United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA 738-R-95-032 June 1995

Reregistration Eligibility Decision (RED)

Ancymidol

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case [enter case name here] which includes the active ingredients [enter chemical names here]. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative [enter your name and phone number here].

Sincerely yours,

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

Enclosures

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

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

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

ANCYMIDOL

LIST C

CASE 3017

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

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ANCYMIDOL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

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Eric Maurer	**Economic Analysis Branch**

Environmental Fate and Effects Division

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George Tompkins	**Environmental Fate and Groundwater Branch**

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Kevin Lee	**Pesticide Branch**

Office of Compliance Monitoring

Amar Singh	**Pesticide Enforcement Policy Branch**

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision (RED) addresses the eligibility for reregistration of pesticide products containing the active ingredient ancymidol (alpha-cyclopyl-alpha-(4-methoxyphenyl) -5-pyrimidinemethanol). Ancymidol is a plant growth regulator used in commercial production of ornamental plants. It is used to treat herbaceous plants and ornamental woody shrubs and vines. It acts by inhibiting gibberellin biosynthesis. Two products containing ancymidol are currently registered.

The Agency has completed its review of the target database for ancymidol and has determined that the uses of ancymidol as labeled and specified in this RED will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. No additional data on the generic active ingredient is needed to confirm this reregistration eligibility decision.

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

I. INTRODUCTION

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

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

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

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Ancymidol

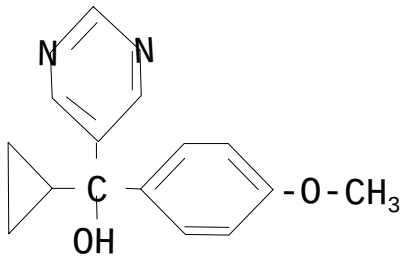
- **Chemical Name:** Alpha-cyclopropyl-alpha-(4-methoxyphenyl)-5-pyrimidinemethanol

- **CAS Registry Number:** 12771-68-5

- **OPP Chemical Code:** 108601

- **Empirical Formula:** $C_{15}H_{16}N_2O_2$

- **Structural Formula:**



- **Trade and Other Names:** Ancymidol, "A-Rest"

- **Basic Manufacturer:** Sepro Corporation

B. Use Profile

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

Ancymidol is a plant growth regulator registered for treating container-grown herbaceous plants, ornamental woody shrubs, and bedding plants grown in greenhouses and other plant bedding areas for primarily commercial production. Growth regulator effects produced by ancymidol are the result of inhibition of gibberellin biosynthesis. It produces a more compact growth form by suppressing internode elongation. The amount of active ingredient required for an optimum growth response depends on pot size, stage of growth, method of application, season, and varietal response.

Type of Pesticide: Plant growth regulator

Use Sites: Terrestrial nonfood (greenhouses and other plant bedding areas.)

Container-grown ornamental herbaceous plants, ornamental woody shrubs and bedding plants

Target Pests: none

Formulation Types Registered:

Single Active Ingredient (AI) Products
Soluble concentrate/liquid--0.0264%
Technical/solid--98%

Method and Rates of Application:

Soluble concentrate/liquid
At containerized stage, apply soil drench treatment at 15.6mg (0.0000344 lb) ai/gal to 4" pots (0.21 lb ai/A of bench area) or 6" pots (0.19 lb ai/gal of bench area). At cutting, foliar, or plant bed stage, spray by backpack or tank-type sprayer at 0.0011 lb ai/gal or 0.022 lb ai/A.

Use Practice Limitations:

Do not apply through any type of irrigation system.

C. Data Requirements

The Agency required data to support reregistration through a Data Call-In Notice (2/18/93) for ancymidol. Requirements included studies on ecological effects, product chemistry, environmental fate, and toxicology.

These data were required to assess the potential risk from uses identified on current labels. Appendix B includes all data requirements, identified by the Agency for currently registered uses, needed to support reregistration.

D. Regulatory History

The first pesticide product containing ancymidol as an active ingredient was registered by the Agency in 1973. Currently, there are two registered products, a technical formulation for manufacturing-use only and a 0.0264% end-use product. In 1993 the Agency issued a Data Call-in requiring the registrant to provide appropiate chemistry, toxicological and environmental fate data on this active ingredient to support reregistration.

