of liver centrilobular hypertrophy (both sexes)] and in histopathology of the thyroid (thyroid follicular hypertrophy in both sexes) and anterior pituitary (cellular hypertrophy in males) were observed. Based on the results, the liver, thyroid, and pituitary appear to be the target organs in subchronic oral intoxication of rats with pronamide. This study has satisfied the toxicological data requirement for a subchronic feeding study (GL # 82-1) in rodents (MRID 42669403).

In a 90-day feeding study in non-rodents, beagle dogs (1/sex/group) were fed diets containing 0, 450, 1350, or 4050 ppm pronamide (0, 11.25, 33.75, or 101.25 mg/kg/day) for 3 months (MRID 00085507). The results

indicated the liver as a possible target organ; serum alkaline phosphatase and liver (absolute and relative) weight were higher in the single male and female dogs treated with the high dose than in the respective control dogs. This study was classified "core supplementary" because the number of animals used was inadequate. The requirement for a subchronic study in non-rodent (GL# 82-1) is, however, satisfied by a chronic 1-year feeding study in dogs (MRIDs 41807601 and 41807602).

c. Chronic toxicity

The required chronic toxicity study in rodents (GL# 83-1) is satisfied by a chronic/carcinogenicity feeding study in rats (See section III.B.d. Carcinogenicity for details on the results of this study). (MRIDs 41714001 and 41714002)

In a chronic toxicity feeding study in non-rodents, beagle dogs (6/sex/group) were fed diets containing 0, 300, 875, or 1750 ppm pronamide (0, 11.9, 33.1, or 67.7 mg/kg/day in males; 0, 11.9, 36.1, or 69.0 mg/kg/day in females) for 52 consecutive weeks. A NOEL was established at 300 ppm (11.9 mg/kg/day). A LOEL was established at 875 ppm [33.1 mg/kg/day (M); 36.1 mg/kg/day (F)], based on increases in serum alkaline phosphatase in males and thyroid weight in females, and in liver pathology in both sexes (increases in liver absolute and relative weight and in incidence of hepatocyte hypertrophy, granular brown pigmentation, mononuclear infiltration, and granular brown pigmentation in Kupffer cells). The high dose additionally caused decreases in body weight/feed consumption without any alteration in feed efficiency and increases in serum alkaline phosphatase and gamma glutamyl transferase in both sexes, increases in serum alanine aminotransferase in females, and increases in testes relative weight in males. Based on the results, the liver appears to be a target organ in chronic oral intoxication of dogs with pronamide. This study has satisfied the toxicological data requirement for a chronic feeding study (GL # 83-1) in non-rodent (MRIDs 41807601 and 41807602).

d. Carcinogenicity

In a carcinogenicity feeding study in mice, B6C3F1 mice (100/sex/group) were fed diets containing 0, 1000, or 2000 ppm pronamide (approximately 0, 150, or 300 mg/kg/day) for 18 months. Additional groups of 25 mice/sex/group were assigned to the 6-month interim sacrifice. Survival rates (> 90%) were comparable between groups with no gender differences. A dose-related increase in incidence of hepatocellular carcinomas (respective rates at 0, 1000, and 2000 ppm were 7/100, 18/100, and 24/99) was observed in male mice sacrificed at 18

months. The increases in tumor rates observed at 1000 and 2000 ppm were both statistically significant by pair-wise comparison with the controls. Pronamide did not induce hepatocellular carcinomas in female mice (respective rates at 0, 1000, and 2000 ppm were 0/100, 1/100, and 2/100 at 18 month). The dosing was considered to be adequate based on body weight gain depressions in high dose females and increases in relative (to body) weight of the liver at $\geq$1000 ppm in both sexes. This study has satisfied the data requirement for a carcinogenicity study (GL # 83-2) in mice (MRID 00107968).

The results of the above study were confirmed by a special carcinogenicity feeding study conducted in male mice. In this study male B6C3F1 mice (63/group) were fed diets containing 0 (control 1), 0 (control 2), 20, 100, 500, or 2500 ppm pronamide (approximately 0, 0, 3, 15, 75, or 375 mg/kg/day) for 24 months. Additional groups were assigned to interim sacrifices at 6 months (42 at 0 ppm; 42 at 2500 ppm) and at 15 and 18 months (42/group including controls 1 and 2, and 20, 100, 500, and 2500 ppm groups). Survival rates were >93% for all groups. The results confirmed that long term exposure (24 months) of male mice to pronamide was associated with an increased incidence of hepatocellular carcinomas (respective rates at 0, 0, 20, 100, 500, or 2500 ppm at the 24-month sacrifice were 5/63, 5/63, 9/63, 12/63, 18/63, and 14/61; positive trend observed with significant pair-wise comparison with controls at $\geq$ 100 ppm). Additionally, hepatocellular adenomas were observed (respective rates at 0, 0, 20, 100, 500, or 2500 ppm at the 24-month sacrifice were 4/63, 6/63, 6/63, 7/63, 8/63, and 28/61; positive trend observed with significant pair-wise comparison with controls at 2500 ppm). There was an apparent progression from benign to malignant tumors. This special study provided confirmatory information regarding the carcinogenic effect of pronamide in mice (MRID No. 00114114).

In a chronic/carcinogenicity feeding study in rats, Crl:CD (SD)BR rats (60/sex/group) were fed diets containing 0, 40, 200, or 1000 ppm pronamide (0, 1.73, 8.46, or 42.59 mg/kg/day/male and 0, 2.13, 10.69. or 55.09 mg/kg/day/female) for 24 months. Ten extra animals/sex/dose group were assigned to be sacrificed after 6 and 12 months of treatment. The following neoplastic findings were observed: (1) rats treated with the high dose for 24 months showed an increased incidence of thyroid follicular cell adenomas (respective rates at 0, 40, 200, and 1000 ppm were 4/68, 2/70, 6/69, and 14/67 for males and 1/59, 2/58, 1/58, and 6/59 for females) and benign testicular interstitial cell tumors (respective rates at 0, 40, 200, and 1000 ppm were 5/58, 5/60, 3/59, and 15/56 for males), (2) thyroid tumors were not observed until week 53 for males and week 82 for females and testicular tumors were not observed until week 67, (3) both increases in

thyroid tumor rate (statistically significant by pair-wise comparison with controls in males; positive trend for both sexes) and testicular tumor rate (statistically significant by pair-wise comparison with controls; positive trend) exceeded historical control ranges, and (4) there was no progression to carcinomas. The following non-neoplastic findings were observed: (1) liver pathology in both sexes (centrilobular hypertrophy and eosinophilic cell alteration; dose-related; significant pair-wise comparison with controls at the high dose; observed during both the 1st and second year), (2) thyroid follicular cell hypertrophy (positive trend in both sexes; significant pair-wise comparison with controls at the high dose in females; observed during the first year), and (3) ovarian sertoliform tubular hyperplasia in females (positive trend with significant pair-wise comparison with controls at the high dose; observed during the 2nd year). The dosing was considered to be adequate based on body weight gain depression. Survival rates were comparable between groups with no gender differences. This study has satisfied the data requirement for a chronic feeding/carcinogenicity study (GL#s 83-1 and 83-2) in rats (MRIDs 41714001 and 41714002).

Two special studies were conducted to evaluate pronamide's effect on hormonal balance in support of a threshold mechanism for the induction of thyroid and testicular neoplasms.

In the first study, a special thyroid function study, male Crl:CD (SD)BR rats were fed diets containing 0, 40, 1000, or 4000 ppm pronamide (approximately 0, 3, 67, or 279 mg/kg/day) for 4 or 15 weeks. Reversibility of the thyroid effects was studied by feeding a group of rats with a diet containing 4000 ppm pronamide for 4 weeks followed by control diet for 11 weeks. The following findings were observed:

1. Serum T4 was reduced in a dose-related manner both after 4 and 15 weeks, serum TSH was reduced after 4 weeks of treatment with 1000 ppm but not with 4000 ppm, and serum levels of T3 and rT3 were not affected.

2. Incidence of thyroid follicular cell hypertrophy/hyperplasia was equally increased at 1000 and 4000 ppm (respective incidences at 0, 40, 1000, and 4000 ppm were 2/10, 4/10, 10/10, and 10/10 after 4 weeks and 3/10, 5/10, 9/10, and 10/10 after 15 weeks.

3. Hepatic UDP-glucuronosyl transferase activity was increased at 4000 ppm, both after 4 or 15 weeks of treatment (the effect at 1000 ppm was not studied).

4. Bile flow, biliary clearance of ^{125}I-T4 and ^{125}I-T4-glucuronide, and ^{125}I bile/plasma ratio were increased at 4000 ppm, both after 4 or 15 weeks of treatment (the effect at 1000 ppm was not studied).

5. The changes in T4, thyroid histology, hepatic UDP-glucuronosyl transferase activity, and biliary parameters observed after 4 weeks of treatment with 4000 ppm were either partially or totally reversed after 11 weeks of recovery. This study provided supplemental information regarding a possible endocrine-related mechanism of action for the observed thyroid carcinogenic effect of pronamide in rats (MRID 42093401).

In the second study, a special pilot testicular function study, male Crl:CD (SD)BR rats were fed diets containing 0 or 4000 ppm pronamide (approximately 0 or 273 mg/kg/day) for 13 weeks. Animals treated with pronamide showed the following effects: (1) increase in the number of testicular interstitial cells, (2) increases in serum LH and FSH unaccompanied by a decrease in serum testosterone, (3) modest increases in liver weight and liver microsomal protein content, and (4) increases in the rate of oxidation of testosterone and in activity of the hepatic microsomal enzymes cytochrome-P_{450}, cytochrome-B5, and NADPH-cytochrome C reductase (expressed as μmol product/whole liver). This study provided some supplemental information regarding a possible endocrine-related mechanism of action for the observed testicular carcinogenic effect of pronamide in rats (MRID 42139601). A 13-week testicular hormonal study, voluntarily submitted by the registrant, was also reviewed by the Agency. The information contained in the 13-week testicular hormonal study did not alter the weight of evidence with respect to the cancer classification or the use of a unit risk to estimate excess cancer risk to humans. (MRID No. 42987501)

On September 30, 1992, the OPP Carcinogenicity Peer Review Committee concluded that 1) the data on thyroid mechanism were suggestive of a thyroid-pituitary hormonal control mechanism but were not conclusive, based on the Agency's six criteria for a threshold model for thyroid carcinogenicity (e.g., there were no dose-related and/or sustained increases in TSH levels, no dose-related increases in incidence of thyroid hypertrophy/hyperplasia, and no information on thyroid hormone synthesis ....) and 2) the Agency currently has no policy regarding a threshold model for testicular neoplasm, but, even if a testes-pituitary hormonal control mechanism exists for the testes, the evidence that pronamide-induced testicular tumors in the rat may be related to a disruption in the testes-pituitary balance is very limited (e.g., there was no clear increase in interstitial cell hypertrophy/hyperplasia, no alteration in testosterone level,

no information on testicular hormone synthesis and reversibility of testicular lesions). Consequently, the Peer Review Committee reclassified pronamide as a Group B2 carcinogen - a probable human carcinogen with inadequate evidence in humans (a change from the previous classification as a Group C carcinogen - possible human carcinogen, based on carcinogenic effect on the liver of mice; 1986 Registration Standard). The classification was based on the findings of two types of tumors in the rat (uncommon benign testicular interstitial cell tumors and thyroid follicular cell adenomas) and one type (liver carcinomas) in the mouse. The estimated Q_1^* is 1.54×10^{-2} $(mg/kg/day)^{-1}$ based on the 18-month mouse carcinogenicity study [a 3.75% reduction from the previously estimated value of 1.63×10^{-2} $(mg/kg/day)^{-1}$; 1986 Registration Standard].

e. Developmental Toxicity

In a developmental toxicity study in rabbits, artificially inseminated 6-month old New Zealand white rabbits (18/group) were administered 0, 5, 20, or 80 mg/kg/day of pronamide by gavage, during gestation days 7 through 19. The liver appeared to be the target organ. The maternal NOEL was established at 20 mg/kg/day, based upon the recommendations of the OPP RfD Committee which met on January 21, 1993. The maternal LOEL was established at 80 mg/kg/day, based on one mortality, 5/16 abortions, body weight loss, and liver histopathology (punctate vacuolation of hepatocytes, swollen hepatocytes, necrosis, pigmentation of Kupffer cells, and eosinophilic hepatocytes). The developmental NOEL was 20 mg/kg/day. The developmental LOEL was 80 mg/kg/day, based on late resorption (two of the 5 high dose does which aborted each showed one incidence of late resorption). This study has satisfied the data requirement for a developmental toxicity study (GL# 83-3) in rabbits (MRID 00148064 and 00148065).

In a developmental toxicity study in rats, groups of 25 mated female Crl:CD®(SD)BR rats were given pronamide at doses of 0, 5, 20, 80, or 160 mg/kg/day by oral gavage, on gestation days 6 through 15. The only effects observed were minimal decreases in (1) group mean body weight (4.6% below control) for the 160 mg/kg/day dose group at day 13 of gestation and (2) body weight gains (<3% of the absolute body weight) for the 80 mg/kg/day group (gestation days 6-8) and the 160 mg/kg/day group (gestation days 6-8 and 8-10). Because of the absence of clinical signs of toxicity, these minor changes in body weight/weight gain were not considered adverse maternal effects. The study was classified core supplementary, based on the absence of maternal toxicity or developmental toxicity and no explanation for selection of the dose levels tested. However, this study need not be repeated since the rabbit developmental

toxicity study demonstrated a lower NOEL; the developmental study in rats was considered adequate for risk assessment purposes (MRID 41540301).

f. Reproductive Toxicity

In a two-generation reproduction study, Crl:CD®(SD)BR rats (25/sex/group) were fed diets containing 0, 40, 200, or 1500 ppm pronamide through two successive generations (approximately 0, 3.0, 15.4, or 114.0 mg/kg/day/P1 males and 0, 3.2, 16.5, or 127.3 mg/kg/day/P2 males during pre-mating period; group time-weighted average approximately 0, 4.1, 20.2, and 158.2 mg/kg/day/P1 females and 0, 4.0, 19.8, or 157.4 mg/kg/day/P2 females), with one mating per generation. No treatment-related mortalities and/or clinical signs were observed in either parental generations. A NOEL for parental systemic effects was established at 200 ppm (15.4 mg/kg/day/P1 male; 16.2 mg/kg/day/P2 male; 20.2 mg/kg/day/P1 female; 19.8 mg/kg/day/P2 female). The LOEL was 1500 ppm (114.0 mg/kg/day/P1 male; 127.3 mg/kg/day/P2 male; 158.2 mg/kg/day/P1 female; 157.4 mg/kg/day/P2 female), based on decreased body weight and food consumption and histopathology of the liver (centrilobular hypertrophy) and adrenal (zona glomerulosa cellular hypertrophy) in both sexes, the thyroid (follicular cell hypertrophy) in females, and the anterior pituitary (cellular hypertrophy) in males. These effects were observed in both P1 and P2 generations. The reproductive NOEL was 200 ppm. The reproductive LOEL was 1500 ppm, based on decreased combined male/female pup weight per litter (F1 pups at birth and through lactation period; F2 pups at lactation days 14 and 21); pups were not weighed separately by sex. This study has satisfied the data requirement for a 2-generation reproduction toxicity study (GL# 83-4) in rats (MRID 40334501).

g. Mutagenicity

Results of mutagenicity studies indicate that pronamide does not appear to be mutagenic. The results of these studies are summarized in the table below.

Mutagenicity Studies With Pronamide

Study Type	GL No.	Results
Gene Mutation/Ames	84-2	Negative, with or without metabolic activation (HDT = 5 mg/plate). (MRID 40090602)
Forward Gene Mutation (CH V79 cells)	84-2	Negative, with or without metabolic activation (HDT = 40 ug/ml). (MRID 40211106)

Study Type	GL No.	Results
Structural Chromosome Aberration in-vitro	84-2	Negative, with or without metabolic in CHO cells (HDT = 1.5 mg/ml). (MRID 40211108)
Structural Chromosome Aberration in-vivo	84-2	Negative in mouse bone marrow cells (HDT = 4.94 g/kg by oral gavage). (MRID 40211105)
UDNA Synthesis	84-4	Negative in primary hepatocytes of rats (HDT = 50 ug/ml). (MRID 40211107)

h. Metabolism

Two complementary metabolism studies are available. In the first study (MRID 41801801), single doses (2 or 100 mg/kg) of ^{14}C-pronamide were administered by oral gavage to male and female Crl:CD®BR rats to study radioactivity distribution and excretion. The following results were observed:

1. Over a 7-day period, most of the radioactivity administered (93-103% of dose) was recovered in the urine (40-61% of dose) and feces (40-60% of dose).

2. Following a low dose (2 mg/kg), urinary and fecal radioactivity excretion were comparable in males (47% of dose in urine; 46% in feces). In females, urinary excretion (57% of dose) was higher than fecal excretion (40% of dose). Absorption of pronamide (as reflected by urinary excretion of radioactivity) appears to be slightly higher in females than in males.

3. Following a high dose (100 mg/kg), urinary radioactivity excretion (35-39% of dose) was lower than fecal excretion (57-60% of dose) in both sexes, indicating that the absorption process was likely saturated.

4. Peak plasma radioactivity occurred within 8 hours of dosing, and the label was detected throughout the body with the highest concentrations (in decreasing order) in fat, adrenal gland, bone marrow, thyroid, liver, kidney, and plasma. No sex difference was apparent in the rate of excretion of the test material. Plasma half-life ($t_{1/2}$) of a low dose was biphasic [rapid (α) phase = 12.6 hrs (males) and 12.7 hrs (females); slow phase (β) = 36.6 hrs (males) and 45.3 hrs (females)], and that of the high dose rats was monophasic [$t_{1/2}$ = 24.1 hrs (males) and 24.8 hrs (females)].

5. Very little radioactivity was recovered in tissues (< 0.22% of dose) and carcasses (< 2.44% of dose) 7 days after dosing.

In the second study (MRID 41922901), a partial characterization of ^{14}C-pronamide urinary metabolites was conducted, using the samples collected in the first study. The results indicated that:

1. Very little unchanged pronamide (< 0.5% urine total radioactivity) was recovered in urine.

2. Twenty metabolites were found but only thirteen (constituting ≤ 51.6% of the total radioactivity in urine) were clearly identified.

The previous two studies combined did not completely satisfy the data requirement for a metabolism study in rats (GL# 85-1). Additional data providing a complete characterization of fecal and urinary metabolites were reviewed and found acceptable in a third study. In this study, (MRID 42858001) identification of the urinary and fecal metabolites of pronamide in rats given single oral dose (2 or 100 mg/kg) or multiple low doses (20 ppm a.i. in diet for 14 days) followed by as low dose (2 mg/kg) of ^{14}C-pronamide was made. The following results were observed:

1. No significant difference in urinary metabolite profile was observed between sexes or dose. The major urinary metabolites were SS47-70 (3.0-5.9% of the dose) and metabolite 10 (12.7-18.9%). In the urine, approximately 27 unidentified metabolites were found and none exceeded 3.3% of the dose.

2. Fecal excretion of parent ranged from 9.2-10.9% of the dose for the low dose and low repeated dose groups and 37.4-40.9% for the high dose group. In the feces, almost all of the unknowns are under 1% of the dose. The registrant postulated metabolic pathways of the test compound in rats.

The data from the previous studies (MRIDs 418018001 and 41929901) when combined with the results from the present study (MRID 42858001), satisfy the toxicological requirement for adequate metabolism studies in rats (GL# 85-1).

i. Dermal Absorption

A dermal absorption study is available (MRIDs 40256701C and 41117201). The following briefly describes the study and results:

1. Rats were dermally exposed for six hours to 50W and 3.3F formulations at nominal doses of 0.08 or 4.40 mg/cm^2.

2. The dermal absorption rates per 6 hours were 19% and 17% for 50W and 15.1% and 5.4% for 3.3F, respectively.

The study was considered unacceptable because 1) the actual doses applied to the skin were not determined and 2) there were discrepancies in recovery for the 50W doses (78% and 122% of nominal doses). However, another study is not required because based on worst-case assumptions, the risk appears acceptable.

j. Other Toxicity Considerations

Pronamide appears to be a liver toxicant. Adverse liver-related effects (increases in liver weight and/or liver-related serum enzymes and/or histopathology) were consistently observed in every animal species studied, including the rat (subchronic, chronic, and 2-generation studies), mouse (carcinogenicity study), rabbit (developmental study), and dog (subchronic and chronic studies). Pronamide also appears to be a toxicant to several endocrine organs including the thyroid (in rats; increase in weight and/or histopathology observed in subchronic, special 13-week thyroid, chronic/carcinogenicity, and 2-generation reproduction studies), testes [in rats (histopathology in chronic/carcinogenicity study) and dogs (increase in weight in chronic study)], and pituitary (in rats; histopathology observed in subchronic and 2-generation reproduction studies). Many chemicals belonging to the class of organochlorine chemicals are known to produce disruption of the endocrine system (Hileman 1993). Pronamide is related to this class of chemicals.

k. Reference Dose

A RfD was established for pronamide at 0.08 mg/kg/day, based on the chronic/carcinogenicity feeding study in rat, with respective male and female NOELs of 8.46 and 10.69 mg/kg/day and an uncertainty factor of 100 to account for interspecies extrapolation and intraspecies variability. Critical effects (observed at 42.59 mg/kg/day/male and 55.09 mg/kg/day/female) were decreased body weight/body weight gain and increased liver weight, as well as an increased incidence of hepatic centrilobular hypertrophy, eosinophilic cell alterations, and thyroid follicular cell hypertrophy in both sexes. This RfD was approved by the OPP RfD Committee on January 29, 1993, but has not yet been verified by the Agency RfD Committee. A toxicological evaluation has not been performed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to establish an Acceptable Daily Intake (ADI). (MRIDs 41714001 and 41714002).

2. Exposure Assessment

a. Dietary Exposure

Plant Metabolism

Studies with alfalfa and lettuce indicate that pronamide is readily absorbed by plants through the root system, translocated upward, and distributed into the entire plant. The degree of translocation from leaf absorption is not appreciable. Metabolism primarily occurs by conjugation to malonyl glucose. No evidence of fragmentation or loss of the chloro substituent from the aromatic ring was observed. The terminal residues of concern are pronamide and its metabolites containing the 3,5-dichlorobenzoyl moiety. (MRIDs 00107957, 00107958, 40494802, and 40494803).

Animal Metabolism

Studies with lactating goats and laying hens indicate that the primary route of elimination is by excretion (urine and feces). Minimal residues were distributed to goat and poultry muscle. The metabolic pathway involves modification of the aliphatic portion of pronamide. The terminal residues of concern are pronamide and its metabolites containing the 3,5-dichlorobenzoyl moiety. (MRIDs 00107954, 00107958, 42043401, and 42614201).

Residue Analytical Method

A Gas Liquid Chromatography (GLC) method with electron capture detection (designated as Method I, PAM Vol. II) converts residues of pronamide and its metabolites to methyl 3,5-dichlorobenzoate. The listed detection limits are 0.2 ppm in/on plant commodities and 0.01 ppm in animal commodities. A revised version of the PAM II method, which includes an alkaline hydrolysis to release bound residues, resulted in increased method efficiency and has been submitted for the enforcement of tolerances in animal commodities. The revised method remains to be validated by an independent laboratory.

The FDA Pestrak database (PAM Vol. I, Appendix II) contains data concerning the applicability of all FDA multi-residue methods (except Protocol E for fatty food) to pronamide *per se*. No data are available concerning the applicability of multi-residue methods to pronamide metabolites containing the 3,5-dichlorobenzoyl moiety. For FDA enforcement monitoring purposes, the Agency currently requires that representative plant and animal tissue samples bearing metabolites of pronamide be subjected to analysis by FDA multi-residue protocols C, D, and E from PAM Vol. I. In addition, the Agency

requires that representative samples containing residues of pronamide *per se* be analyzed according to protocol E for fatty foods. (MRIDs 00035563, 00035565, 00035566, 00070933, 00070934, 00074523, 00077215, 00107957, 00107958, 00107959, 00107960, 00107961, 00107965, 00107967, 00125382, 42043401, 42614201).

Storage Stability

In plant commodities, storage stability data [GL# 171-4(e)] have been submitted for alfalfa, apples, and lettuce; however, these data were generated by Craven Laboratories and no storage stability data for other crops are available. In animal commodities, pronamide is stable in poultry eggs and tissues under frozen conditions for up to 34 months. For the purposes of reregistration, the Agency will extrapolate and apply storage stability data on poultry liver to ruminants and plants; based on the storage stability data on poultry, residues of pronamide and its metabolites are assumed to be stable in plant and animal commodities for up to 34 months. Confirmatory storage stability data on milk, lettuce, apples, plums, grapes, and alfalfa, and the processed commodities of apples, grapes, and plums are required. (MRIDs 41570101 and 42614201).

Magnitude of Residue in Meat, Milk, Poultry and Eggs

Studies in which cattle and poultry were fed pronamide at several dose levels are available. Based on animal diets of alfalfa hay in cattle and alfalfa meal in poultry, the current tolerances are adequate to cover the secondary residues of pronamide that may transfer to meat, milk, poultry, and eggs. All data requirements for magnitude of the residue in animals have been fulfilled. (MRIDs 00107958, 00107959, 00107967, 40494801, 40782201, 42043401, and 42614201).

Magnitude of the Residue in Plants

Residue data are available reflecting the use pattern as prescribed on the current labels for the various crops. All data for the magnitude of the residue in plants have been evaluated and deemed acceptable except for alfalfa seed, artichoke, and dried winter peas. Data are still required as follows:

Alfalfa seed: Confirmatory residue data are required since all available seed residue data were generated by Craven Laboratories. Tolerances which currently exist on alfalfa forage will support this use until these data are generated. (MRIDs 00033380, 00107958, 00107965, 00107967, and 00157804).

Artichoke: Data reflecting early season use are acceptable. Data reflecting the established 1-day PHI were generated by Craven Laboratories; therefore, label revision deleting the 1-day PHI or replacement of artichoke field trial data is required. (MRIDs 00077215 and 00125382).

Dried winter peas: Confirmatory residue data are required since the tolerance was established using data generated by Craven Laboratories (alternate data from Europe are available to support the established tolerance in the interim, until the required data are submitted and reviewed).

Processed Food/Feed

The only available data for the processed commodities of alfalfa, apples, grapes, and plums were generated by Craven Laboratories. However, field residue data resulting from up to 2x label rates show non-detectable residues of pronamide and its metabolites in apples, grapes and plums. Based on the available data, the Agency concluded that residues of pronamide are not likely to concentrate significantly in processed commodities of these crops, and no food or feed additive tolerances are currently required. However, the Agency is requiring data on the following processed commodities of the following RACs to confirm this assessment: apples, grapes, and plums.

b. Occupational and Residential

Pronamide is a selective systemic pre- and postemergent herbicide used to control grasses and broadleaf weeds in lettuce, endive, alfalfa, rhubarb, pome and stone fruits, artichokes, berries, grapes, legumes, woody ornamentals, Christmas trees, nursery stock, lawns, turf, and fallow land.

Pronamide end-use products (Kerb®) are formulated as granulars (0.125% - 1.0% a.i.) and wettable powders (50% a.i.; in water-soluble pouches). The wettable powder formulations are used for all crop spray uses and commercial and residential lawns and turf; the granular products are applied to both commercial and residential areas (i.e., ornamental and Bermuda grass turf (such as golf courses), lawns, and athletic fields).

Application methods include ground boom, aerial, and hand-spray applications (the latter method is used only for ornamentals and nursery stock). Depending on the site and weed problem, the application rates range from 0.5 to 4.0 lbs. of product per acre, (0.125 - 2.0 lbs a.i.).

Based on its carcinogenic potential, the following restrictions were imposed in the 1986 Pronamide Registration Standard and are assumed for this exposure assessment. These restrictions currently exist on pronamide product registration labels:

- All 50% wettable powder end-use products are classified as restricted use and must be packaged in water-soluble pouches.

- All end-use products with outdoor agricultural uses which are applied to crops involving hand labor are required to bear precautionary label language regarding farmworker safety.

- Protective clothing [Midforearm waterproof gloves, long-sleeved shirts and long pants, preferably one piece (coveralls)] are required during the mixing and application of wettable powder formulations with the following exceptions:

  - When using water soluble packaging, mixers/loaders are exempt from protective clothing requirements and,

  - Applicators in enclosed tractor cabs with filtered air supply or in enclosed cockpits are exempt from protective clothing requirements.

  - Waterproof boots or shoe coverings are additionally required for workers using hand-sprayers or hand-spreaders.

- Hand-spray applications are limited to ornamentals and nursery stock.

- Sites treated with granular formulations must be thoroughly watered after application.

Mixer/Loader/Applicator Exposure

There is a potential for mixer/loader/applicator exposure to pronamide sprays and dusts via the dermal and inhalation routes during the ground boom, aerial, and hand-spray applications. The major route of exposure is via the dermal route. Inhalation exposure appears to be very low via either ground boom or hand-spray method of application, according to the data available in Pesticide Handlers Exposure Database (PHED).

Mixer/loader/applicator dermal exposure data were submitted by the registrant for the end-use product Kerb® 50W herbicide packed in water-soluble packages and applied by ground boom (MRID 41117202). The results, based on a worker weighing 70 kg, wearing currently required protective clothing, and treating 50 acres/day at the rate of 2.0 lbs a.i./acre, indicate the following:

- A mixer/loader is exposed to 0.025 mg/lb active ingredient. Without protective clothing (which provides approximately 80% protection), the exposure would be 0.10 mg/lb active ingredient.

- An applicator is exposed to 1.2 mg a.i./hr. Assuming that 6 hours are needed to treat 50 acres, the applicator is exposed daily to 0.10 mg a.i./kg/day.

There are no chemical-specific data on dermal exposure of the applicator using a low pressure hand sprayer. Based on the data available in the Pesticide Handlers Exposure Database (PHED), such an applicator, treating 2 acres/day, at a rate of 2.0 lb a.i./acre, is exposed to 2.84 mg/lb a.i.

Estimated daily exposure (EDE), average daily exposure (ADE) and lifetime average daily exposure (LADE), in mg/kg/day, may be estimated using the above exposure values (actual/PHED) and the following equations and assumptions:

EDE (mixer/loader or applicator using hand-spray) =

$$\frac{\text{mg/lb a.i. x \# acres/day x application rate}}{\text{kg b.w.}}$$

EDE (applicator using ground boom) =

$$\frac{\text{mg/lb a.i./hr x 6-hr day x \# acres/6 hrs x application rate}}{\text{kg b.w.}}$$

ADE = EDE x # application/yr x 1 day/365 days

LADE = ADE x 35 yrs/70 yrs

Assumptions:

- a mixer/loader/applicator weighs 70 kgs,

- the individual wears PPE as currently required in 1986 Registration Standard,
- water soluble packaging or protective clothing (as described in Registration Standard) provides 80% protection,
- # applications/yr = 10,
- # acres treated/day = 50/ground boom and 2/hand-spray,
- application rate = 2 lbs a.i./acre, and
- 100% dermal absorption.

EDE, ADE, and LADE for handlers of wettable powder formulations in water-soluble pouches are shown in the following table:

Dermal Exposure for Handlers of Wettable Powder Formulations

Worker Category	EDE	ADE	LADE
	(mg/kg/day)		
Mixer/loader			
with PPE	0.04	1.10×10^{-3}	5.47×10^{-4}
without PPE	0.18	4.93×10^{-3}	2.47×10^{-3}
Applicator with PPE			
Ground boom	0.10	2.74×10^{-3}	1.37×10^{-3}
Hand-sprayer	0.40	1.12×10^{-2}	5.60×10^{-3}
Combined Mixer/loader/applicator			
Mixer/loader with PPE	0.14	3.84×10^{-3}	1.92×10^{-3}
Mixer/loader no PPE	0.28	7.67×10^{-3}	3.84×10^{-3}

All values are rounded to the nearest two decimals.

Adequate mixer/loader/applicator exposure data for the granular formulations are not currently available. Potential exposure to the granular formulation is expected to be less than exposure to the wettable powder formulation according to the exposure assessment provided in the 1986 Pronamide Registration Standard. Therefore, the Agency is requiring confirmatory mixer/loader/applicator exposure data for granular formulations of pronamide because there is a potential for mixer/loader/applicator exposure to pronamide through the dermal and inhalation routes following ground boom, aerial and handspray applications of the wettable powder formulation.

Post-application/Reentry Exposure (Worker and Residential)

There is a potential for post-application dermal exposure to foliar dislodgeable residues and soil residues resulting from the use of both granular and wettable powder formulations. There may be less dermal exposure on agricultural sites, if pronamide is applied as a pre-emergence herbicide when the protected crop is still dormant. Despite several factors which aid in the reduction of available foliar dislodgeable residues and soil residues (i.e., watering in the granular formulation for the turf use), the potential for post-application dermal exposure exists and may be significant.

Currently, the Agency does not have the data to make a reregistration decision on pronamide for use on residential lawns. An estimate of risk is not feasible because of numerous uncertainties in potential exposure levels, especially for children. Regulatory decisions relating to postapplication reentry will be developed after the foliar dislodgeable dissipation [GL# 132-1(a)] and dermal passive dosimetry (GL# 133-3) studies required to support the residential lawn use are submitted and reviewed. However, pronamide is acceptable for commercial turf, because the restricted entry interval imposed by the Agency is expected to provide an adequate margin of exposure for commercial turf uses. Regulatory decisions data relating to postapplication reentry to commercial turf will also be determined after the foliar dislodgeable dissipation and dermal passive dosimetry studies required to support commercial turf uses are submitted and reviewed. Also, because of the potential for significant hand contact associated with the use of pronamide on lettuce, the Agency is requiring the same post-application reentry data for use on lettuce. These data will be considered confirmatory. Post-application inhalation exposure is expected to be minimal.

3. Risk Assessment

a. Dietary

The following were used to assess pronamide's dietary risk:

Toxicological Endpoints

- A RfD of 0.08 mg/kg bodyweight per day (See B.1.k. above for details), and

- An upper bound (95%) of the estimated unit risk (Q_1*) which is 1.54 x 10^{-2} $(mg/kg/day)^{-1}$ (See B.1.d. above for details).

Tolerance, Anticipated Residue, and Percent Crop Treated Data

Dietary risk analysis was done using 1) percent crop treated data (for several commodities) and anticipated residue data, and 2) all reassessed tolerances values from the Tolerance Reassessment Summary table (See Section IV.B.1.).

Results

In January 1994, anticipated residue assessment resulted in an estimated excess carcinogenicity risk of 1.52×10^{-6}. However, additional anticipated residue information, as well as percent crop treated data (alfalfa) allowed the refinement of the data supporting the pronamide dietary exposure estimates and provided a more accurate (and lower) estimate of the dietary exposure and concomitant risk.

The following table represents the revised anticipated residues and risk assessment for red meat and milk (commodities that contributed the most to the anticipated residue contribution exposure assessments). In the previous assessment, alfalfa hay was assumed to be only major feed item for both beef and dairy cattle with pronamide tolerances. The previous assessment utilized the average pronamide residues in animal tissues and milk resulting from the highest dosing levels, and used a linear extrapolation to the dietary burdens of beef and dairy cattle of 1.35 ppm and 4.27 ppm, respectively. The assessment assumed 100% crop treated. This revised assessment assumes that in any given region, 10% of alfalfa crop consumed by dairy cattle was treated with pronamide since the percent crop treated for alfalfa is $<1\%$. Since the assessment included only alfalfa in estimating the dietary burden, and used linear extrapolation to estimate anticipated residues and risks for red meat and milk, the previous values are divided by 10 (100% CT / 10% CT = 10).

Revised Anticipated Residues and Risk Estimates for Pronamide Residues in Red Meat and Milk

Tissue	Anticipated Residue		Carcinogenic Risk	
	Previous	New	Previous	New
Muscle	0.002	0.0002	2.08×10^{-7}	2.08×10^{-8}
Fat	0.016	0.0016		
Liver	0.05	0.005		
Kidney	0.04	0.004		
Milk	0.006	0.0006	9.48×10^{-7}	9.48×10^{-8}
Other	NA	NA	3.61×10^{-7}	3.61×10^{-7}
Total			1.52×10^{-6}	4.77×10^{-7}

The new dietary exposure of the U.S. Population as a whole to pronamide based on Anticipated Residue Contribution (ARC) and reassessed tolerances is estimated at 3.2 E^{-5} mg/kg/day or 0.040% of the Reference Dose (RfD). Based on the incorporation of the anticipated residues and percent of crop treated in the risk analysis, the upper bound estimated excess carcinogenic risk for the dietary exposure for the general population to pronamide is approximately 5 x 10^{-7}.

Conclusions

Dietary exposure to pronamide is associated with an estimated upper bound excess carcinogenic risk of 5 x 10^{-7}.

Pronamide's dietary exposure/risk that have been calculated by DRES in the analysis discussed above are likely to be overestimates for the following reasons:

1. For the commodity milk, the percent crop treated is <1%, actually ca. 0.05% for alfalfa (the major animal feed item to which pronamide may be applied). Our calculations assumed that no more than 10% of the alfalfa crop consumed by dairy cattle was treated with pronamide.

2. Where a range of percent crop treated data is presented for a commodity, the highest value in the range was used in the DRES analysis. Twelve crops are affected: artichokes, blackberries, blueberries, boysenberries, cherries, endive, grapes, lettuce, nectarines, peaches, pears, and raspberries.

3. Where no percent crop treated data are available for a commodity, the level is assumed to be 100%.

Incorporation of reassessed tolerance levels instead of just anticipated residue data in the pronamide DRES data increased the exposure/carcinogenicity risk estimate but only by a small amount. This incremental exposure does not significantly change the general level of the carcinogenicity exposure/risk estimate.

Chronic exposure to pronamide in the diet is only a very small fraction of the RfD and does not appear to be a cause for concern at this time.

b. Occupational and Residential

There is a concern for carcinogenicity associated with lifetime exposure of mixer/loader/applicators and homeowoners to pronamide.

Estimates of Occupational Carcinogenic Risk

Mixers/loaders/applicators may be at risk for carcinogenic effects. For workers handling the wettable powder formulations and applying the pesticide by either ground boom equipment or low pressure hand-sprayers, excess carcinogenic risks may be estimated using the equation:

$$\text{Excess carcinogenic risk} = Q_1^* \times \text{LADD}$$

Lifetime average daily dose (LADD) is identical to the lifetime average daily exposure (LADE) because 100% dermal absorption is assumed. LADE estimates may be found under B.2.b.

Mixer/loader/applicator excess upper bound carcinogenic risks are shown in the following table:

Worker Category	LADD (mg/kg/day)	Estimated Upper Bound Excess Carcinogenic Risk $1.54 \times 10^{-2} \times$ LADD
Mixer/loader		
with PPE*	5.47×10^{-4}	8×10^{-6}
without PPE	2.47×10^{-3}	4×10^{-5}
Applicator with PPE		
Ground boom	1.37×10^{-3}	2×10^{-5}
Hand-sprayer	5.60×10^{-3}	9×10^{-5}
Combined Mixer/loader/applicator		
Mixer/loader with PPE	1.92×10^{-3}	3×10^{-5}
Mixer/loader no PPE	3.84×10^{-3}	6×10^{-5}

* PPE are those required by the 1986 Registration Standard.

Estimated upper bound excess carcinogenic risks ranged from 8×10^{-6} for the mixer/loader wearing currently required PPE to 9×10^{-5} for the applicator using a low pressure hand-sprayer. For the applicator using ground boom equipment, the estimated upper bound risk was 2×10^{-5}.

The pronamide occupational exposure/risks that have been estimated are conservative for the following reasons:

1. Dermal absorption was assumed to be 100%. Although the dermal absorption study was judged supplementary, the results, nevertheless, were suggestive of a dermal absorption rate well below 100% (MRIDs 40256701C and 41117201). Based on information from these studies, use of 10% as a dermal absorption factor would lead to estimates of carcinogenic risk one order of magnitude lower for workers.

2. Worst-case scenarios of exposure were used for the applicator, based on maximum rates of application (2 lbs. a.i./acre), number of applications per year (# = 10), and number of acres treated per day (50 acres/ground boom; 2 acres/hand-spray).

Carcinogenic risk for the worker applying granular formulations will be estimated when the required dermal/inhalation exposure data at outdoor sites are submitted and evaluated. Based on information available for the 1986 Pronamide Registration Standard, potential risk is expected to be less for this use than the wettable powder formulation.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

Detailed information regarding the fate of pronamide in the environment is presented below:

Degradation

Carbonyl-labeled [^{14}C]pronamide, at 1.5 ppm, was stable in sterile buffered solutions (pH 4.7, 7.4, and 8.8) during 28 days of incubation at 20°C followed by 14 days at 40°C. Less than 4% of the extractable residues were identified as RH24644, RH24580, and RH25891 at each of the 7 sampling periods (MRID 00107980).

Phenyl-labeled [^{14}C]pronamide degraded with a half-life of 41 days in a sterile, nonsensitized aqueous pH 7 buffer solution that was irradiated with artificial light (xenon arc lamp) continuously for 30 days. The half-life would be equivalent to 82 days on the basis of 12 hour light/12 hour dark cycle. Seven degradation products (RH24644, RH24580, RH26702, RH25891, RH25059, 3,5-dichlorobenzamide, and 3,5-dichlorobenzoic acid) were identified in the irradiated solutions during the study. In the dark control for

nonsensitized pronamide buffered solution, pronamide remained relatively stable during the testing period of 30 days (MRIDs 40320601 and 40420301).

Phenyl-labeled [^{14}C]pronamide photodegraded with a half-life of 57 days on sandy loam soil that was continuously irradiated with an artificial light source (xenon lamp) at 19-25°C for up to 28 days. Two degradates (RH24580 and RH24644) were identified; a compound "similar to RH26702" was also detected. The half-life of pronamide in the dark control samples was 110 days (MRID 41913504).

Metabolism

Phenyl-labeled [^{14}C]pronamide degraded with a half-life of 392 days when applied to sandy loam soil incubated under aerobic conditions in the dark at 25°C for 12 months. Three major degradation products (RH24644, RH24580, and RH26521) were identified at maximum concentrations of 27%, 14%, and 4% of the applied material (MRID 41568901 and 41913502).

Phenyl-labeled [^{14}C]pronamide degraded slowly in sandy loam soil incubated anaerobically for 60 days following a 31-day aerobic incubation in the dark at 21-29°C. The registrant did not estimate, based on the available data, the half-life of pronamide in this soil under anaerobic conditions. Instead, the registrant reported that the half-life of pronamide under aerobic and/or anaerobic conditions is greater than 90 days. Although there were limited data available for the estimation of the half-life in the anaerobic soil metabolism study, it appears that the anaerobic soil half-life for pronamide could be greater than 392 days. Only one degradation product (RH24644) was identified in the soil. At 90 days posttreatment (or 60 days of anaerobic incubation), RH24644 comprised 6-13% of the recovered radioactivity (MRID 41913505).

Mobility

Pronamide was shown to be relatively mobile in soils [adsorption coefficient (K_{ads})=3.2-10.1; or soil organic carbon adsorption coefficient (K_{oc}) =548-1,340]. One of the two major degradation products (RH24644) has a medium mobility (K_{ads}=2.3-9.9; or K_{oc}=993-3,910). However, the other major degradation product (RH24580) is very mobile and its K_{ads} ranges from 1.3-2.4 (or K_{oc}=96-210) (MRIDs 40211103, 40211104, and 41913501).

Dissipation

Based on supplemental data from an unacceptable field dissipation study, pronamide dissipated with half-lives of 36 and 16 days in the upper 12 inches of bare ground plots containing loam and loamy sand soils, respectively, that

were located in Central California. During the course of the study, pronamide was not detected below 6 inches in the loam soil or 12 inches in the loamy sand soil. The registrant characterized the degradation products as total residues by converting the degradates and the parent to a common moiety. The total residues, however, remained unidentified. The unidentified residues were detected in the soil as early as 7 days after application and the percentage of the total residues unidentified increased with time. Two months after treatment approximately half of the total residues in the 0-3 inch soil were the unidentified degradation products. This study has a number of deficiencies. In addition, soil residue data for this study were generated by Craven Laboratories. The Agency has determined that these data must be replaced. The deficiencies for this study include:

1) The study sites are not representative of the areas where the pesticide is expected to be used because they are located in two counties (approximately 100 miles apart) in central California.

2) Pronamide was apparently not applied at the maximum rate at the Madera site in CA. The total residues recovered from the 0-3 inch soil depth on Day 0 were a maximum of 1.7 ppm, equivalent to an approximate rate of 1.5-2 lbs a.i. per acre.

3) The registrant did not analyze for degradation products; rather, soil samples were analyzed for parent compound and for total pronamide residues only, using two different analytical methods. The analytical method for the total pronamide residues would determine parent compound, and its degradation products which could be converted to methyl 3,5-dichlorobenzoate (the final analyte for GC analysis). These degradation products include two commonly-detected degradates (RH24644 and RH24580), and others (i.e., RH26521, RH25891, RH25059, RH26702).

Based on the laboratory data, pronamide is very stable in water, photolytically persistent in water and on soil. It is very persistent in soil under aerobic conditions and even more persistent under anaerobic conditions. A chemical with these properties is expected to be relatively persistent and mobile in the field. Supplemental data from an unacceptable field dissipation study suggested that pronamide is neither persistent nor mobile under field conditions. However, this data is not reliable since it was generated by Craven Laboratories. A new field dissipation study is required.

Accumulation

In a confined rotational crop study, pronamide residues accumulated in lettuce, carrots, and wheat planted 30 days, 6 months, and 1 year after phenyl-

labeled [^{14}C]pronamide was applied at 4 lbs a.i. per acre to sandy loam soil. In mature lettuce, total residues were 0.737 ppm in plants from the 30-day rotation interval, 0.055 ppm in plants from the 6-month rotation, and 0.021 ppm in plants from the 1-year rotation. In mature carrot greens from the 6-month rotation, pronamide was 0.020 ppm. In the mature wheat straw from the 1-year rotation, pronamide was not detected. In the 0-3 inch soil layer, pronamide residues were 1.96 ppm immediately posttreatment, 1.39 ppm at the 30-day planting, 0.318 ppm at the 182-day planting, and 0.432 ppm at the 365-day planting. This study has a number of deficiencies:

(1) The revised application rate (62%) was significantly lower than the theoretical value.

(2) The effects of the low application rate on the failure to identify the low residue levels in carrots from the 6-month and 1 year rotation interval, and in wheat grains from the 1-year interval are unknown. The registrant did not address the concerns raised by the Agency on the identification of two unknown degradation products at levels of 0.069-0.216 ppm. Furthermore, only 44% of the residues recovered in the mature lettuce from the 6-month rotation were characterized.

(3) The fate of pronamide under frozen conditions is unknown, because the Agency does not have available storage stability data on pronamide in soil samples.

(4) The effects of long-term storage on the residue levels in plant samples remain unknown, since the submitted storage stability data were generated by Craven Laboratories.

Although, there are a number of deficiencies in the confined rotational crops study, a new confined rotational crop study is not required because sufficient data are available for risk assessment purposes. However, the field rotational crop study is now required in order to determine proper plantback intervals and whether crop rotational tolerances are needed. The registrant will be required to revise their current rotational crop restrictions for pronamide. The plantback intervals for leafy vegetables and carrots should be expanded. Field rotational crop studies are to be conducted on lettuce and carrots in order to determine the plantback intervals. Also, in order to determine the plantback interval or whether tolerances are needed for rotational grain crops, field rotational crop studies are to be conducted on wheat.

Because the octanol water partition coefficient (K_{ow}) is greater than 1,000 and the aqueous photolysis half-life is 82 days, once pronamide reaches a water body, it has the potential to bioaccumulate in fish. However, because the required bioaccumulation in fish study has not been submitted, the uptake

and accumulation of pronamide in fish is uncertain. A fish bioaccumulation study is currently being reviewed by the Agency.

Spray Drift

Data are needed to support the spray drift data requirements (201-1 Droplet Size Spectrum and 202-1 Drift Field Evaluation) because: (1) pronamide can be applied by aerial equipment to lettuce, artichoke, endive, Christmas tree plantations, and fallow lands; and (2) the Agency is concerned about the off-target damage by drift of a toxic substance. The registrant is not currently a member of the Spray Drift Task Force; therefore, data are needed to support the spray drift data requirements. If the registrant commits to join the Spray Drift Task Force, the Agency will hold these two data requirements in reserve pending submission of the final task force report. If the findings of the task force are inconclusive, then new studies may be required.

b. Environmental Fate Assessment

Based on laboratory data, pronamide is very stable in water, and photolytically persistent in water and on soil. It is very persistent in soil under aerobic conditions, with an estimated half-life of 13 months, and even more persistent under anaerobic conditions, with an estimated half-life greater than 13 months. Two major degradation products (RH24644 and RH24580) were detected in soil under aerobic conditions. Only RH24644 was found in the anaerobic soil metabolism study. Pronamide has a relatively low vapor pressure ($8.5x10^{-5}$ mmHg at 25°C). It is relatively mobile in soil [adsorption coefficient (Kd)=3.2-10.1; Koc=548-1,340). RH24644 has a medium mobility (Kd=2.3-9.9; or Koc=993-3,910). RH24580 is very mobile and its Kd ranges from 1.3-2.4 (or Koc=96-210). A chemical with the above properties is expected to be relatively persistent and mobile in the field. Supplemental data from an unacceptable field dissipation study suggested that pronamide is neither persistent nor mobile under field conditions. However, the Agency cannot rely on this data because the soil data was generated by Craven Laboratories. A new field dissipation study is required.

The field dissipation study is expected to provide useful information to demonstrate the rates of pronamide dissipation through the combined-fate processes (i.e., degradation, metabolism, adsorption, leaching, volatilization, runoff) in the field.

The following data are required to confirm the environmental fate assessment for pronamide:

(1) A field dissipation study must be conducted in at least two locations at representative use areas (such as one site in California for the use on

lettuce; another site in Wisconsin for the use in forage). The maximum application rate must be used.

(2) A field rotational crop is required in order to determine plantback intervals and whether tolerances are needed.

(3) Spray drift studies are required but may be fulfilled through the Spray Drift Task Force if the registrant joins the Spray Drift Task Force and the Task Force studies are timely and adequate.

2. Ecological Effects

a. Ecological Hazard

(1) Effects to Non-Target Birds

Avian Acute Oral Toxicity			
Species	% a.i.	LD_{50} (mg/kg)	Conclusions
Jap. Quail	75	8770	Practically nontoxic
Mallard	75	20,000	

There is sufficient information from the study cited above to characterize technical grade pronamide as practically nontoxic to birds when exposed orally to a single dose. (MRID 00107997)

Avian Subacute Dietary Toxicity			
Species	% a.i.	LC_{50} (ppm)	Conclusions
Bobwhite[1]	94.5	>4000	Practically nontoxic
Mallard[2]	94.9	>10,000	
Bobwhite[3]	94.9	>10,000	
Bobwhite[4]	94.5	>30*	

*4-week dietary study, 30 ppm was highest level tested.
1-4 refer to MRIDs 00107993, 00108002, 00108003, and 00107994.

The studies listed above are sufficient to characterize technical pronamide as practically nontoxic when exposure is through the diet to upland game birds (bobwhite quail) and waterfowl (mallard duck).

Because of the persistence of pronamide demonstrated in laboratory studies, the Agency considered requesting two avian reproduction studies (GL# 71-4) on mallard duck and bobwhite quail. These studies are not being required in spite of the persistence because pronamide is typically applied only once a year, either in fall, winter or spring; is soluble in water and would wash off avian food items; and has low toxicity to birds.

(2) Effects to Other Non-Target Terrestrial Organisms

Pronamide is practically non-toxic to mammals. The reproduction two-generation test on rats concluded with a decrease in body weight and feed consumption with a NOEL=200 ppm. Carcinogenicity studies in rats and mice indicated that pronamide was carcinogenic at or above 1000 ppm (rats) and 100 ppm (mice).

(3) Effects to Non-Target Fish

Freshwater Fish Acute Toxicity			
Species	% a.i.	LC_{50} (ppm)	Conclusions
Bluegill[1]	50	>100	Slightly toxic
Trout[2]	75	72	
Catfish[2]	75	>200<500	
Goldfish[2]	75	350	
Guppy[2]	75	150	

1-2 refer to MRIDs 00107196 and 00107996, respectively.

The studies listed above are sufficient to characterize pronamide as slightly toxic to coldwater and warmwater fish. Because of the persistence of pronamide demonstrated in laboratory studies, the Agency considered requesting (GL# 72-4) Early Life Stage of Fish. This study is not being required because of low acute toxicity to fish.

(4) Effects to Non-Target Aquatic Invertebrates

Freshwater Invertebrate Acute Toxicity			
Species	% a.i.	LC_{50} (ppm)	Conclusions
Daphnia magna	93.8	>5.6*	Moderately toxic

* Several solvents were used but 5.6 ppm was the highest solution that could be tested.

There is sufficient information to characterize technical pronamide as moderately toxic to freshwater invertebrates. The Aquatic Invertebrate Life Cycle study (GL# 72-4B) is required due to the possible persistence of pronamide in the aquatic environment; acute toxicity for Daphnids; and the solubility of pronamide which indicates that it may be transported to aquatic habitat. Based on existing data, the Agency anticipates that these new data would confirm that pronamide does not represent a major problem for aquatic organisms, however, this study is required to confirm this assessment for pronamide because a potential chronic risk to aquatic invertebrates is possible. (MRID 00098313).

(5) Effects to Non-Target Estuarine and Marine Organisms

No data on estuarine studies were required in the 1986 Registration Standard for pronamide. The Agency is now requiring estuarine studies because the use on turf, hay, clover, alfalfa and pasture may expose estuarine species to pronamide. Historically, the Agency has found that at least one of the estuarine species will usually exhibit greater sensitivity to a pesticide than any freshwater species. Therefore, the Agency is now requiring estuarine studies for a pesticide used on sites adjacent to estuaries, including turf, hay, clover, alfalfa and pasture land.

In order to establish the toxicity to estuarine and marine organisms, the following tests are typically required using the technical grade material: either a Mollusc 48-hour embryo larvae study using Pacific oyster, Eastern oyster, mussel (preferably *Mytilus edulis*) or Quahog (*Mercenaria*) or a Mollusc 96-hour Flow-Through Shell Deposition study using Pacific oyster or Eastern oyster; and a Shrimp 96-hour acute toxicity test using white, pink, brown, grass or mysid shrimp species; and a 96-hour toxicity testing using estuarine fish (preferably silverside or sheepshead minnow). However, because of the low toxicity pronamide demonstrates for freshwater fish, only the 72-3(b) mollusc and 72-3(c) shrimp study are required. The 72-3(a) estuarine fish study is not required. Based on the low toxicity of pronamide to freshwater fish and moderate toxicity to freshwater invertebrates, the Agency anticipates that these new data will confirm that pronamide does not represent a major problem to aquatic organisms. To confirm this assessment, the Agency is requiring the testing of other estuarine species.

(6) Effects to Non-Target Insects (Beneficial Insects)

No studies were evaluated under this topic. Application of pronamide is made in the fall or early winter when bees are not generally expected to be exposed to pronamide.

(7) Effects to Non-Target Plants

Terrestrial

Germination			
Common Name	% a.i.	EC_{25} (lb ai/A)	Conclusions
Oat	96.8	0.0067	The study is classified as supplemental because an NOEC was not determined. For terrestrial plants, the grasses seem to be the most susceptible.
Tomato	96.8	0.0720	

Seedling Emergence			
Common Name	% a.i.	EC_{25} (lb ai/A)	Conclusions
Ryegrass	96.8	0.0067	This study was classified as supplemental. The results were valid for monocot species; however, the results were considered invalid for the dicot species. Additional data are needed to determine the most sensitive dicot species.

Vegetative Vigor			
Common Name	% a.i.	EC_{25} (lb ai/A)	Conclusions
Oat	96.8	0.0088	The study is classified as supplemental because an NOEC was not determined.
Tomato	96.8	0.0104	

There are supplemental data available for the seed germination and vegetative vigor studies. These studies are classified as supplemental because a NOEC was not determined; however, they are acceptable for risk asssessment purposes (MRIDs 42176801 and 42176802). For the seedling emergence study, the data are classified as supplemental due to invalid cucumber results. The tomato and cucumber were found to be the most sensitive dicot species. Since a large number of endangered plant species may be affected, the results of the dicots would determine the certainty of risk to endangered plant species as well as other non-target terrestrial plants. A new

cucumber test is required. The tomato test must be repeated along with the cucumber test for comparative analysis.

Aquatic

Aquatic Plant Toxicity			
Species	% a.i.	EC_{50} (ppm)	Conclusions
Selenastrum capricornutum	96.8	0.76	Pronamide is toxic to green algae.

There are supplemental data to characterize pronamide as toxic to green algae. The only species tested is *Selenastrum capricornutum* (MRID 42176802). However, additional testing is required on the other four species of aquatic plants: *Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and freshwater diatom. These data are needed for assessing the effects to endangered aquatic plant species and aquatic habitat in general.

b. Ecological Effects Risk Assessment

(1) Non-Endangered Species

Terrestrial Organisms

The maximum expected residues immediately after application do not exceed the avian acute LC_{50} or the mammalian acute LC_{50}. Application of pronamide is made in the fall or early winter when bees are not generally expected to be exposed to pronamide. Therefore, it appears that the use of pronamide at the labeled rate will have minimal adverse acute effects on insects, birds and mammals. Calculated residues immediately after application exceed the mammalian NOEL as determined in a reproduction two-generation study. In addition, immediate residues on short grasses in lettuce fields in Michigan exceed the mammalian carcinogenic NOEL. However, pronamide is applied only once per season and due to the solubility of the chemical, it would likely wash off much of the treated mammal and bird food items before chronic exposure at maximum exposure levels could occur. Chronic data are not available on birds but chronic exposure is expected to be limited for both birds and mammals.

Aquatic Organisms

The aquatic invertebrate life cycle is considered very important in conducting a risk assessment for pronamide. The Daphnids are possibly the most sensitive of the aquatic organisms ($LC_{50} > 5.6$ ppm). Historical data have

shown that it is not uncommon for some pesticides to have chronic effects at levels as low as 0.01 of the LC_{50} (5.6/100= 0.056 ppm). The aquatic EEC does not exceed the LC_{50} for fish or the LC_{50} for aquatic invertebrates. In this case, with expected aquatic exposures of 0.024 to 0.073 ppm in deep water (6 feet) and 0.25 to 0.881 ppm in shallow water (6 inches), and given the possible persistence of pronamide in water, chronic exposure potentially suggests that chronic risk to aquatic invertebrates is likely. Chronic concern for fish is minimal because of the high LC_{50} values. Based on existing data, the Agency anticipates that additional data would confirm that pronamide does not represent a major problem for aquatic organisms. However, a chronic aquatic invertebrate study is required to confirm this assessment because a potential chronic risk to aquatic invertebrates is possible.

Aquatic Plants

Although it appears that there may be minimal adverse effects for algae, the aquatic plant data are insufficient to accurately assess hazards to aquatic plants in general. Testing on the additional four species of aquatic plants is required.

Terrestrial Plants

Non-target terrestrial plants may be adversely affected from runoff and/or drift from the application of pronamide at the labeled rates on all of the use sites except hay and grass forage. For hay and grass forage sites, drift from aerial application may adversely affect non-target plants. Data on dicots are insufficient to accurately assess hazard. Additional testing with tomato and cucumber for the seedling emergence study is required to determine the most sensitive dicot species.

(2) Endangered Species

Calculated residues on terrestrial food items exceed 1/10th the avian LC_{50}'s on lettuce sites in Michigan. However, endangered birds in Michigan are either predatory or insect eaters. These birds will not eat short grasses located near lettuce fields. Therefore, it appears that pronamide may not adversely affect endangered birds.

In six inches of water, the aquatic EEC exceeds 1/20th the LC_{50}'s for endangered aquatic invertebrates. However, habitats for endangered species of aquatic invertebrates comprising six inches of lentic water could not be found near sites on which pronamide may be used. Therefore, it appears that pronamide may not adversely affect endangered aquatic invertebrates.

Data are incomplete for assessing aquatic and terrestrial plant hazard. With no data on *Lemna gibba*, it has not been determined if there are adverse effects to aquatic macrophytes. Therefore, risk to aquatic plants is uncertain at this time.

For terrestrial plants, the estimated ground application EEC exceeds the seedling emergence EC_{25} for all sites except hay and grass forage. The estimated aerial application EEC exceeds the seedling emergence EC_{25} for all sites when application is at the maximum labeled rate. Therefore, endangered terrestrial plants may be adversely affected by pronamide applied at maximum labeled 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 pronamide 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 pronamide as the sole active ingredient. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of pronamide, 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 pronamide and to determine that pronamide can be used without resulting in unreasonable adverse effects to humans; however, pronamide exceeded endangered species triggers for terrestrial plants and there may also be a risk to aquatic plants. The Agency, therefore, finds that all products containing pronamide as the sole active ingredient, except for those products registered for use on residential lawns and late season use (1-day PHI) on artichokes, are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that all, but two uses of pronamide 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 pronamide, if new information comes to the Agency's attention or if the data requirements for reregistration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients pronamide, the Agency has sufficient information on the human health effects of pronamide and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing pronamide as the sole active ingredient for all uses, except for the broadcast application on residential lawns and turf and the late season use on artichokes, are eligible for reregistration.

The Agency has determined that pronamide products, labeled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable risks or adverse effects to humans; however, they may pose adverse effects to terrestrial plants and there may be a risk to aquatic plants as well.

2. Eligible and Ineligible Uses

The Agency has determined that pronamide wettable powder and granular products registered for use on the food crops listed in the Tolerance Reassessment Summary Table (See Section IV.B.1.), as well as, woody ornamentals, Christmas trees, nurserystock, commercial turf, and fallow land uses are eligible for reregistration.

There are insufficient exposure data for use of pronamide by broadcast application on residential lawns and turf and a reregistration eligibility decision for this use cannot be made until appropriate postapplication/reentry exposure data on foliar dislodgeable dissipation and dermal passive dosimetry studies are submitted and evaluated.

In addition, residue data on late season use on artichokes were generated by Craven Laboratories. The Agency has determined that these data must be replaced. A reregistration eligibility decision for this use cannot be made until these residue data are submitted and evaluated.

B. Regulatory Position

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

1. Tolerance Reassessment

The Agency will propose modifying the 40 CFR tolerance expression under §180.317(a) and (b) to state: "... are established for the combined residues of the herbicide 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety and calculated as 3,5-dichloro-N-(1,1-

dimethyl-2-propynyl)benzamide)..." to clarify which metabolites of pronamide are determined by the enforcement methods and are included in the tolerance expression.

Tolerances Listed Under 40 CFR §180.317(a):

The tolerances listed in 40 CFR §180.317(a) are for the combined residues of 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide and its metabolites calculated as 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide. Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.317(a) for: alfalfa, fresh; alfalfa, forage; alfalfa, hay; apples; artichokes; blackberries; blueberries; boysenberries; cattle, fat; cattle, kidney; cattle, liver; cattle, meat byproducts (except kidney, liver); cattle, meat; cherries; clover; crown vetch; eggs; endive; goats, fat; goats, kidney; goats, liver; goats, meat byproducts (expect kidney, liver); goats, meat; grapes; hogs, fat; hogs, kidney; hogs, liver; hogs, meat byproducts (except kidney, liver); hogs, meat; horses, fat; horses, kidney; horses, liver; horses, meat byproducts (except kidney, liver); horses, meat; lettuce; milk; nectarines; peaches; pears; plums; poultry, fat; poultry, kidney; poultry, liver; poultry, meat byproducts (except kidney, liver); poultry, meat; raspberries; sainfoin; sheep, fat; sheep, kidney; sheep, liver; sheep, meat byproducts (except kidney, liver); sheep, meat; and trefoil. (See Tolerance Reassessment Summary Table for modifications in commodity definitions).

A crop group tolerance of 10 ppm must be proposed for residues of pronamide in/on the forage and hay of the non-grass animal feeds group. The available data satisfy the requirements for crop group tolerance establishment. Tolerances for alfalfa (fresh, forage, and hay at 10 ppm) and clover (5 ppm) do not vary by more than a factor of 5 from the tolerances for any other crop in the group. Concomitant with this tolerance proposal, the established tolerances for "alfalfa, fresh", "alfalfa, forage", "alfalfa, hay", "clover", "crown vetch", "sainfoin", and "trefoil" should be deleted.

A crop group tolerance of 0.1 ppm must be proposed for residues of pronamide in/on the stone fruits group. Adequate data are available to support the established tolerances for the representative commodities, cherries, peaches, and plums/fresh prunes, all at 0.1 ppm. The registered uses on these crops are also identical. Concomitant with this tolerance proposal, the established tolerances for "cherries", "nectarines", "peaches", and "plums" must be deleted.

The available residue data support a reduction in the tolerance for residues in/on endive from 2.0 ppm to 1.0 ppm.

The available residue data support a tolerance of 1.0 ppm for head lettuce only but not leaf lettuce; the correct commodity definition in this case must be "lettuce, head." Alternatively, the label must incorporate a PHI of 35 days for leaf lettuce (direct seeded or transplanted).

As a result of the improvement in the enforcement method for animal commodities, the Agency will propose to amend the tolerances for the kidney and liver of cattle, goats, hogs, horses, and sheep from 0.2 ppm to 0.4 ppm. In addition, the tolerance for sheep meat was incorrectly listed in 40 CFR §180.317(a) as 0.2 ppm and must be changed to the correct tolerance of 0.02 ppm.

Tolerances Listed Under 40 CFR §180.317(b):

The tolerances listed in 40 CFR §180.317(b) have regional registration and are for the combined residues of 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide and its metabolites calculated as 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide. Sufficient data are available to ascertain the adequacy of the established tolerance listed in 40 CFR §180.317(b) for rhubarb.

The tolerance for dried winter peas was established using data generated by Craven Laboratories; alternate data from Europe were submitted and will be used to support the established tolerance until acceptable confirmatory data from studies conducted in the U.S. have been submitted.

Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 180.317(a):			
Alfalfa, fresh Alfalfa, forage Alfalfa, hay Clover Crown vetch Sainfoin Trefoil	10.0 10.0 10.0 5.0 5.0 5.0 5.0	Include all in a group and establish at 10	*Non-grass animal feeds group*
Apples	0.1	Unchanged	
Artichokes	0.1	Unchanged	
Blackberries	0.05	Unchanged	
Blueberries	0.05	Unchanged	
Boysenberries	0.05	Unchanged	
Cattle, fat	0.02	Unchanged	
Cattle, kidney	0.2	0.4	Change due to improved efficiency in the enforcement procedure for animal commodities.
Cattle, liver	0.2	0.4	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Cattle, mbyp (except kidney, liver)	0.02	Unchanged	
Cattle, meat	0.02	Unchanged	
Cherries Nectarines Peaches Plum	0.1 0.1 0.1 0.1	Include all in a group and establish at 0.1	*Stone fruits group*
Eggs	0.02	Unchanged	
Endive (escarole)	2.0	1.0	Residue data support a tolerance reduction.
Goats, fat	0.02	Unchanged	
Goats, kidney	0.2	0.4	Change due to improved efficiency in the enforcement procedure for animal commodities.
Goats, liver	0.2	0.4	
Goats, mbyp (except kidney, liver)	0.02	Unchanged	
Goats, meat	0.02	Unchanged	
Grapes	0.1	Unchanged	
Hogs, fat	0.02	Unchanged	
Hogs, kidney	0.2	0.4	Change due to improved efficiency in the enforcement procedure for animal commodities.
Hogs, liver	0.2	0.4	
Hogs, mbyp (except kidney, liver)	0.02	Unchanged	
Hogs, meat	0.02	Unchanged	
Horses, fat	0.02	Unchanged	
Horses, kidney	0.2	0.4	Change due to improved efficiency in the enforcement procedure for animal commodities.
Horses, liver	0.2	0.4	
Horses, mbyp (except kidney, liver)	0.02	Unchanged	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Horses, meat	0.02	Unchanged	
Lettuce	1.0	Unchanged	*Lettuce (head)*; only head lettuce is supported by acceptable data; otherwise, label must add PHI for leaf lettuce.
Milk	0.02	Unchanged	
Pears	0.1	Unchanged	
Poultry, fat	0.02	Unchanged	
Poultry, kidney	0.2	Unchanged	
Poultry, liver	0.2	Unchanged	
Poultry, mbyp (except kidney, liver)	0.02	Unchanged	
Poultry, meat	0.02	Unchanged	
Raspberries	0.05	Unchanged	
Sheep, fat	0.02	Unchanged	
Sheep, kidney	0.2	0.4	Change due to improved efficiency in the enforcement procedure for animal commodities.
Sheep, liver	0.2	0.4	
Sheep, mbyp (except kidney, liver)	0.02	Unchanged	
Sheep, meat	0.2	0.02	Tolerance was incorrectly listed in the 40 CFR.
Tolerances listed under 180.317(b):			
Peas, dried (winter)	0.05	Unchanged	
Rhubarb	0.1	Unchanged	

2. Restricted Use Classification

The wettable powder formulations of pronamide as currently registered will maintain the restricted use classification imposed in the 1979 Special Review for pronamide.

3. Endangered/Threatened Species Statement

The Agency does have concerns about the exposure of endangered terrestrial plant species to pronamide as discussed above in the science assessment chapter.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses. The Agency plans to publish in the Federal Register in 1994 a description of the program and by 1995 have available enforceable 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.

4. Labeling Rationale

In order to remain in compliance with FIFRA, it is the Agency's position that the labeling of all registered pesticide products containing pronamide must comply with the Agency's current pesticide labeling requirements. The Agency has determined that the current manufacturing and end-use label precautions are still appropriate and required for product reregistration. In addition, it is the Agency's position that the label statements/precautions listed in Section V of this RED must be included on all affected products in order to remain in compliance with FIFRA.

a. Postapplication/Reentry Requirements

The Worker Protection Standard (WPS) for Agricultural Pesticides -- 40 CFR Parts 156 and 170 -- established an interim restricted-entry interval of 12 hours for pronamide, because the acute toxicity category of pronamide for acute dermal toxicity is Toxicity Category III. However, since pronamide is classified as a Group B2 carcinogen, the Agency requires a REI of 24 hours for all WPS sites as a more conservative measure to mitigate risk to workers entering treated areas after application. Furthermore, given the known toxicological concerns for pronamide, the Agency considers the additional protections offered by the requirements in the WPS essential to its decision that a 24-hour restricted entry interval for this chemical will offer sufficient risk mitigation to workers. Therefore, during the REI the Agency will allow workers to enter areas treated with pronamide during the REI only for the few narrow exceptions allowed in the WPS.

The Agency has determined that the entry restrictions discussed in this section for uses within the scope of the WPS do NOT apply to uses of pronamide not within the scope of the Worker Protection Standard for Agricultural Chemicals (e.g., residential lawns). The predicted frequency, duration, and degree of exposure due to such uses should not warrant the risk mitigation measures being required for persons engaged in the production of agricultural plants for commercial or research purposes.

All pronamide end-use products within the scope of the Worker Protection Standard for Agricultural Pesticides (see PR Notice 93-7) -- must, within the timeframes listed in PR Notice 93-7 and 93-11, revise their labeling to be consistent with the WPS, as directed in those notices and the requirements of this RED.

b. Personal Protective Equipment (PPE) Requirements

Although pronamide has been classified as a Toxicity Category III chemical for acute dermal toxicity, the Agency is requiring PPE for applicators and other handlers as well as early entry workers consistent with the PPE level (as established by 40 CFR Part 156, the Worker Protection Standard) required for pesticides classified as Toxicity Category II for acute dermal toxicity. This is due to the known toxicological concerns for pronamide, including its classification as a Group B2 carcinogen.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of pronamide for the above eligible uses has been reviewed and determined to be substantially complete for all uses except residential lawns and turf and the late season use on artichokes. However, additional confirmatory data are needed to fulfill requirements for the studies listed below:

Product Identity - Confidential Statement of Formula for 92% Technical
Aquatic Invertebrate Life Cycle - required for use on turf, hay, clover, alfalfa, and pasture use sites
Estuarine and Marine Organisms (Mollusc and Shrimp) - required for use on turf, hay, clover, alfalfa, and pasture use sites
Terrestrial Field Dissipation - required for all use sites

Field Rotational Crop - required for lettuce and fallowland use sites
Droplet Size Spectrum and Drift Field Evaluation - required because of aerial application to lettuce, artichoke, endive, Xmas tree plantations and fallowland
Foliar Dislodgeable Dissipation - required for commercial turf and lettuce
Dermal Passive Dosimetry - required for commercial turf and lettuce
Estimation of Dermal/Inhalation Exposure at Outdoor Sites - required for granular formulation use on commercial and residential turf
Residue Analytical Method - plant/animal (Independent Lab Validation)
Storage Stability - required for milk, lettuce, apples, plums, grapes, and alfalfa and the processed commodities of apples, grapes, and plums
Magnitude of Residue - Plants (Alfalfa Seed and Dried Winter Peas)
Processed Food - required for apples, grapes, plums

Certain data, which are not part of the target database for pronamide, are required to support the continued registration of pronamide. These data include:

Seed Germination/Seedling Emergence
Aquatic Plant Growth

The following data are required to support the use of granular and wettable powder formulations by broadcast application on residential lawn and turf:

Foliar dislodgeable dissipation
Dermal passive dosimetry

In order to support the late season use of pronamide on artichokes, registrants are required to amend their labels by deleting the late season use on artichokes or submit the required magnitude of residue data.

2. Labeling Requirements for Manufacturing-Use Products

The Agency has determined that the current label precautions are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA (see 1986 Pronamide Registration Standard).

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, including product chemistry and acute dermal toxicity data for all end-use products. The product specific data requirements are listed in Appendix E, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix E; Attachment 5) 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. Compliance with the Worker Protection Standard

In order to remain in compliance with FIFRA, it is the Agency's position that any product whose labeling reasonably permits use in the production of an agricultural plant on any agricultural establishment (farm, forest, nursery, or greenhouse) must comply with the labeling requirements of 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 the deadlines specified in the WPS, unless official EPA guidance specifies otherwise. EPA has issued 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 contain specific instructions to registrants about how to complete the required WPS labeling changes and offer guidance and deadline-options for making those changes. Unless otherwise specifically directed in this RED, all statements required by the WPS (and reflected in PR Notices 93-7 and 93-11) are to be on the product labeling.

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

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

b. Entry Restrictions; Labeling

--Uses Within the Scope of the WPS: In order to be in compliance with FIFRA, a 24-hour restricted entry interval (REI) is required for all uses within the scope of the WPS (see PR Notice 93-7) on all end-use products, except

those intended primarily for home use (see scope criteria in PR Notice 93-7 and 93-11). This REI must be inserted into the standardized REI statement specified the WPS as explained in teh EPA guidance in PR Notice 93-7. The personal protective equipment for early entry must be the PPE required for applicators of pronamide (except no apron or respirator (if any) is required). This PPE must be inserted into the standardized REI statement specified by the WPS as explained in the EPA guidance in PR Notice 93-7.

In order to be in compliance with FIFRA, labels of sole-active-ingredient end-use products that contain pronamide must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

In order to be in compliance with FIFRA, labels of multiple-active-ingredient end-use products that contain pronamide must bear the more protective of either the entry restrictions set forth in this section or the entry restrictions on the current labeling. For purposes of implementation, a specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled" and a longer REI is more protective than a shorter one.

--**Uses Not Within the Scope of the WPS**: Do not add any additional entry restrictions for uses not within the scope of the WPS; however, any entry restrictions on the current product labeling for those uses must be retained.

c. Personal Protective Equipment Requirements; Labeling

--**Uses On Products NOT Primarily Intended for Home Use**: The personal protective equipment (PPE) requirement for "pesticide handlers on all end-use products is:

"Applicators and other handlers must wear:
--Coveralls over short-sleeved shirt and short pants
--Chemical-resistant or waterproof gloves (see
instructions * below)
--Chemical-resistant footwear plus socks
--Chemical-resistant headgear for overhead exposure
--Chemical-resistant apron when cleaning equipment,
mixing, or loading"

* The glove statement for pronamide end-use products should be the statement established through the instructions in PR Notice 93-7.

In order to remain in compliance with FIFRA, labels of end-use products that contain pronamide must bear the more protective of either the personal protective equipment requirements set forth in this section or the personal protective equipment requirements, if any, on their current labeling. For guidance in choosing which requirement is more protective, see Supplement Three of PR Notice 93-7.

d. Other labeling Requirements

(1) Labeling for Lawn and Turf Uses.

If a registrant chooses to support lawn and turf uses, he must submit the data required in this Reregistration Eligibility Decision document associated with the lawn and turf uses of pronamide. If a registrant chooses to support the residential lawn uses only, he must add the following exclusionary statement to his labels in order to remove the turf use site from the scope of the WPS in accordance with PR Notice 93-11.

Exclusionary Statement: All granular and wettable powder end-use products that contain pronamide must carry the following statement located (1) on the front panel of the label in association with the product name or (2) near the beginning of the Directions For Use section:

> "Not for use on turf being grown for sale or other commercial use as sod, or for commercial seed production, or for research purposes."

If registrant does not support the residential lawn uses, the registrant must amend his product label by deleting the residential lawn and turf uses in accordance with the procedures in PR Notice 91-1.

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

(2) Labeling for Fish and Wildlife Hazard

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

End Use - Wettable Powder and Granular Formulations

"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. 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 Document (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; State of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell pronamide 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.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Msx. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES											
AGRICULTURAL FALLOW/IDLELAND				Use Group: TERRESTRIAL FOOD+FEED CROP							
Broadcast., December., Aircraft.	WP	NA	.5 lb A	*	1/C	NS	NS	NS			C46
Broadcast., December., Ground.	WP	NA	.5 lb A	*	1/C	NS	NS	NS			C46
Broadcast., September., Aircraft.	WP	NA	.5 lb A	*	1/C	NS	NS	NS			C46
Broadcast., September., Ground.	WP	NA	.5 lb A	*	1/C	NS	NS	NS			C46
ALFALFA				Use Group: TERRESTRIAL FEED CROP							
Broadcast., Postemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., Preemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Soil incorporated treatment., Preemergence., Irrigation.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
APPLE				Use Group: TERRESTRIAL FOOD+FEED CROP							
Band treatment., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS			C46, G99
Band treatment., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS			C46, G99
Directed spray., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS			C46, G99
Directed spray., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS			C46, G99

SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
ARTICHOKE (EARLY SEASON USE ONLY)					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Ratoon., Low pressure ground.	WP	NA	4 lb A	*	2/C		NS	NS	CA		C46, H01(60)
Band treatment., Transplant., Low pressure ground.	WP	NA	2 lb A	*	2/C		NS	NS	CA		C46, H01(60)
Broadcast., Postplant., Aircraft.	WP	NA	2 lb A	*	1/C		NS	NS	CA		C46, H01(60)
Broadcast., Postplant., Ground.	WP	NA	2 lb A	*	1/C		NS	NS	CA		C46, H01(60)
Broadcast., Preemergence., Aircraft.	WP	NA	2 lb A	*	1/C		NS	NS	CA		C46, H01(60)
Broadcast., Preemergence., Ground.	WP	NA	2 lb A	*	1/C		NS	NS	CA		C46, H01(60)
Broadcast., Ratoon., Aircraft.	WP	NA	4 lb A	*	2/C		NS	NS	CA		C46, H01(60)
Broadcast., Ratoon., Ground.	WP	NA	4 lb A	*	2/C		NS	NS	CA		C46, H01(60)
Broadcast., Transplant., Aircraft.	WP	NA	2 lb A	*	2/C		NS	NS	CA		C46, H01(60)
Broadcast., Transplant., Ground.	WP	NA	2 lb A	*	2/C		NS	NS	CA		C46, H01(60)
BLACKBERRY					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Fall., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS	NS	OR, WA		C46
Band treatment., Winter., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS	NS	OR, WA		C46
Low volume spray (concentrate)., Fall., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS	NS	OR, WA		C46
Low volume spray (concentrate)., Winter., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS	NS	OR, WA		C46
BLUEBERRY					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Fall., Low pressure ground.	WP	NA	2 lb A	*	1/Y		NS	NS			C46

SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
BLUEBERRY (con't)					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Winter., Low pressure ground.	WP	NA	2 lb A	*	1/Y		NS	NS			C46
Low volume spray (concentrate)., Fall., Low pressure ground.	WP	NA	2 lb A	*	1/Y		NS	NS			C46
Low volume spray (concentrate)., Winter., Low pressure ground.	WP	NA	2 lb A	*	1/Y		NS	NS			C46
BOYSENBERRY					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Fall., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS	NS		OR, WA	C46
Band treatment., Winter., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS	NS		OR, WA	C46
Low volume spray (concentrate)., Fall., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS	NS		OR, WA	C46
Low volume spray (concentrate)., Winter., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS	NS		OR, WA	C46
CHERRY					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	 4 lb AI/C	NS	NS			C46, G99
Band treatment., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	 4 lb AI/C	NS	NS			C46, G99
Directed spray., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	 4 lb AI/C	NS	NS			C46, G99
Directed spray., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	 4 lb AI/C	NS	NS			C46, G99

SITE Application Type, Application Timing, Application Equipment -- Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
CLOVER			Use Group: TERRESTRIAL FEED CROP								
Broadcast., Postemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., Preemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
ENDIVE (ESCAROLE)			Use Group: TERRESTRIAL FOOD CROP								
Band treatment., Postemergence., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	NS	NS	NS	NS			C46
Band treatment., Postplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	NS	NS	NS	NS			C46
Band treatment., Preplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	NS	NS	NS	NS			C46
Band treatment., Transplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	NS	NS	NS	NS			C46
Broadcast., Postemergence., Ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	NS	NS	NS	NS			C46
Broadcast., Postplant., Aircraft.	WP	NA	2 lb A	*	1/C	NS	NS	NS	AZ		
Broadcast., Postplant., Ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	NS	NS	NS	NS			C46
Broadcast., Preplant., Aircraft.	WP	NA	2 lb A	*	1/C	NS	NS	NS	AZ		
Broadcast., Preplant., Ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	NS	NS	NS	NS			C46

SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
ENDIVE (ESCAROLE) (con't)						**Use Group: TERRESTRIAL FOOD CROP (con't)**					
Broadcast., Transplant., Ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	NS		NS	NS			C46
Soil incorporated treatment., Postemergence., Ground.	WP	NA	2 lb A 2 lb A 2 lb A	C M F	NS		NS	NS			C46
Soil incorporated treatment., Postplant., Ground.	WP	NA	2 lb A 2 lb A 2 lb A	C M F	NS		NS	NS			C46
Soil incorporated treatment., Preplant., Ground.	WP	NA	2 lb A 2 lb A 2 lb A	C M F	NS		NS	NS			C46
Soil incorporated treatment., Transplant., Ground.	WP	NA	2 lb A 2 lb A 2 lb A	C M F	NS		NS	NS			C46
GRAPES						**Use Group: TERRESTRIAL FOOD+FEED CROP**					
Band treatment., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS			C46, G99
Band treatment., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS			C46, G99
Directed spray., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS			C46, G99
Directed spray., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS			C46, G99

SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
LETTUCE					**Use Group: TERRESTRIAL FOOD CROP (con't)**						
Band treatment., Postemergence., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
	WP	NA	1.5 lb A 1.5 lb A 1.5 lb A	C M F	1/C		NS NS	NS	CA		H01(35)
Band treatment., Postplant., Ground.	WP	NA	6 lb A	*	1/C		NS NS	NS	MI		H01(55)
	WP	NA	6 lb A	*	1/C		NS NS	NS	OH		H01(55)
Band treatment., Postplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
	WP	NA	1.5 lb A 1.5 lb A 1.5 lb A	C M F	1/C		NS NS	NS	CA		H01(35)
Band treatment., Preemergence., Ground.	WP	NA	6 lb A	*	1/C		NS NS	NS	MI		H01(55)
	WP	NA	6 lb A	*	1/C		NS NS	NS	OH		H01(55)
Band treatment., Preplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
	WP	NA	1.5 lb A 1.5 lb A 1.5 lb A	C M F	1/C		NS NS	NS	CA		H01(35)

SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
LETTUCE (con't)			**Use Group: TERRESTRIAL FOOD CROP (con't)**								
Bend treatment., Transplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	1/C		NS	NS			C46, H01(55)
	WP	NA	1.5 lb A 1.5 lb A 1.5 lb A	C M F	1/C		NS	NS	CA		H01(35)
Broadcast., Not on label., Aircraft.	WP	NA	2 lb A	*	NS		NS	NS	CA		
Broadcast., Postemergence., Aircraft.	WP	NA	2 lb A	*	1/C		NS	NS	AZ		
Broadcast., Postemergence., Ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	1/C		NS	NS			C46, H01(55)
Broadcast., Postemergence., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 1.5 lb A	C M F	1/C		NS	NS	CA		H01(35)
Broadcast., Postplant., Aircraft.	WP	NA	2 lb A	*	1/C		NS	NS	AZ		
Broadcast., Postplant., Ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	1/C		NS	NS			C46, H01(55)
	WP	NA	6 lb A	*	1/C		NS	NS	MI		H01(55)
	WP	NA	6 lb A	*	1/C		NS	NS	OH		H01(55)
Broadcast., Postplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 1.5 lb A	C M F	1/C		NS	NS	CA		H01(35)
Broadcast., Preemergence., Ground.	WP	NA	6 lb A	*	1/C		NS	NS	MI		H01(55)
	WP	NA	6 lb A	*	1/C		NS	NS	OH		H01(55)
Broadcast., Preplant., Aircraft.	WP	NA	2 lb A	*	1/C		NS	NS	AZ		

SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
LETTUCE (con't)			**Use Group: TERRESTRIAL FOOD CROP (con't)**								
Broadcast., Preplant., Ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
Broadcast., Preplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 1.5 lb A	C M F	1/C		NS NS	NS	CA		H01(35)
Broadcast., Transplant., Ground.	WP	NA	1.5 lb A 1.5 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
Broadcast., Transplant., Low pressure ground.	WP	NA	1.5 lb A 1.5 lb A 1.5 lb A	C M F	1/C		NS NS	NS	CA		H01(35)
Soil incorporated treatment., Postemergence., Ground.	WP	NA	2 lb A 2 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
Soil incorporated treatment., Postplant., Ground.	WP	NA	2 lb A 2 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
Soil incorporated treatment., Preplant., Ground.	WP	NA	2 lb A 2 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
Soil incorporated treatment., Transplant., Ground.	WP	NA	2 lb A 2 lb A 2 lb A	C M F	1/C		NS NS	NS			C46, H01(55)
NECTARINE			**Use Group: TERRESTRIAL FOOD CROP**								
Band treatment., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	 4 lb AI/C	NS NS	NS			C46, G99

SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
NECTARINE (con't)					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS	NS		C46, G99
Directed spray., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS	NS		C46, G99
Directed spray., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS	NS		C46, G99
PEACH					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS	NS		C46, G99
Band treatment., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS	NS		C46, G99
Directed spray., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS	NS		C46, G99
Directed spray., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS	NS		C46, G99
PEAR					**Use Group: TERRESTRIAL FOOD CROP**						
Band treatment., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS	NS	NS		C46, G99

SITE Application Type, Application Timing, Application Equipment -- Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
PEAR (con't)			**Use Group: TERRESTRIAL FOOD CROP**								
Band treatment., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	NS NS 4 lb AI/C		NS			C46, G99
Directed spray., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C 1/C	NS NS 4 lb AI/C		NS			C46, G99
Directed spray., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	NS NS 4 lb AI/C		NS			C46, G99
PEAS (UNSPECIFIED)			**Use Group: TERRESTRIAL FOOD+FEED CROP**								
Broadcast., Early Winter., Ground.	WP	NA	1.5 lb A	*	1/C	NS NS		NS	ID, OR, WA		C46, GB7, G03
Broadcast., Fall., Ground.	WP	NA	1.5 lb A	*	1/C	NS NS		NS	ID, OR, WA		C46, GB7, G03
PLUM			**Use Group: TERRESTRIAL FOOD CROP**								
Band treatment., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	NS NS 4 lb AI/C		NS			C46, G99
Band treatment., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	NS NS 4 lb AI/C		NS			C46, G99
Directed spray., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	NS NS 4 lb AI/C		NS			C46, G99
Directed spray., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	 1/C	NS NS 4 lb AI/C		NS			C46, G99

SITE Application Type, Application Timing, Application Equipment -- Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED (con't)											
PRUNE			**Use Group: TERRESTRIAL FOOD CROP**								
Band treatment., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS NS	NS			C46, G99
Band treatment., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS NS	NS			C46, G99
Directed spray., Nonbearing., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS NS	NS			C46, G99
Directed spray., Postharvest., Low pressure ground.	WP	NA	2 lb A 3 lb A 4 lb A	C M F	1/C	4 lb AI/C	NS NS	NS			C46, G99
RASPBERRY (BLACK, RED)			**Use Group: TERRESTRIAL FOOD CROP**								
Band treatment., Fall., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS NS	NS	OR, WA		C46
Band treatment., Winter., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS NS	NS	OR, WA		C46
Low volume spray (concentrate)., Fall., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS NS	NS	OR, WA		C46
Low volume spray (concentrate)., Winter., Low pressure ground.	WP	NA	3 lb A	*	1/Y		NS NS	NS	OR, WA		C46
RHUBARB			**Use Group: TERRESTRIAL FOOD CROP**								
Band treatment., Dormant., Low pressure ground.	WP	NA	2 lb A	*	1/Y		NS NS	NS	OR, WA		C46, H01(38)
Band treatment., Fall., Low pressure ground.	WP	NA	2 lb A	*	1/Y		NS NS	NS	OR, WA		C46, H01(38)
Band treatment., Winter., Low pressure ground.	WP	NA	2 lb A	*	1/Y		NS NS	NS	OR, WA		C46, H01(38)

SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED (con't)											
RHUBARB (con't)			**Use Group: TERRESTRIAL FOOD CROP**								
Broadcast., Dormant., Low pressure ground.	WP	NA	2 lb A	*	1/Y	NS	NS	NS	OR, WA		C46, H01(38)
Broadcast., Fall., Low pressure ground.	WP	NA	2 lb A	*	1/Y	NS	NS	NS	OR, WA		C46, H01(38)
Broadcast., Winter., Low pressure ground.	WP	NA	2 lb A	*	1/Y	NS	NS	NS	OR, WA		C46, H01(38)
SAINFOIN			**Use Group: TERRESTRIAL FEED CROP**								
Broadcast., Postemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., Preemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
SUGAR BEET			**Use Group: TERRESTRIAL FOOD+FEED CROP**								
Broadcast., Early winter., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS	OR		C46, C14
Broadcast., Fall., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS	OR		C46, C14
Broadcast., Postemergence., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS	OR		C46, C14
TREFOIL			**Use Group: TERRESTRIAL FEED CROP**								
Broadcast., Postemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., Preemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
VETCH			**Use Group: TERRESTRIAL FEED CROP**								
Broadcast., Postemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., Preemergence., Ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
NON-FOOD/NON-FEED											
CHRISTMAS TREE PLANTATIONS			**Use Group: TERRESTRIAL NON-FOOD CROP**								
Band treatment., Fall., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46

SITE Application Type, Application Timing, Application Equipment -- Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
CHRISTMAS TREE PLANTATIONS (con't)			Use Group: TERRESTRIAL NON-FOOD CROP								
Broadcast., Fall., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., When needed., Aircraft.	WP	NA	3 lb A	F	NS	NS	NS	NS	OR		
	WP	NA	3 lb A	F	NS	NS	NS	NS	WA		
GOLF COURSE TURF			Use Group: TERRESTRIAL NON-FOOD CROP								
Broadcast., Fall., Not on label.	G	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Fall., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Late winter., Not on label.	G	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Late winter., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Not on label., Not on label.	G	NA	1.5 lb A	*	NS	NS	NS	NS			
Broadcast., Not on label., Sprayer.	WP	NA	1.5 lb A	*	NS	NS	NS	NS			
ORNAMENTAL AND/OR SHADE TREES			Use Groups: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Band treatment., Fall., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Band treatment., Nurserystock., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., Fall., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., Nurserystock., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
ORNAMENTAL HERBACEOUS PLANTS			Use Group: TERRESTRIAL NON-FOOD CROP								
Broadcast., Postemergence., Low pressure ground.	WP	NA	2 lb A	*	4/C	16 lb/Y	NS	NS	FL		

SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL HERBACEOUS PLANTS (con't)				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Broadcast., Postplant., Low pressure ground.	WP	NA	2 lb A	*	4/C	16 lb/Y	NS	NS	FL		
Broadcast., Preemergence., Low pressure ground.	WP	NA	2 lb A	*	4/C	16 lb/Y	NS	NS	FL		
ORNAMENTAL LAWNS AND TURF				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Broadcast., Dormant., Not on label.	G	NA	.0228 lb 1K sq.ft	*	NS	NS	NS	NS			GB9
Broadcast., Early winter., Low pressure ground.	WP	NA	1.5 lb A	*	NS	NS	NS	NS			C46, C14, GB9, GC1
Broadcast., Fall., Low pressure ground.	WP	NA	1.5 lb A	*	NS	NS	NS	NS			C46, C14, GB9, GC1
Broadcast., Fall., Not on label.	G	NA	1 lb A	*	NS	NS	NS	NS			
	G	NA	.0228 lb 1K sq.ft	*	NS	NS	NS	NS			GB9
Broadcast., Fall., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Late winter., Not on label.	G	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Late winter., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Not on label., Not on label.	G	NA	1.5 lb A	*	NS	NS	NS	NS			
Broadcast., Not on label., Sprayer.	WP	NA	1.5 lb A	*	NS	NS	NS	NS			
Broadcast., Postemergence., Not on label.	G	NA	.0228 lb 1K sq.ft	*	NS	NS	NS	NS			GB9
Broadcast., Winter., Not on label.	G	NA	.0228 lb 1K sq.ft	*	NS	NS	NS	NS			GB9
ORNAMENTAL WOODY SHRUBS AND VINES				**Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL**							
Band treatment., Fall., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Band treatment., Nurserystock., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46

SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL WOODY SHRUBS AND VINES (con't)			**Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL**								
Broadcast., Fall., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
Broadcast., Nurserystock., Low pressure ground.	WP	NA	2 lb A	*	NS	NS	NS	NS			C46
PYRETHRUM (INSECTICIDAL USE) (SPECIALIZED FIELD CROP)			**Use Group: TERRESTRIAL NON-FOOD CROP**								
Broadcast., Postemergence., Ground.	WP	NA	2 lb A	*	2/Y	NS	NS	NS	CA		C46, GB9, GC1
Broadcast., Posttransplant., Ground.	WP	NA	2 lb A	*	2/Y	NS	NS	NS	CA		C46, GB9, GC1
RECREATION AREA LAWNS			**Use Group: TERRESTRIAL NON-FOOD CROP**								
Broadcast., Fall., Not on label.	G	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Fall., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Late winter., Not on label.	G	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Late winter., Sprayer.	WP	NA	1 lb A	*	NS	NS	NS	NS			
Broadcast., Not on label., Not on label.	G	NA	1.5 lb A	*	NS	NS	NS	NS			
Broadcast., Not on label., Sprayer.	WP	NA	1.5 lb A	*	NS	NS	NS	NS			
End of USES ELIGIBLE FOR REREGISTRATION											

SITE Application Type, Application Timing, Application Equipment – Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES FOR WHICH A REREGISTRATION ELIGIBILITY DECISION HAS NOT BEEN MADE PENDING RECEIPT OF ADDITIONAL DATA											
FOOD/FEED USES											
ARTICHOKE [1-DAY PHI (LATE SEASON USE)]					Use Group: TERRESTRIAL FOOD CROP USES						
Band treatment., Ratoon., Low pressure ground.	WP	NA	4 lb A	*	2/C	NS NS		NS	CA		C46, H01(60)
Band treatment., Transplant., Low pressure ground.	WP	NA	2 lb A	*	2/C	NS NS		NS	CA		C46, H01(60)
Broadcast., Postplant., Aircraft.	WP	NA	2 lb A	*	1/C	NS NS		NS	CA		C46, H01(60)
Broadcast., Postplant., Ground.	WP	NA	2 lb A	*	1/C	NS NS		NS	CA		C46, H01(60)
Broadcast., Preemergence., Aircraft.	WP	NA	2 lb A	*	1/C	NS NS		NS	CA		C46, H01(60)
Broadcast., Preemergence., Ground.	WP	NA	2 lb A	*	1/C	NS NS		NS	CA		C46, H01(60)
Broadcast., Ratoon., Aircraft.	WP	NA	4 lb A	*	2/C	NS NS		NS	CA		C46, H01(60)
Broadcast., Ratoon., Ground.	WP	NA	4 lb A	*	2/C	NS NS		NS	CA		C46, H01(60)
Broadcast., Transplant., Aircraft.	WP	NA	2 lb A	*	2/C	NS NS		NS	CA		C46, H01(60)
Broadcast., Transplant., Ground.	WP	NA	2 lb A	*	2/C	NS NS		NS	CA		C46, H01(60)
NON-FOOD/NON-FEED											
ORNAMENTAL LAWNS AND TURF					Use Group: OUTDOOR RESIDENTIAL						
Broadcast., Dormant., Not on label.	G	NA	.0228 lb 1K sq.ft	*	NS	NS NS		NS			
	G	NA	.0228 lb 1K sq.ft	*	NS	NS NS		NS			GB9
Broadcast., Early winter., Low pressure ground.	WP	NA	1.5 lb A	*	NS	NS NS		NS			C46
Broadcast., Fall., Low pressure ground.	WP	NA	1.5 lb A	*	NS	NS NS		NS			C46

SITE Application Type, Application Timing, Application Equipment - Surface Type & Efficacy Influencing Factor (Antimicrobial only)	Form	Minimum Application Rate	Maximum Application Rates	Soil Text (Max Dse)	Max. Apps @ Max Rate	Maximum Dose /crop cycle, or /year	Min. Interv (days)	Restr. Entry Interv (days)	Geographic Allowed	Geographic Disallowed	Use Limitations Codes
USES FOR WHICH A REREGISTRATION ELIGIBILITY DECISION HAS NOT BEEN MADE PENDING RECEIPT OF ADDITIONAL DATA											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL LAWNS AND TURF (con't)						Use Group: OUTDOOR RESIDENTIAL (con't)					
Broadcast., Fall., Not on label.	G	NA	.0228 lb 1K sq.ft 1 lb A	*	NS		NS NS	NS			
	G	NA	.0228 lb 1K sq.ft	*	NS		NS NS	NS			GB9
Broadcast., Fall., Sprayer.	WP	NA	1 lb A	*	NS		NS NS	NS			
Broadcast., Late winter., Not on label.	G	NA	1 lb A	*	NS		NS NS	NS			
Broadcast., Late winter., Sprayer.	WP	NA	1 lb A	*	NS		NS NS	NS			
Broadcast., Not on label., Not on label.	G	NA	1.5 lb A	*	NS		NS NS	NS			
Broadcast., Not on label., Sprayer.	WP	NA	1.5 lb A	*	NS		NS NS	NS			
Broadcast., Postemergence., Not on label.	G	NA	.0228 lb 1K sq.ft	*	NS		NS NS	NS			
	G	NA	.0228 lb 1K sq.ft	*	NS		NS NS	NS			GB9
Broadcast., Winter., Not on label.	G	NA	.0228 lb 1K sq.ft	*	NS		NS NS	NS			
	G	NA	.0228 lb 1K sq.ft	*	NS		NS NS	NS			GB9
END of USES FOR WHICH A REREGISTRATION ELIGIBILITY DECISION HAS NOT BEEN MADE PENDING RECEIPT OF ADDITIONAL DATA											

LEGEND

HEADER ABBREVIATIONS
Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
G : GRANULAR
WP : WETTABLE POWDER

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label)

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

USE LIMITATIONS CODES
C14 : Grown for seed only.
C46 : Do not apply through any type of irrigation system.
G03 : Do not graze livestock in treated areas.
G99 : Do not feed or graze animals on treated areas.
GB7 : Do not feed treated vines to livestock.
GB9 : Do not feed clippings to livestock.
GC1 : Do not graze treated areas.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
AZ : Arizona
CA : California
FL : Florida
ID : Idaho
MI : Michigan
OH : Ohio
OR : Oregon
WA : Washington

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

GUIDE TO APPENDIX B

.ppendix B contains listings of data requirements which support the reregistration for active ingredients within the ase pronamide covered by this Reregistration Eligibility Decision Document. It contains generic data equirements that apply to pronamide in all products, including data requirements for which a "typical ormulation" 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 0 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide .ssessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal .oad, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. he 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 ientifying number of each study. This normally is the Master Record Identification (MRID) number, but may be "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete tation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
PRODUCT CHEMISTRY			
61-1	Chemical Identity		40211101 - DATA GAP
61-2	Start. Mat. & Mnfg. Process	ABK	00165026, 42078501
61-3	Formation of Impurities	ABK	40211101, 42078501
62-1	Preliminary Analysis	ABK	40211101
62-2	Certification of Limits	ABK	40211101
62-3	Analtyical Method	ABK	40211101
63-2	Color	ABK	00061661, 00107962, 00107964
63-3	Physical State	ABK	00061661, 00107962, 00107964
63-4	Odor	ABK	00165026
63-5	Melting Point	ABK	00061661, 00107962, 00107964
63-6	Boiling Point		N/A - Not required.
63-7	Density	ABK	00061661, 00107962, 00107964
63-8	Solubility	ABK	00061661, 00107962, 00107964
63-9	Vapor Pressure	ABK	00061661, 00107962, 00107964
63-10	Dissociation Constant	ABK	00165026
63-11	Octanol/Water Partition	ABK	00143745
63-12	pH	ABK	00165026

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
PRODUCT CHEMISTRY			
63-13	Stability	ABK	00165026, 42078502
63-17	Storage Stability		Not required.
64-1	Submittal of Samples		Not required.
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	ABCK	00107997
71-1B	Acute Avian Oral - Quail/Duck - TEP	ABCK	00107997
71-2A	Avian Dietary (LC_{50}) - Quail	ABCK	00107993, 00107994, 00108003
71-2B	Avian Dietary (LC_{50}) - Duck	ABCK	00108002
71-3	Wild Mammal Toxicity	ABCK	N/A - Not required.
71-4A	Avian Reproduction - Quail	ABCK	WAIVED
71-4B	Avian Reproduction - Duck	ABCK	WAIVED
71-5A	Simulated Field Study	ABCK	N/A - Not required.
71-5B	Actual Field Study	ABCK	N/A - Not required.
72-1A	Fish Acute (LC_{50}) - Bluegill	ABCK	00107996

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
ECOLOGICAL EFFECTS			
72-1B	**Fish Acute (LC_{50}) - Bluegill (TEP)**	ABCK	00107196
72-1C	**Fish Acute (LC_{50}) - Rainbow Trout**	ABCK	00107996
72-1D	**Fish Acute (LC_{50}) - Rainbow Trout (TEP)**	ABCK	N/A - Not required.
72-2A	**Aquatic Invertebrate (EC_{50})**	ABCK	00098313
72-2B	**Aquatic Invertebrate (EC_{50}) (TEP)**	ABCK	N/A - Not required.
72-3A	**Estuarine/Marine Toxicity - Fish**	BC	N/A - Not required
72-3B	**Estuarine/Marine Toxicity - Mollusk**	BC	**DATA GAP**
72-3C	**Estuarine/Marine Toxicity - Shrimp**	BC	**DATA GAP**
72-4A	**Early Life Stage Fish**	ABCK	N/A - Not required
72-4B	**Life Cycle Invertebrate**	ABCK	**DATA GAP**
72-5	**Life Cycle Fish**	ABCK	**RESERVED** - pending the results of 72-4 Fish Early Life Cycle or Aquatic Invertebrate Life Cycle

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
ECOLOGICAL EFFECTS			
72-6	**Aquatic Organism Accumulation**	ABCK	**RESERVED** - pending enviornmental fate data on bioaccumulation.
72-7A	**Simulated Field - Aquatic Organisms**	ABCK	N/A - Not required due to low toxicity and low expected ecological effect.
72-7B	**Actual Field - Aquatic Organisms**	ABCK	N/A - Not required due to low toxicity and low expected ecological effect.
123-1A	**Seed Germination/Seedling Emergence**	ABCK	42176801 - **DATA GAP**
123-1B	**Vegetative Vigor**	ABCK	42176801
123-2	**Aquatic Plant Growth**	ABCK	42176802 - **DATA GAP**
124-1	**Terrestrial Field Study**	ABCK	N/A - Not required.
124-2	**Aquatic Field Study**	ABCK	**RESERVED** - pending results of Tier II tests.
141-1	**Honey Bee Acute Contact Toxicity**	ABCK	00028772
141-2	**Honey Bee Toxicity of Residues on Foliage**	ABCK	N/A - Not required.[2]
141-5	**Field Testing for Pollinators**	ABCK	N/A - Not required.[1]
142-1	**Acute Toxicity to Aquatic Insects**	ABCK	**RESERVED**
142-2	**Aquatic Insect Life Cycle Study**	ABCK	**RESERVED**

[2] Application of pronamide is made in fall or early winter when bees are not expected to be exposed to this chemical.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
ECOLOGICAL EFFECTS			
142-3	**Simulated or Actual Field Testing for Aquatic Insects**	ABCK	**RESERVED**
143-1 thru 143-3	**NonTarget Insect Testing - Predators and Parasites**	ABCK	**RESERVED**
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	ABK	00083663
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	ABK	00083663
81-3	**Acute Inhalation Toxicity - Rat**	ABK	00083663
81-4	**Eye Irritation**	ABCK	00083663
81-5	**Dermal Irritation**	ABK	00126574
81-6	**Dermal Sensitization**	ABK	00062605
81-7	**Acute Delayed Neurotoxicity - Hen**		N/A - Not required because pronamide is neither an organophosphate, nor an analog of a neurotoxic compound.
82-1A	**90-Day Feeding - Rodent**		N/A - Not required.
82-1B	**90-Day Feeding - Non-rodent**		N/A
82-2	**21-Day Dermal - Rabbit/Rat**		N/A
82-3	**90-Day Dermal - Rodent**		N/A
82-4	**90-Day Inhalation - Rat**		N/A

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
TOXICOLOGY			
82-5A	90-Day Neurotoxicity - Hen		N/A - Not required because pronamide is neither an organophosphate, nor an analog of a neurotoxic compound.
82-5B	90-Day Neurotoxicity - Mammal		N/A - Not required because pronamide is neither an organophosphate, nor an analog of a neurotoxic compound.
83-1A	Chronic Feeding Toxicity - Rodent	ABK	41714001
83-1B	Chronic Feeding Toxicity - Non-Rodent	ABK	00107949
83-2A	Oncogenicity - Rat	ABK	41714002
83-2B	Oncogenicity - Mouse	ABK	00107968
83-3A	Developmental Toxicity - Rat	ABK	40334501
83-3B	Developmental Toxicity - Rabbit	ABK	00148064, 00148065
83-4	2-Generation Reproduction - Rat	ABK	41540301
84-2A	Gene Mutation (Ames Test)	ABK	40090602, 40211108
84-2B	Structural Chromosomal Aberration	ABK	40211106
84-4	Other Genotoxic Effects	ABK	40211105
85-1	General Metabolism	ABK	41929901, 42858001

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
TOXICOLOGY			
85-2	Dermal Penetration	ABK	Although submitted studies were unacceptable, a new study is not required because based on worst-case assumptions, the risk appears acceptable.
86-1	Domestic Animal Safety		N/A - Not required.
POST-APPLICATION/REENTRY EXPOSURE			
132-1A	Foliar Residue Dissipation	ABCK	DATA GAP
132-1B	Soil Residue Dissipation	AC	N/A - Not required.
133-3	Dermal Passive Dosimetry Exposure	ABCK	DATA GAP
133-4	Inhalation Passive Dosimetry Exposure		N/A - Not required.
APPLICATION EXPOSURE			
231	Estimation of Dermal Exposure at Outdoor Sites	ABCK	DATA GAP
232	Estimation of Inhalation Exposure at Indoor Sites	ABCK	DATA GAP
ENVIRONMENTAL FATE			
161-1	Hydrolysis	ABCK	00107980
161-2	Photodegradation - Water	ABC	40320601, 40420301

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
ENVIRONMENTAL FATE			
161-3	Photodegradation - Soil	ABC	41913504
161-4	Photodegradation - Air		N/A - Not required because of relatively low vapor pressure.
162-1	Aerobic Soil Metabolism	ABCK	41568901, 41913502
162-2	Anaerobic Soil Metabolism	ABC	41913505
162-3	Anaerobic Aquatic Metabolism		WAIVED
162-4	Aerobic Aquatic Metabolism		N/A - Not required.
163-1	Leaching/Adsorption/Desorption	ABCK	40211104, 40420103, 41913501
163-2	Volatility - Lab	AB	WAIVED
163-3	Volatility - Field	AB	N/A - Not required because 163-2 Volatility - Lab study was waived.
164-1	Terrestrial Field Dissipation	ABCK	40925401 - DATA GAP
164-2	Aquatic Field Dissipation		N/A - Not required.
164-3	Forest Field Dissipation		WAIVED
164-4	Combination and Tank Mixes		N/A - Not required because pronamide is not registered for combination and tank mixes with other chemicals.
164-5	Long-Term Soil Dissipation	ABCK	RESERVED - pending the results of field dissipation study.
165-1	Confined Rotational Crop	ABC	N/A - Not required.
165-2	Field Rotational Crop	ABC	DATA GAP
165-3	Irrigated Crops		N/A - Not required.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
ENVIRONMENTAL FATE			
165-4	Bioaccumulatin in Fish	ABC	DATA GAP - study currently being reviewed by the Agency.
165-5	Bioaccumulation - Aquatic Non-Target Organisms	ABC	N/A - Not required.
201-1	Droplet Size Spectrum	ABC	DATA GAP
202-1	Drift Field Evaluation	ABC	DATA GAP
RESIDUE CHEMISTRY			
171-4A	Nature of Residues - Plants		00107953, 00107957, 00107958, GS008201, 40494802, 40494803
17I-4B	Nature of Residues - Livestock		00107954, 00107958, 42043401, 42614201
171-4C	Residue Analytical Method - Plants		00035563, 00035565, 00107958, 00107959 - DATA GAP[3]
171-4D	Residue Analytical Method - Animal		00035566, 00070933, 00070934, 00074523, 00077215, 00107957, 00107960, 00107961, 00107965, 00107967, 00125382 - DATA GAP[2]
171-4E	Storage Stability		41559101, 42614201 - DATA GAP
171-4F	Magnitude of Residue - Potable H_20		N/A
171-4G	Magnitude of Residue - Fish		N/A

[3] Validation of the revised residue analytical method for animal commodities is required. Representative plant and animal tissue samples must be tested by MRM protocols C, D, and E.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
RESIDUE CHEMISTRY			
171-4H	**Magnitude of Residue - Irrigated Crop**		N/A
171-4I	**Magnitude of Residue - Food Handling Establishment**		N/A
171-4J	**Magnitude of Residues - Meat/ Milk/Poultry**		00107958, 00107959, 00107967, 40494801, 40782201, 42043401, 42614201
171-4K	**Cropfield Trials**	ABC	
	Leafy Vegetables		
	Endive		00107957
	Lettuce		00070933, 00107957, 00107958
	Rhubarb (Pacific Northwest)		N/A - Not required.
	Legume Vegetables Group		**DATA GAP**
	Peas, dried (winter) [Pacific Northwest]		
	Stone Fruits Group		
	Cherries		00074523
	Nectarines		00074523
	Peaches		00035565, 00074523
	Plums (fresh prunes)		00074523

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Pronamide

REQUIREMENT		USE PATTERN	CITATION
RESIDUE CHEMISTRY			
171-4K	Cropfield Trials - continued		
	Small Fruits and Berries Group		
	Blackberries		00107960
	Blueberries		00035566, 00153419
	Boysenberries		N/A
	Grapes		00074523
	Raspberries		00107960
	Non-Grass Animal Feeds		
	Alfalfa		00033380, 00107958, 00107965, 00107967 - DATA GAP
	Clover		00107958, 00107965
	Sainfoin		00107965
	Trefoil		00107965
	Vetch		00107965
	Miscellaneous Commodities		
	Artichoke		00077215, 00125382 - DATA GAP
171-4L	Processed Food	ABC	
	Apples		DATA GAP
	Grapes		DATA GAP
	Plums		DATA GAP
171-5	Reduction of Residues		N/A

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

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION

--------- Hileman, B., April 19, 1993. Concerns Broaden over Chlorine and Chlorinated Hydrocarbons- Calls for Gradual Phaseout of Classes of Chlorinated Organics Are Being Made in Response to Evidence of Adverse Health Effects on Humans and Wildlife. C & E News, Volume 71, No. 16, pp. 11-20.

00002646 Agamalian, H. (1973) Report of Planned Work Accomplished: Selective Herbicides in Vegetables (Tomatoes): Report No. 38169. (Unpublished study received May 6, 1976 under 3125-277; prepared by Univ. of California, Agricultural Extension Service, submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CDL:224187-Z)

00028772 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1973) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. Rev. By Univ. of California--Riverside, Dept. of Entomology. Riverside, Calif.: UC, Agricultural Extension Service. (Also in unpublished submission received Apr 2, 1980 under 464-556; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242149-Z)

00033380 Lodge, M.D.; Santelmann, P.W.; Lawrence, S.C.; et al. (1972) Analytical Results of Kerb Residue: R.A.R. No. 2-71-128. (Unpublished study including R.A.R. nos. 2-70-71, 2-70-86, 2-70-78..., received Dec 20, 1972 under 3F1317; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:092251-A)

00035563 Chollet, C.C.; Chennault, B.; Ryan, J.B.; et al. (1973) Analytical Results of Kerb Residue: R.A.R. No. 2-69-160. (Unpublished study including R.A.R. nos. 2-71-240, 2-71-241, 2-71-242..., received Aug 23, 1973 under 4G1426; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:093801-D)

00035564 Chollet, C.C.; Lawrence, S.C. (1972) Analytical Results of Kerb Residue: R.A.R. No. 2-71-239. (Unpublished study including R.A.R. no. 2-72-333, received Aug 23, 1973 under 4G1426; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:093801-E)

00035565 Chollet, C.C.; Lawrence, S.C. (1972) Analytical Results of Kerb Residue: R.A.R. No. 2-71-195. (Unpublished study including R.A.R. no. 2-72-110,

BIBLIOGRAPHY

MRID	CITATION

received Aug 23, 1973 under 4G1426; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:093801-F)

00035566 Lawrence, S.C.; Neidlinger, T.J.; Doughty, C.C.; et al. (1972) Analytical Results of Kerb Residue: R.A.R. No. 2-69-66. (Unpublished study including R.A.R. nos. 2-71-155, 2-71-268, 2-72005..., received Aug 23, 1973 under 4G1426; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:093801-G)

00062605 Sinkeldam, E.J. (1974) Sensitization Test with Kerb Technical in Guinea Pigs: Report No. R 4448. (Unpublished study received Feb 25, 1977 under 707-98; prepared by Central Instituut voor Voedingsonderzoek TNO, Netherlands, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:233726-C)

00070933 Rohm and Haas Company (1981) Kerb(R) 50-W Herbicide (707-98): Lettuce Residue Studies. Interim rept. (Unpublished study received Mar 5, 1981 under 707-98; prepared in cooperation with Craven Laboratories, Inc.; CDL:244519-A)

00070934 Adler, I.L.; Gordon, C.F.; Haines, L.D.; et al. (1972) Determination of residues from herbicide ~N~-(1,1-dimethylpropynyl)-3,5dichlorobenzamide by electron capture gas-liquid chromatography. Journal of the Association of Official Analytical Chemists 55(4):802-805. (Also ~In~ unpublished submission received Mar 5, 1981 under 707-98; submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:244519-B)

00074523 Rohm & Haas Company (1979) Summary and Discussion: Kerb. (Compilation; unpublished study received Jun 24, 1981 under 707-159; CDL:070157-A)

00077215 Rohm & Haas Company (1980) Summary and Discussion: Kerb(R). (Compilation; unpublished study received Jun 24, 1981 under 707-159; CDL:070158-A)

00083663 Powers, M.B. (1970) Final Report: Acute Oral--Rats; Draize Eye-Rabbits; Acute Dermal--Rabbits; Primary Skin--Rabbits; Acute Inhalation Exposure--Rats: Project Nos. 417-337; 417-339; 417-341; 417-340; 417-338. (Unpublished study received Mar 13, 1971 under 1F1139; prepared by TRW, Inc., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:090919-C)

BIBLIOGRAPHY

MRID	CITATION

00085504 Larson, P.S.; Borzelleca, J.F. (1968) Acute Oral Toxicity of RH315, W.P. in Albino Rats. (Unpublished study received Jun 15, 1969 under 9G0821; prepared by Medical College of Virginia, Dept. of Pharmacology, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:091422-B)

00085511 Larson, P.S.; Borzelleca, J.F. (19??) Percutaneous Toxicity Study of RH-315 WP in Rabbits. (Unpublished study received Jun 15, 1969 under 9G0821; prepared by Medical College of Virginia, Dept. of Pharmacology, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:091422-I)

00098313 Vilkas, A.G.; Browne, A.M. (1980) The Acute Toxicity of Kerb Technical (No Clay) to the Water Flea ~ Daphnia magna ~ Straus: UCCES Project No. 11506-33-43. (Unpublished study received Apr 1, 1982 under 707-159; prepared by Union Carbide Corp., submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:247155-A)

00107196 McCann, J. (1971) Kerb 50-W: Bluegill: Test No. 325. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:130346-A)

00107949 Larson, P.; Borzelleca, J. (1970) Toxicologic Study on the Effect of Adding RH-315 to the Diet of Beagle Dogs for a Period of Two Years. (Unpublished study received Mar 12, 1971 under 1F1139; prepared by Medical College of Virginia, Dept. of Pharmacology, submitted by Rohm & Haas Co., Philadelphia, PA; CDL:090918-A)

00107953 Yih, R.; Swithenbank, C. (1970) Identification of Metabolites of N-(1,1-dimethylpropynyl)-3,5-dichlorobenzamide in Soil and Alfalfa. (Unpublished study received Mar 12, 1971 under 1F1139; submitted by Rohm & Haas Co., Philadelphia, PA; CDL:090918-G)

00107954 Yih, R.; Swithenbank, C. (1970) Identification of Metabolites of N-(1,1-dimethylpropynyl)-3,5-dichlorobenzamide in Rat and Cow Urine and Rat Feces. (Unpublished study received Mar 12, 1971 under 1F1139; submitted by Rohm & Haas Co., Philadelphia, PA; CDL:090918-H)

00107957 Rohm & Haas Co. (1971) Results of Tests on the Amount of Residue Remaining in or on Lettuce and Related Crops and Soil Including a

BIBLIOGRAPHY

MRID	CITATION
	Description of the Analytical Method: Kerb. (Compilation; unpublished study received Mar 11, 1971 under 1F1139; CDL: 090917-A; 090916)
00107958	Rohm & Haas Co. (1969) Results of Tests on the Amount of Residues Remaining on or in Crops, Animal Tissues, Milk, and Soil Investigated and the Analytical Methods Used: RH-315. (Compilation; unpublished study received Jun 16, 1969 under 9G0821; CDL: 091423-A)
00107959	Rohm & Haas Co. (1970) Kerb: 3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) Benzamide: Report on a Study To Determine Residue Levels in Eggs and Tissues from Poultry Feed Kerb. (Compilation; unpublished study received on unknown date under 9G0821; CDL: 091424-A)
00107960	Rohm & Haas Co. (1972) Results of Tests on the Amount of Residues Remaining in the Treated Canefruit Crops; A Description of the Analytical Method: Kerb 75-W. (Compilation; unpublished study received May 15, 1973 under 3F1317; CDL:092128-A)
00107961	Rohm & Haas Co. (1969) Residues of RH-315 in Lettuce, Alfalfa and Milk. (Compilation; unpublished study received Feb 17, 1971 under 1F1139; CDL:093447-A)
00107962	Rohm & Haas Co. (1969) The Name, Chemical Identity and Composition of the Pesticide Chemical: Kerb. (Compilation; unpublished study received Feb 17, 1971 under 1F1139; CDL:093447-B)
00107963	Rohm and Haas Co. (19??) Kerb ... Report on a Study to Determine Residue Levels in Eggs and Tissues From Poultry Feed Kerb. (Unpublished study received Apr 2, 1969 under 9G0821; CDL:093523-A)
00107964	Rohm & Haas Co. (1969) The Name, Chemical Identity and Composition of the Pesticide Chemical: RH-315. (Compilation; unpublished study received Apr 2, 1969 under 9G0821; CDL:093523-B)
00107965	Rohm & Haas Co. (1972) Results of Tests on the Amount of Residue Remaining in or on Alfalfa, Clover, Crown Vetch, Sainfoin and Trefoil (Birdsfoot), Including a Description of the Analytical Method: Kerb. (Compilation; unpublished study received Dec 20, 1972 under 3F1317; CDL:092250-A; 092252)

BIBLIOGRAPHY

MRID	CITATION

00107967 Rohm & Haas Co. (1974) Analytical Methods and Residues: Kerb. (Compilation; unpublished study received Sep 9, 1974 under 5F1552; CDL:094214-A)

00107968 Smith, J. (1974) Eighteen Month Study on the Carcinogenic Potential of Kerb (RH-315; Pronamide) in Mice. (Unpublished study received Sep 16, 1974 under 3F1317; prepared in cooperation with Medical College of Virginia, submitted by Rohm & Haas Co., Philadelphia, PA; CDL:094304-A)

00107980 Rohm and Haas Co. (1973) A Study of the Hydrolysis of the Herbicide Kerb in Water: Laboratory 23 Technical Report No. 23-73-8. (Unpublished study received Apr 27, 1973 under 707-113; CDL: 120314-A)

00107993 Shellenberger, T. (1971) Subacute Toxicity Evaluation of Kerb 3,5dichloro-N-(1,1-dimethyl-2-propynyl)-benzamide with Young Adult Bobwhite Quail (A Seven Day Range Finding Study): GSRI Project No. NC-501. (Unpublished study received May 16, 1972 under 70798; prepared by Gulf South Research Institute, submitted by Rohm & Haas Co., Philadelphia, PA; CDL:120402-N)

00107994 Shellenberger, T. (1971) A Subacute Toxicity and Tissue Residue Study of Kerb 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)-benzamide Herbicide in Young Adult Bobwhite Quail: GSRI Project No. NC-501. Final rept. (Unpublished study received May 16, 1972 under 707-98; prepared by Gulf South Research Institute, submitted by Rohm & Haas Co., Philadelphia, PA; CDL:120402-O)

00107996 Binns, R.; Clark, G. (1969) The Acute Toxicity to Fish of An Experimental Herbicide RH-315-75WP: 2932/69/358. (Unpublished study received Jun 22, 1970 under 707-EX-63; prepared by Huntingdon Research Centre, Eng., submitted by Rohm & Haas Co., Philadelphia, PA; CDL:123888-A)

00107997 Robinson, D.; Shillam, K. (1969) Toxicity of RH-315 to the Japanese Quail and the Mallard Duck: 2839/69/265. (Unpublished study received Jun 22, 1970 under 707-EX-63; prepared by Huntingdon Research Centre, Eng., submitted by Rohm & Haas Co., Philadelphia, PA; CDL:123888-B)

00108002 Fink, R. (1975) Eight-day Dietary LC50--Mallard Duck: Technical Kerb: Project No. 129-107. Final rept. (Unpublished study received Feb 25, 1977

BIBLIOGRAPHY

MRID	CITATION

under 707-98; prepared by Truslow Farms Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL: 233723-A)

00108003 Fink, R. (1975) Eight-day Dietary LC50--Bobwhite Quail: Technical Kerb: Project No. 129-106. Final rept. (Unpublished study received Feb 25, 1977 under 707-98; prepared by Truslow Farms Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL: 233723-B)

00114114 Newberne, P.; McConnel, R.; Essigmann, E.; et al. (1982) Kerb: Chronic Toxicity Study in the Mouse: Project No. 77-1. (Unpublished study received Aug 31, 1982 under 707-98; prepared by Massachusetts Institute of Technology, Dept. of Nutrition and Food Science, Animal Pathology Laboratory, submitted by Rohm and Haas Co., Philadelphia, PA; CDL:248233-A)

00125382 Rohm & Haas Co. (1982) Kerb 50-W Herbicide Use on Artichokes. (Compilation; unpublished study received Feb 4, 1983 under 707-159; CDL:249475-A)

00126574 WARF Institute, Inc. (1972) Report: WARF No. 2060619. (Unpublished study received Apr 23, 1974 under 538-115; submitted by O.M. Scott & Sons Co., Marysville, OH; CDL:028337-B)

00133112 Powers, M. (1970) Acute Oral--Rats/Draize Eye--Rabbits/Acute Dermal--Rabbits/Primary Skin--Rabbits/Acute Inhalation Exposure-Rats: Kerb 50-W. Final rept. (Unpublished study received Feb 25, 1971 under 707-98; prepared by Hazleton Laboratories, Inc., submitted by Rohm & Haas Co., Philadelphia, PA; CDL:004358-A)

00143745 Martinson, J. (1985) Octanol/Water Partition Coefficient of Pronamide: Project No. 84-E-216POW: Second Revised Final Report. Unpublished study prepared by Biospherics Incorporated. 37 p.

00148064 Costlow, R.; Kane, W. (1985) Range-finding Teratology Study with Kerb in Rabbits: Report No. 83R-025. Unpublished study prepared by Rohm and Haas Co. 145 p.

BIBLIOGRAPHY

MRID	CITATION
00148065	Costlow, R.; Kane, W. (1985) Teratology Study with Kerb Technical (No inert ingredient) in Rabbits: Report No. 83R-026. Unpublished study prepared by Rohm and Haas Co. 151 p.
00153419	Rohm and Haas Co. (1985?) Residue Chemistry: Kerb 50-W Herbicide in Water Soluble Pouches: Use on Blueberries: Includes Analytical Methods 1809-1 and JAOAC-55-72, and Residue Data. Unpublished compilation. 91 p.
00165026	Rohm and Haas Co. (1986) KERB Product Chemistry. Unpublished compilation. 104 p.
40090602	Shirasu, Y.; Moriya, M.; Koyashiki, R. (1978) Mutagenicity of Kerb (Propyzamide) in Bacteria: Report No. 78RC-1018. Unpublished study prepared by Institute of Environmental Toxicology. 9 p.
40211101	Nichols, R. (1987) Kerb Product Chemistry: Laboratory Project ID: RWN-87-051. Unpublished compilation prepared by Rohm and Haas Co. 74 p.
40211104	Nelson, S. (1987) Adsorption/Desorption of Carbon 14 RH-24,580 and Carbon 14 RH-24,644: Rohm and Haas Technical Report No. 31C-87-15. Unpublished study prepared by Rohm and Haas Co. 350 p.
40211105	Sames, J.; Mcleod, P.; McCarthy, K. (1984) Kerb in vivo Cytogenic Study in Mice: Final Report: Report No. 84R-112. Unpublished study prepared by Rohm and Haas Co. 47 p.
40211106	Tippins, R.; McSheehy, T.; Forster, R.; et al. (1984) Gene Mutation in Chinese Hamster V79 Cells: Kerb Technical: Final Report: Report No. 84RC-038. Unpublished study prepared by Life Science Research, Roma Toxicology Center. 51 p.
40211108	Kumaroo, P. (1987) Kerb Technical Herbicide: Test for Chemical Induction of Chromosome Aberration Using Monolayer Cultures of Chinese Hamster Ovary (CHO) Cells with and without Metabolic Activation: SITEK Study No. 0046-3100. Unpublished study prepared by Sitek Research Laboratories. 107 p.

BIBLIOGRAPHY

MRID	CITATION
40256701	DiDonato, L.; Hazelton, G. (1987) Kerb Herbicide: Dermal Absorption Study in Male Rats: Protocol No. 86P-467: Report No. 86R-225. Unpublished study prepared by Rohm and Haas Co. 136 p.
40320601	Nelson, S. (1987) Characterization of Degradates from the Photolysis of Pronamide: Rept. No. 31C-87-27. Unpublished supplemental report prepared by Rohm and Haas Co. 58 p.
40334501	Solomon, H.; Holz, J. (1987) Kerb Herbicide: Oral (Gavage) Developmental Toxicity Study in Rats: Protocol No. 86P-354B: Rept. No. 87R-003. Unpublished study prepared by Rohm and Haas Co. 265 p.
40420301	Carpenter, M.; Fennessey, M. (1987) Determination of the Photolysis Rate of Carbon 14-phenyl Pronamide in pH-7 Aqueous Solution: ABC Final Report No. 35172. Unpublished study prepared by Rohm and Haas Co. in cooperation with Analytical Bio-Chemistry Laboratories, Inc. 1028 p.
40494801	Jameson, C.; Tillman, A. (1987) Metabolism of Carbon 14-Pronamide in Lactating Goats: ABC Final Report No. 35133; Technical Report No. 31C-88-01. Unpublished compilation prepared by Analytical Bio-chemistry Laboratories, Inc., and Rohm and Haas Research Laboratories. 1343 p.
40494802	Nelson, S. (1987) Metabolism of Carbon 14-Pronamide in Lettuce: Technical Report No. 31C-88-02. Unpublished study prepared by Rohm and Haas Co., in cooperation wuth Pan-Agricultural Labs, Inc., and Others. 357 p.
40494803	Reibach, P. (1988) Metabolism of Pronamide by Alfalfa Under Field Conditions: Technical Report No. 31C-88-03. Unpublished study prepared by Rohm and Haas Research Laboratories in cooperation with Pan Agricultural Labs., and Others. 323 p.
40782201	Jameson, C.; Korsch, B.; Smith, S. (1988) Metabolism of carbon 14 Pronamide in Laying Hens: Technical Report No. 34C-88-44; Final Report No. 35133. Unpublished study prepared by Rohm and Haas Co., in cooperation with Analytical Bio-chemistry Labs, Inc., and Others. 816 p.
40925401	Nelson, S.; Zogorski, W. (1988) Kerb Herbicide Terrestrial Field Dissipation: Two Sites: Project ID. 34C-88-54. Unpublished study prepared by Rohm and

BIBLIOGRAPHY

MRID	CITATION
	Haas Co. in cooperation wtih Craven Laboratories and Pan-Agricultural Associates. 1609 p.
41117201	DiDonato, L.; Hazelton, G. (1989) Report Amendment 1 to Kerb Herbicide: Dermal Absorption Study in Male Rats: Protocol No. 86P467. Unpublished study prepared by Rohm and Haas Co. 35 p.
41540301	Solomon, H.; Brown, W. (1990) Pronamide: Two-generation Reproduction Study in Rats: Protocol No. 88P-309: Report No. 88R-257. Unpublished study prepared by Rohm and Haas Co., Toxicology Dept. 582 p.
41568901	Olson, G., Lawrence, L. (1990) Aerobic Metabolism of Carbon 14 Pronamide in Sandy Loam Soil: Lab Project Number: 1250: 309. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 67 p.
41714002	Bailey, D. (1990) Kerb Herbicide (Technical, No Clay): 24-Month Dietary Chronic Toxicity/Oncogenicity Study in Rats: 24-Month Oncogenicity Study in Rats: Lab Project Number: HLA 417-426M: 87RC-62. Unpublished study prepared by Hazleton Laboratories America, Inc. 2218 p.
41913501	Nelson, S. (1987) Mobility Studies Related to Pronamide: Response to EPA review (Shaughnessy No. 101701): Lab Project Number: 3491-40. Unpublished study prepared by Rohm amd Haas Company. 8 p.
41913502	Nelson, S. (1991) Aerobic Soil Metabolism of 14C-Pronamide in Sandy Loam Soil: Response to EPA Review (Shaughnessy No. 101701): Lab Project Number: 34-91-39. Unpublished study prepared by Rohm and Haas Company. 7 p.
41913504	Carpenter, M. (1987) Soil Photolysis of 14-C-Phenyl Pronamide: Lab Project Number: 35238. Unpublished study prepared by Rohm and Haas Company. 683 p.
41913505	Olson, G.; Lawrence, L. (1989) Anaerobic Metabolism of Carbon 14 Propamide in Sandy Loam Soil: Lab Project Number: 1175: 271. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 54 p.

BIBLIOGRAPHY

MRID	CITATION
41929901	Smith, S. (1991) Rat Metabolism of carbon 14 Pronamide: Lab Project Number: R&H 34-91-43. Unpublished study prepared by Rohm & Haas Co. 248 p.
42043401	Hofmann, C.; Nelson, S. (1991) Pronamide Metabolism in Goats: Residue Analysis of Goat Liver: Supplement to: Lab Project Number: 34-91-63. Unpublished study prepared by Rohm and Haas Co. 53 p.
42078501	Graves, D. (1991) Kerb Technical Product Chemistry: Additional Data : Lab Project Number: APR/SH-91-246. Unpublished study prepared by Rohm and Haas Co. 27 p.
42078502	Graves, D. (1991) Product Chemistry Series: Physical and Chemical Characterization Studies of Kerb Technical 63-13 Sensitivity to Light: Lab Project Number: APR/SH/91/247. Unpublished study prepared by Rohm and Haas Co. 23 p.
42176801	Hoberg, J. (1992) Kerb Technical--Determination of Effects on Seed Germination, Seedling Emergence and Vegetative Vigor of Ten Plant Species: Final Report: Lab Project Number: 91-10-3974: 86.0591.6138.610: RH 91RC-0069. Unpublished study prepared by Springborn Labs, Inc. 218 p.
42176802	Hoberg, J. (1991) Kerb Technical--Toxicity to the Freshwater Green Alga, Selenastrum capricornutum: Lab Project Number: 91-11-4005: 91RC-0070: 86. 0591. 6137. 430. Unpublished study prepared by Springborn Labs, Inc. 65 p.
42614201	Smith, S. (1992) Metabolism of (carbon 14)-Pronamide in Laying Hens: An Addendum: Lab Project Number: 34-92-94. Unpublished study prepared by Rohm and Haas Co. 279 p.
42858001	Smith, S. (1993) Metabolism of (carbon 14) Pronamide in Rats: Supplement A to: (carbon 14)-pronamide (Kerb Herbicide): Pharmacokinetic Study in Rats: Lab Project Number: 34-93-57: 89R-163A. Unpublished study prepared by Rohm and Haas Company, Toxicology Department. 314 p.
42987501	Hazelton, G.; DiDonato, L.; Kaminski, E.; et al. (1993) Pronamide (Kerb Herbicide): Effect of Endocrine Regulation on Rat Testes: Finalized Report:

BIBLIOGRAPHY

MRID	CITATION

Lab Project Number: 92P-053: 92R-053. Unpublished study prepared by Rohm and Haas Co. 298 p.

GS0082001 Yih, R.; Swithenbank, C.; McRae, D. (1970) Transformation of Herbicide N-(1,1-dimethylpropynyl)-3,5-dichlorobenzamide in Soil. Weed Sci. 18:604-607.

APPENDIX D. List of Available Related Documents

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

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Pronamide RED Fact Sheet (Appendix F)

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

Federal publications on pronamide are available and may be purchased from the National Technical Information Service (NTIS), 5825 Port Royal Road, Springfield, VA 22161.

1. Guidance for the Reregistration of Pesticide Products Containing Pronamide as the Active Ingredient (The 1987 Registration Standard): NTIS Stock No. PB87-103735

2. Pesticide Fact Sheet (No. 70) for Pronamide: NTIS Stock No. PB87-124723

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

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

II. BACKGROUND

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

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended

to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

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

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

APPENDIX E. Combined Generic and Product Specific Data Call-In

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

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
JUN 13 1994

Dear Sir or Madam:

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

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

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

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

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

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

b. Use Deletion -

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

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

c. Generic Data Exemption -

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

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

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

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

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

Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one

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

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 Registrant'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 "'[r]aw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

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

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

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

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

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

Option 5. Upgrading a Study

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

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

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

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

Option 6. Citing Existing Studies

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

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

2. Product Specific Data

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

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

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

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

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

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

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

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

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

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

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

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

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

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If

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

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to

FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Daniel M. Barolo, 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 Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms and Confidential Statement of Formula Form with Instructions

Attachment 1. Chemical Status Sheets

Generic and Product Specific Data Call-In

Chemical Status Sheet
for
Pronamide

INTRODUCTION

You have heen sent this **combined Generic and Product Specific Data Call-In** Notice because you have registered pesticide product(s) containing pronamide and these products have uses and/or tolerances which were supported with data generated by Craven Laboratories which the Agency has determined must be replaced.

This combined **Generic and Product Specific Data Call-In Chemical Status Sheet** contains the rationale behind the Agency's requirement for replacement of Craven-generated data, an overview of data required by this combined notice, and points of contact for inquiries pertaining to the reregistration of pronamide. This attachment is to be used in conjunction with:

- The Combined Generic and Product Specific Data Call-In Notice (Appendix E),
- The Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Attachment 2)
- The Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Attachment 3),
- EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration (Attachment 4),
- The EPA Acceptance Criteria (Attachment 5),
- List of registrants receiving this combined DCI (Attachment 6), and
- The Cost Share, Data Compensation, and Confidential Statement of Formula Forms (Attachment 7)

Instructions and guidance accompany each form.

WHY THE REPLACMENT OF CRAVEN-GENERATED DATA IS REQUIRED

This Data Call-In Notice also requires the submission of new, replacement studies in cases where existing data were generated by Craven Laboratories and where the Agency found that such Craven-generated data were the basis for the registration of uses or the setting of associated tolerances. The circumstances necessitating this requirement are discussed further below.

In the latter part of 1990, the Agency received allegations of wrongdoing concerning Craven Laboratories' conduct of studies which may have been submitted to support pesticide registrations and tolerance actions. The Agency immediately initiated its own inquiry into the status of registration and tolerance actions which may be affected by the alleged wrongdoing. Additionally, a criminal investigation commenced relating to the allegations. Based on these allegations and the admissions of wrongdoing by Craven employees, the Agency no longer considers Craven data reliable.

As part of its effort to determine if any studies were in need of replacement, in 1991, the Agency formally asked you and other affected registrants to respond to two voluntary requests. These requests sought information pertaining to Craven-generated data and requested submission of existing alternate data which might be used in place of Craven-generated data. As a result of its comprehensive inquiry and the information obtained from affected registrants, the Agency was able to better define the scope of the Craven situation and the extent of its concerns over the lack of reliability of Craven-generated data. First, the Agency determined that some of the Craven data was not essential to support previous regulatory decisions. Second, the Agency concluded that certain data gaps do exist in areas where Craven data were used to support regulatory decisions (and for which existing alternate data was either not available or inadequate). For this latter group, the Agency has concluded that the Craven-generated data must be replaced in order to provide adequate and reliable data upon which to base decisions on affected pesticide registrations and tolerances in the face of existing concerns. Accordingly, the Agency is requiring through this Data Call-In Notice that these replacement studies be generated and submitted.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of pronamide, please contact Ms. Karen Jones at (703) 308-8047.

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

Ms. Karen Jones, Chemical Review Manager
Reregistration Branch
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460
RE: Pronamide

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

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

Ms. Sue S. Rathman
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Pronamide

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

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. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form. BOTH** "Data Call-In Response" forms must be completed.

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

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

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

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FOR BOTH MUP and EUP products

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

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

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

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.

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0082 Pronamide Chemical # and Name 101701 Propyzamide	GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge thet any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0082 Pronamide	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

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. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

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.

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 Registrant'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

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

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.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

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 cases, please supply all relevant details so that the Agency can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address

SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0082 Pronamide
Chemical # and Name 101701
Propyzamide

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number		5. Study Title	Data Gap	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
61-1	*	Chemical Identity					all	TGAI	3 mos.	
72-3(b)	*	Estu/mari tox. mollusk					ABCK	TGAI	12 mos.	
72-3(c)	*	Estu/mari tox. shrimp					ABCK	TGAI	12 mos.	
72-4(b)	*	Life cycle invertebrate					ABCK	TGAI	12 mos.	
123-1(a)	*	Seed germ/seedling emerg					ABCK	TGAI	12 mos.	
123-2	*	Aquatic plant growth					ABCK	TGAI	12 mos.	
132-1(a)	*	Foliar residue dissipation		Y			ABCK	TEP	24 mos.	
133-3	*	Dermal passive dosimetry expo		Y			ABCK	TEP	24 mos.	
164-1	*	Terrestrial field dissipation		Y			ABCK	TEP	24 mos.	
165-2	*	Field rotational crop		Y	Y		ABC	PAIRA	36 mos.	
171-4(c)	*	Res. analyt. method - plant					ABK	TGAI/METABO	6 mos.	
171-4(d)	*	Res. analyt. method - animal					AB	TGAI/METABO	6 mos.	
171-4(e)	*	Storage stability		Y			ABK	TGAI	24 mos.	
171-4(k)		Cropfield trials								
	*	ALFALFA		Y			ABK	TEP	24 mos.	
	*	ARTICHOKE					ABK	TEP	3 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0082 Pronamide Chemical # and Name 101701 Propyzamide	GENERIC

4. Guideline Requirement Number		5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	*	PEAS, DRIED					ABK	TEP	3 mos.	
171-4(1)		Processed food								
	*	APPLE		Y			AB	TEP	24 mos.	
	*	GRAPES		Y			AB	TEP	24 mos.	
	*	PLUM		Y			AB	TEP	24 mos.	
201-1	*	Droplet size spectrum					ABC	TEP	12 mos.	
202-1	*	Drift field evaluation		Y			ABC	TEP	24 mos.	
231	*	Estimation of Dermal Exposure at Outd					K	TEP	12 mos.	
232	*	Estimation of Inhalation Exposure at					K	TEP	12 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
61-1	The submitted data (MRID 40211101) does not fulfill the guideline requirement for product identity because the CAS Registry Numbers and purpose of all of the ingredients must be provided. The Agency is requiring a new Confidential Statement of Formula (CSF, EPA Form 8570-4) for the 92% Technical Pronamide.
72-3(b)	Estuarine studies are required because of pronamide use on sites adjacent to estuaries, including turf, hay, clover, alfalfa and pasture land. Turf, hay, clover, and pastures may exposure estuarine species to the pesticide. The value added of requesting testing with the estuarine shrimp is much higher than with the estuarine fish species. Since there is some certainty that pronamide is practically non-toxic to fish, the value added of obtaining molluscs data would be to confirm the Agency's presumption of minimal hazard and to ensure that pronamide is not toxic to molluscs while having low toxicity to fish. The Agency is requiring that confirmatory data on the molluscs and shrimp species be submitted.
72-3(c)	See comment for guideline 72-3(b).
72-4(b)	The aquatic invertebrate life cycle study is required due to persistence of pronamide in aquatic environments. Also, the solubility and aerial application would allow pronamide into the aquatic environment and the aquatic EEC is greater than or equal to 0.01 of the LC50 (5.6/100 = 0.056 ppm) for aquatic invertebrates. Since aquatic invertebrates are more sensitive than fish, the Agency is requiring that confirmatory data on aquatic invertebrate life cycle study be submitted.
123-1(a)	The Agency has classified the submitted data (MRID 42176801) as supplemental because a NOEC was not determined for the seed germination study. However, the study is sufficient to use for risk assessment purposes. Therefore, no further testing is required for seed germination. However, the Agency has also classified the submitted

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
	data (MRID 42176801) as supplemental due to invalid cucumber results for the seedling emergence study. Since cucumber and tomato are the two most sensitive dicots, the Agency is requiring that cucumber test be repeated. The tomato test is recommended to be performed with the cucumber for comparative purposes.
123-2	Aquatic plant toxicity study is required for five species - Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, Selenastrum capricornutum, and freshwater diatom because pronamide can be applied by aerial application and the solubility (15 ppm) is greater than 10 ppm. Selenastrum capricornutum is the only species tested (MRID 42176802) and is classified as core minimum. Therefore, the Agency is requiring additional data on the other four species of aquatic plants.
132-1(a)	The Agency is requiring confirmatory postapplication/reentry data derived from the foliar dislodgeable residue dissipation and dermal passive dosimetry (133-3) studies to commercial turf to support the use of pronamide on commercial turf. This same confirmatory data is also being required for use on lettuce based on the potential for significant hand contact associated with this use. The Agency does not have data to make a reregistration decision of pronamide for use on residential lawns/turf. An estimate of risk is not feasible because of numerous uncertainties in potential exposure levels, especially for children, and a recognition that a reentry interval is not practical or enforceable in residential situations. The postapplication/reentry data derived from the foliar dislodgeable residue dissipation and (133-3) dermal passive dosimetry studies to commercial turfgrass can be used to support the use of pronamide on residential lawns/turf.
133-3	See comment for guideline 132-1(a).

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
164-1	The submitted field dissipation study (MRID 40925401) was found unacceptable, but upgradable. In response to concerns raised by the Agency, the registrant submitted a supplemental report (MRID 41913503). This supplemental report did not provide any useful information to upgrade the study. Information were either incorrect (such as "no mention of having to isolate and/or identify degradation products in the Pesticide Assessment Guidelines: Subdivision N - Chemistry - Environmental Fate") or misleading (such as "overemphasizing TLC technique and ignoring other relatively-advanced identification technology GC/MS, GC, and HPLC mentioned in the SEP for the terrestrial field dissipation study"). Furthermore, the study sites are not representative of the areas where the pesticide is expected to be used because they are located in two counties (approximately 100 miles apart) in central California. Pronamide is primarily used for lettuce, and secondarily for turf and forage (including alfalfa and seed clover). Although lettuce is mainly grown in CA, other states (such as AZ and FL) have significant acreage for lettuce. In addition, the total acreages for alfalfa in CA is only half of those in WI. The relatively short dissipation rate for pronamide in the field, resulting in high percentage of residues as unidentified degradation products, is in contradiction to the persistence suggested by the environmental fate laboratory studies. For the above reasons, the Agency is requiring a new field dissipation study. The field dissipation study should be designed to allow additional samplings in order to define the long-term dissipation if pronamide or its major degradation products were found to be persistent during the conduction of the study. The Agency is requiring that the parent compound and its major degradation products be analyzed separately.
165-2	Based on the metabolites identified in lettuce sampled at various intervals and the metabolites found in carrot greens and wheat forage and straw, the Agency concluded that residues of concern in rotated crops following treatment of pronamide consist of pronamide and its metabolites bearing the 3,5-dichlorobenzoyl group. Therefore, the Agency is requiring a field rotation crop study. The registrant is required to revise the current rotational crop restrictions for pronamide. For leafy vegetables and

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
	carrots, the plantback intervals should be expanded. In order to determine the plantback intervals, field rotational crop studies are to be conducted on lettuce and carrots. In the meantime, the plantback interval for lettuce should be changed to 6 months. Rotation to cereal grain crops following treatment of pronamide could lead to detectable residues in grain crops. In order to determine the plantback interval or whether tolerances are needed for rotational grain crops, field rotational crop studies are to be conducted on wheat. According to "Guidance on How to Conduct Studies on Rotational Crops" issued 2/23/93, lettuce, carrots, and wheat should be planted after the minimum aging interval at two sites in which the soil had been treated with pronamide at the maximum label rate and the maximum number of applications [165-2]. The crops should be harvested and all the plant parts prescribed in the Table II of Subdivision O should be analyzed for pronamide and its metabolites containing the 3,5-dichlorobenzoyl group. If these limited field studies show finite residues of pronamide within the 12-month plantback period, then additional field trials will be required in order to establish rotational crop tolerances.
171-4(c)	A revised version of the PAM II method, which includes an alkaline hydrolysis to release bound residues, resulted in increased method efficiency and has been submitted for the enforcement of tolerances in animal commodities. The revised method remains to be validated by an independent laboratory. For FDA enforcement monitoring purposes, the Agency requires that representative plant and animal tissue samples bearing metabolites of pronamide be subjected to analysis by FDA multi-residue protocols C, D, and E from PAM Vol. I.
171-4(d)	See comment for guideline 171-4(c).

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
171-4(e)	The storage stability data for alfalfa, apples, and lettuce (MRID No. 41570101) submitted by Rohm and Haas were generated by Craven Laboratories and no storage stability data for other crops are available. The Agency has determined that these data are insufficient to support reregistration of pronamide and must be repeated. The Agency is requiring storage stability data on milk, alfalfa, apples, grapes, lettuce and plums and the processed commodities of apples, grapes and plums. These data are considered confirmatory.
171-4(k)	ALFALFA (ALFALFA SEED) - Samples from an alfalfa study (meal and seed) were analyzed by Craven Laboratories (MRID No. 40593103). Residues did not concentrate (5X label application rate) in the processed commodities, and it was concluded that no food/feed additive tolerances were required for meal. Data is not required for alfalfa meal because the Agency will translate alfalfa hay data to alfalfa meal. The Agency has determined that the data on alfalfa seed are insufficient to support reregistration and must be repeated. However, the Agency has concluded that enough magnitude of the residue data are available to support the extension of the existing tolerance on alfalfa on an interim basis until the field trial data are replaced. A new cropfield trial study on alfalfa seed is required. The registrant may need to perform a processing study to extract the seed from the plant in order to obtain residue data on alfalfa. These data are considered confirmatory.
171-4(k)	ARTICHOKE Residue data are not available for the Agency to determine whether the existing tolerance is adequate for the labeled use (1 day PHI). The use after ditching with a 1 day PHI relies solely on Craven Laboratories, Inc. data. The Agency has determined that these data are insufficient to support reregistration and must be repeated. The Agency has also concluded that enough magnitude of the residue data are available to support an extension of the existing tolerance on artichokes on an interim basis until the field

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
	trial data are replaced. The existing non-Craven artichoke field trial data will not support all of the current use patterns. Additionally, there are no other crop field trial data that might be translated to this particular use of artichokes. The over-the-plant row application with a 60 day PHI is not affected. The Agency is requiring a label amendment to delete the 1 day PHI use or replacement of artichoke field trial data.
171-4(k)	PEAS, DRIED (AUSTRIAN WINTER PEAS) REGIONAL - Rohm and Haas has identified Craven Laboratories as the source of the analytical field trial data submitted in the IR-4 tolerance petition (PP#6E3457) to support the tolerance for Austrian winter peas. The Agency has determined that these data are insufficient and must be repeated. The Agency has also concluded that enough magnitude of residue data are available to support an extension of the existing tolerance on winter peas on an interim basis until the field trial data are replaced. Summary data from Europe have been submitted to support the pea tolerance. The Agency has determined that these data are also insufficient to support this use. The Agency is requiring confirmatory crop field trial data on dried winter peas. This study is to be conducted in the U.S. (Idaho; Oregon or Washington). These states represent about 99% of domestic Austrian winter pea production. IR-4 or other parties interested in developing the data are advised to consult the Agency before pursuing the trials.
171-4(l)	APPLE Craven Laboratories was identified as the analytical services laboratory for an apple processing study (MRID No. 41034301). No detectable residues of pronamide (5X label rate) were found in juice and dry pomace. It was determined that no food/feed additive tolerances were necessary. The Agency has determined that these data are insufficient to support reregistration and must be repeated. The Agency has also concluded that enough magnitude of the residue data are available to support an extension of the

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
	existing tolerance on apples on an interim basis until the processing data are replaced. The Agency is requiring a new processing study to determine if pronamide and/or its regulated metabolites concentrate in the processed apple products (juice, wet pomace, and dry pomace). These data are considered confirmatory.
171-4(1)	GRAPES Rohm and Haas identified a grape processing study (MRID No. 40593101) as containing Craven data. Residues of pronamide were detected below the established 0.1 ppm tolerance for grapes (1X application rate) in juice, raisins, raisin waste, wet pomace, and dry pomace. Food/feed additive tolerances were not required. The Agency has determined that these data are insufficient to support reregistration and must be repeated. The Agency has also concluded that enough magnitude of the residue data are available to support an extension of the existing tolerance on grapes on an interim basis until the processing data are replaced. The Agency is requiring a new processing study to determine if pronamide and/or its regulated metabolites concentrate in the grape processed commodities. These data are considered confirmatory.
171-4(1)	PLUM Rohm and Haas identified Craven Laboratories as the source of the processing study for plums (MRID No. 40593102). No measurable residues of pronamide were detected in/on fresh plums and prunes from a 5X label rate treatment. It was concluded that no food/feed additive tolerances were necessary. The Agency has determined that these data are insufficient to support reregistration and must be repeated. The Agency has also concluded that enough magnitude of the residue data are available to support an extensioon of the existing tolerance on plums on an interim basis until the processing data are replaced. The Agency is requiring a new processing study to determine if pronamide and/or its regulated metabolites concentrate in prunes (plums). These data are considered confirmatory.

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
201-1	Data must be submitted to support the spray drift data requirements [Droplet size spectrum (201-1) and Drift Field Evaluation (202-2)]. The Agency is requiring these studies because: (a) pronamide can be applied by aerial equipment to lettuce (AZ790036 and CA790002), artichoke (Reg. No. 707-159 and CA870078), endive (AZ790036), Christmas tree plantations (OR830013 and WA910043), and fallow lands (Reg. No. 707-159); and (2) the Agency is concerned about the off-target damage drift of a toxic substance. The registrant is not currently a member of the Spray Drift Task Force, therefore these studies are required. However, if the registrant joins the Spray Drift Task Force and provides the Agency with documentation, these data requirements will be held in reserve status pending the submission of the final Task Force report. If the findings of the Task Force are inconclusive, then new studies may be required.
202-1	See comment for guideline 201-1.
231	Mixer/loader/applicator exposure data are required when both the exposure and toxicity criteria are met. The potential for dermal and inhalation exposure exists during the mixing and loading of pronamide products and during the ground boom, aerial, and hand-spray applications of the wettable powder formulation of pronamide. Data are available for the wettable powder formulation of pronamide, but data are needed to confirm that the potential worker exposure when using the granular formulation does not result in an unacceptable risk to workers, especially the mixer/loaders. Pronamide has been classified as a B2 carcinogen. Therefore, the Agency is requiring confirmatory mixer/loader/applicator exposure data for the granular formulations of pronamide. In lieu of conducting a study, the registrant may submit surrogate data in support of the reregistration requirements. Engineering controls, protective clothing and equipment, and risk mitigation procedures as appropriate for the current label should be discussed. Additional worker activity/use information which would clarify the actual exposure may also be submitted for evaluation.

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

GUIDELINE	COMMENT
232	See comment for guideline 231.

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0082 Pronamide EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
61-2(a)	Descriptn starting materials, (1,2) productn & formulatn process					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
62-1	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-5	Melting point (6)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
63-6	Boiling point (7)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0082 Pronamide

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility						ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-9	Vapor pressure						ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-10	Dissociation constant						ABCDEFGHIJKLMNO	TGAI/PAI	8 mos.	
63-11	Octanol/water partition coefficient	(8)					ABCDEFGHIJKLMNO	PAI	8 mos.	
63-12	pH	(9)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
63-13	Stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-14	Oxidizing or reducing action	(10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-15	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-16	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-17	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-18	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-19	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-20	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,36,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
81-3	Acute inhalation toxicity-rat	(3)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0082 Pronamide EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
81-4	Primary eye irritation-rabbit (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-5	Primary dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
81-6	Dermal sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0082 Pronamide

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

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

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
6 Required if technical chemical is solid at room temperature.
7 Required if technical chemical is liquid at room temperature.
8 Required if technical chemical is organic and non-polar.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0082 Pronamide

Footnotes (cont.):

3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.
37 Testing of the EP dilution is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

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

EPA'S DECISION ON BATCHING PRODUCTS CONTAINING **PRONAMIDE** FOR PURPOSES OF MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient pronamide, the Agency considered batching products. This process involves grouping similar products 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. Acute toxicity data on individual products has frequently been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to 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 cited, the registrant must clearly identify the material tested by its 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.

Table I identifies 1 batch.

Table I.

Batch No.	EPA Reg. No.	% of pronamide & other Active ingredients	Formulation Type
1	707-159	50	wettable powder
	707-98	50	wettable powder
	8660-85	50	wettable powder
	CA79000200	50	wettable powder
	CA86006500	50	wettable powder
	CA91000700	50	wettable powder
	FL91000700	50	wettable powder
	OR983001300	50	wettable powder
	OR9000400	50	wettable powder
	OR9000400	50	wettable powder
	WA91004300	50	wettable powder

Table II lists the products which could not be batched. For the purposes of acute toxicity batching, these products were not considered similar, or their similarity could not be determined with the information available. The registrants of these products are responsible for meeting the acute toxicity data requirements specified in the data matrix for end-use products.

Table II.

EPA Reg. No.	% of pronamide & other Active Ingredients	Formulation Type
707-113	92.0	technical
5481-170	1.0	granular
8660-132	0.57	granular
8660-134	0.57	granular

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

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

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

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

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

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

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

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color

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

63-3 Physical State

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

63-4 Odor

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

63-5 Melting Point

____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point

____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

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

63-8 Solubility

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

63-9 Vapor Pressure

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

63-10 Dissociation Constant

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

63-11 Octanol/water Partition Coefficient

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

63-12 pH

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

63-13 Stability

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

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0082 Pronamide
Chemical # and Name
101701 Propyzamide

Company Number	Company Name	Additional Name	Address	City & State	Zip
000707	ROHM & HAAS CO	ATTN: ROBERT H. LARKIN	100 INDEPENDENCE MALL WEST	PHILADELPHIA PA	19106
005481	AMVAC CHEMICAL CORP		4100 EAST WASHINGTON BLVD	LOS ANGELES CA	90023
008660	ANDERSONS, (THE), LAWN FERTILIZER	AGENT FOR: ANDERSONS, THE	BOX 119	MAUMEE OH	43537
065147	BOTANICAL RESOURCES INC		5465 HALLS FERRY RD	INDEPENDENCE OR	97351

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA	United States Environmental Protection Agency Washington, DC 20460 CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA	Form Approved OMB No. 2070-0108 2070-0057 Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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

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 reregistration 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)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-95)

APPENDIX F. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-94-007 May 1994

EPA R.E.D. FACTS

Pronamide

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED for pronamide, also known by the trade name Kerb.

Use Profile

Pronamide is a selective, systemic, pre- and post-emergence herbicide that acts by inhibiting plant cell division. It is used to control grasses and broadleaf weeds in food and feed crops including lettuce (the largest use site), endive, alfalfa, rhubarb, pome and stone fruits, artichokes, berries, grapes and legumes, as well as on woody ornamentals, Christmas trees, nursery stock, lawns, turf and fallow land. Formulations include a wettable powder and a granular. Pronamide may be applied using ground spray equipment, by soil incorporation or by aircraft.

Regulatory History

Pronamide was first registered as a pesticide in the U.S. in 1972. Between 1977-1979, EPA conducted a Special Review based on a study indicating that pronamide caused cancer in mice. In concluding this review, the Agency required: 1) restricted use classification for the 50% active ingredient end-use products; 2) use of protective clothing during mixing and application of the wettable powder formulations; 3) water-soluble packaging for the wettable powders; and 4) lowering of the tolerance on lettuce from 2 ppm to 1 ppm, to reduce dietary exposure.

EPA issued a Registration Standard for pronamide in April July 1986 (NTIS #PB87-103735), requiring additional generic data. A Data Call-In issued in 1990 required additional product chemistry, residue chemistry, plant protection and environmental fate data. The RED reflects EPA's assessment of all data received, to date.

Currently, 18 products are registered which contain the active ingredient (ai) pronamide. The 13 wettable powder products (each containing 50% ai) are registered for food, feed and outdoor residential uses. The 3 granular products (each containing up to 1% ai) are registered only for use on lawns and turf. A formulation intermediate and a technical grade manufacturing product also are registered.

Human Health Assessment

Toxicity

In acute toxicity studies, pronamide technical is practically non-toxic by the oral route, and has been placed in Toxicity Category IV (the lowest of four categories) for this effect. It is slightly toxic by the dermal and inhalation routes, and has been placed in Toxicity Category III for these effects. In subchronic toxicity studies using rats, the liver, thyroid and pituitary appear to be the target organs.

In chronic feeding studies, pronamide causes an increased incidence of liver cancer in male mice, and benign testicular and thyroid tumors in rats. EPA has classified pronamide as a Group B2 (probable human) carcinogen.

Pronamide appears to be a toxicant to the liver and several endocrine organs including the thyroid, testes and pituitary. Pronamide is related to the organochlorine class of chemicals, many of which disrupt the endocrine system. Pronamide is not mutagenic.

Dietary Exposure

Some of the residue chemistry studies on pronamide were generated by Craven Laboratories, which has been convicted of producing fraudulent data. EPA has extrapolated information to draw satisfactory conclusions about pronamide residues in food. However, several confirmatory residue studies must be provided--for example, on alfalfa seed, dried winter peas and early season use on artichokes.

Tolerances or maximum residue limits are established for residues of pronamide in or on a number of food and feed crops, meat and milk (see 40 CFR 180.317(a)). Crop group tolerances must be proposed for residues in/on forage and hay of the non-grass animal feeds group, and for the stone fruits group. The tolerance for endive must be reduced from 2.0 ppm to 1.0 ppm. Certain animal organ tolerances must be raised from 0.2 ppm to 0.4 ppm, due to improved efficiency of enforcement residue detection methods.

Based on the anticipated residue contributions of red meat and milk (which contribute the most to anticipated residues in the diet) and reassessed tolerances, EPA estimates that the overall U.S. population is exposed to 0.04% of the Reference Dose (RfD) or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. Dietary exposure to pronamide is associated with an estimated upper bound cancer risk of 5 x 10-7, or five extra incidences of cancer per 10,000,000. This assessment still overestimates the actual degree of risk, which is likely to be less.

Occupational and Residential Exposure

Pesticide handlers (mixers, loaders and applicators) may be exposed to pronamide sprays and dusts via skin and inhalation during ground boom, aerial and hand-spray applications. The major route of exposure is the dermal route, and exposure is estimated for use of the wettable powder formulation in water-soluble pouches.

Workers and homeowners also may be dermally exposed post-application to pronamide residues on treated foliage and soil. To reduce exposure and risk, EPA is imposing a restricted entry interval following commercial food, feed and turf uses. However, the Agency is unable to estimate risks associated with use of pronamide on residential lawns, and cannot impose a reentry interval for residential situations. Therefore, EPA is unable to make a reregistration eligibility decision about pronamide use on residential lawns, pending the results of several exposure studies.

Similarly, post-application reentry data are required for pronamide use on lettuce because of the potential for significant hand contact.

Human Risk Assessment

Pronamide is of relatively low acute toxicity, but has been demonstrated to cause liver cancer in male mice and is classified as a B2 "probable" human carcinogen. People may be exposed to residues of pronamide in a number of food crops, meat and milk. However, chronic exposure to pronamide in the diet is at a very low level (only a small fraction of the RfD), and is not a cause for concern at this time.

There is a concern for cancer associated with lifetime exposure of mixers/loaders/applicators and homeowners to pronamide. The combined risk for mixer/loader/applicators wearing personal protective equipment (PPE) is estimated to be 3 x 10-5. However, this estimate is conservative and actual risk is likely to be lower.

Environmental Assessment

Environmental Fate

Pronamide is stable to hydrolysis, and to photolysis in water and on soil. It is very persistent in soil under aerobic conditions, and even more persistent under anaerobic conditions (with an estimated half-life greater than 13 months). Pronamide has a relatively low vapor pressure and is relatively mobile in soil. Leaching appears to be its major route of dissipation.

A chemical with these properties is expected to be persistent and mobile in the field. Therefore, a study generated by Craven Laboratories which suggests that pronamide is neither persistent nor mobile must be replaced by a new field dissipation study.

Ecological Effects

Pronamide is practically nontoxic to birds and mammals on an acute basis. It is slightly toxic to freshwater fish and moderately toxic to freshwater invertebrates. Although toxicity to aquatic organisms is not anticipated, confirmatory estuarine studies are required. Pronamide is toxic to green algae. Testing on four other aquatic plants is required, therefore, to assess effects on the aquatic habitat and endangered aquatic plant species.

Ecological Effects Risk Assessment

Use of pronamide as directed by product labeling will have minimal adverse acute effects on insects, birds and mammals. However, chronic risk to aquatic invertebrates is possible, due to pronamide's persistence in water. EPA is requiring an aquatic invertebrate life cycle study to assess this potential risk. Testing on four additional aquatic plant species is required, as mentioned above. Risks to non-target terrestrial plants also will be further explored.

Regarding endangered species, pronamide may not adversely effect endangered birds or aquatic invertebrates, but risk to aquatic plants is uncertain. Terrestrial plants may be adversely affected by pronamide applied at maximum label rates. EPA may require additional labeling and use modifications when implementing the Endangered Species Protection Program.

Additional Data Required

EPA is requiring the following additional generic data for pronamide to confirm its regulatory assessments and conclusions:

Product Identity

Aquatic Invertebrate Life Cycle

Estuarine and Marine Organisms (Mollusc and Shrimp)

Terrestrial Field Dissipation

Field Rotational Crop

Droplet Size Spectrum and Drift Field Evaluation

Foliar Dislodgeable Dissipation

Dermal Passive Dosimetry

Estimation of Dermal/Inhalation Exposure at Outdoor Sites

Residue Analytical Method

Storage Stability

Magnitude of Residue

Processed Food

The following studies which are not part of the target data base also are required:

Seed Germination/Seedling Emergence

Aquatic Plant Growth

The following studies are required to support use of products on residential lawn and turf:

Foliar Dislodgeable Dissipation

Dermal Passive Dosimetry

To support the late season use of pronamide on artichokes, registrants must delete this use from their product labels or submit the following study:

Magnitude of Residue

The Agency also is requiring product-specific data including product chemistry and acute dermal toxicity studies, and revised labeling for reregistration.

Product Labeling Changes Required

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

Worker Protection Standard (WPS) - All pronamide products within the scope of the Worker Protection Standard (WPS) for Agricultural Pesticides (see PR Notice 93-7) must, within the timeframes listed in PR Notices 93-7 and 93-11, revise their labeling to be consistent with the WPS, as directed in those notices and the requirements of the RED.

Entry Restrictions

Uses Within the Scope of the WPS - A 24-hour restricted entry interval (REI) is required on all end-use products, except those intended primarily for home use. The PPE for early entry must be that required for applicators of pronamide except no apron or respirator is required.

- Labels of Sole AI Products - Revise to adopt these entry restrictions. Remove any conflicting entry restrictions on current labeling.

- Labels of Multiple-AI Products - Must bear the more protective of either the entry restrictions set forth here, or those on current labeling.

Uses Not Within the Scope of the WPS - Do not add any entry restrictions, but retain any on current labeling.

Personal Protective Equipment (PPE) Requirements

Uses on Products NOT Primarily Intended for Home Use The PPE requirement for pesticide handlers on all end-use products is:

"Applicators and other handlers must wear:

--Coveralls over short sleeved-shirt and short pants

--Chemical-resistant or waterproof gloves

--Chemical-resistant footwear plus socks

--Chemical-resistant headgear for overhead exposure

--Chemical-resistant apron when cleaning equipment, mixing or loading."

Pronamide products must bear these PPE requirements or those on current labeling, which ever is more protective.

Lawn and Turf Uses - If a registrant chooses to support the residential lawn uses only, he/she must add the following exclusionary statement on the front panel of the product label near the product name, or near the beginning of the Directions for Use section:

"Not for use on turf being grown for sale or other commercial use as sod, or for commercial seed production, or for research purposes."

If the registrant does not support the residential lawn uses, he/she must amend the product label to delete lawn and turf uses.

Fish and Wildlife Hazard - Labels must bear the following statement in the Precautionary Statements section under the subheading Environmental Hazards:

"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."

Restricted Use Pesticide Classification - The wettable powder products must maintain the Restricted Use Pesticide classification imposed at the conclusion of the Special Review.

Regulatory Conclusion

The use of all currently registered pesticide products containing pronamide in accordance with approved labeling, except residential lawn and turf uses and late season use on artichokes, will not pose unreasonable risks or adverse effects to humans; however, they may pose adverse effects to terrestrial plants and perhaps to aquatic plants. Products containing pronamide for all uses, except broadcast application on residential lawns

and turf, and the late season use on artichokes, are eligible for reregistration.

EPA has insufficient data at this time to make a reregistration eligibility decision regarding the use of pronamide on residential lawns and turf, or the late season use on artichokes. An eligibility decision cannot be made for broadcast application to residential lawns and turf until post-application/reentry exposure data are submitted and evaluated. A decision cannot be made for late season use on artichokes until residue data are submitted and evaluated.

Products that are eligible will be reregistered once the required confirmatory generic data, product specific data and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for pronamide during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

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

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

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