III. SCIENCE ASSESSMENT

Below is a summary of the physical chemistry data bases reviewed by the Agency for the purpose of determining the physical and chemical properties of ancymidol. The specific studies reviewed for guidelines 61-1 through 63-13 are referenced in Appendix B.

A. Physical Chemistry Assessment

- **Color:** white to buff
- **Physical State:** crystalline granular
- **Odor:** Slightly aromatic
- **Melting Point:** 111-112 °C.
- **Boiling Point:** Not Required for a Solid
- **Density :** Loose 0.418 g/ml
  Settled 0.510 g/ml
- **Solubility:**

Solvent	gms/100 ml
Water	0.065
Acetone	>25
Acetonitrile	7
Benzene	3.7
Chloroform	>50
Hexane	0.019
Methanol	>25
Methyl Cellosolve	>25

- **Vapor Pressure:** 2 X 10^{-7} Torr at 25°C.

- **Octanol/Water Partition Coefficient:** Log K=1.91
- **pH:** 7.06 for 10% slurry in deionized water
- **Stability:** Stable in glass or fiber drums

B. Human Health Assessment

Below is a summary of the toxicology and exposure data bases reviewed by the Agency for the purpose of determining the potential risk to human health from the use of ancymidol.

1. Toxicology Assessment

a. Acute Toxicity

Table 1 describes the acute toxicity of ancymidol.

Table 1: ACUTE TOXICITY DATA

TEST	RESULTS	CATEGORY
Oral LD_{50} - rat	1721 mg/kg M; 1016 mg/kg F	III
Dermal LD_{50} - rabbit	LD_{50} = >5000 mg/kg (limit dose)	IV
Inhalation LC_{50} - rat	LC_{50} = 0.59 mg/l	III
Ocular irritation - rabbit	mild irritant	III
Primary dermal irritation - rabbit	Primary Irritation Index (P.I.I.) = 0.0	IV
Dermal sensitization - guinea pig	Non-sensitizer	

* Note: Data pertaining to primary eye irritation, primary dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

In an acute oral toxicity study [MRID#: 424806-01], male and female Fischer 344 rats were administered ancymidol at doses of 0, 750, 1375, or 2500 mg/kg/day. The LD_{50} for males and females was 1721 and 1016 mg/kg, respectively. Treatment-related signs included decreased body weight gain, hypoactivity, tremors, ataxia, lethargy, chromodacryorrhea and a minimal decrease in testicular size. Based on these results, ancymidol was determined to have an acute oral Toxicity Category of III. This study satisfies data requirements for an acute oral toxicity study in rats.

The acute dermal toxicity (LD_{50}) and primary dermal irritation potential [MRID#: 419379-01] of ancymidol was evaluated in 5 male and 5 female New Zealand White rabbits. The "limit dose" of 5000 mg/kg was applied topically and occluded for 24-hours after which it was removed. The rabbits remained on study for 14 days and were sacrificed. There were no treatment-related clinical findings upon observation of test animals. All animals survived to the end of the study period. There was no dermal irritation on any animal. Based on the results of this study, the dermal LD_{50} for ancymidol is >5000 mg/kg (limit dose) and the primary irritation index (P.I.I.) = 0.0; ancymidol is not considered to be a dermal irritant. Both acute dermal toxicity and primary dermal irritation studies were determined to indicate a Toxicity Category of IV. This study satisfies the requirements for an acute dermal (LD_{50}) toxicity study and a primary dermal irritation study in rabbits.

In an acute inhalation toxicity study [MRID# 42130801], groups of Fischer 344 rats [10/sex/group] were exposed for a 4-hour "nose only" period to a liquid droplet aerosol containing 7.5% ancymidol + acetone or acetone alone. The total gravimetric exposure concentration was 0.63 mg/l of air and the activity concentration was 0.59 mg ancymidol/L of air. The mass median equivalent aerodynamic diameter (MMEAD) and the activity median equivalent aerodynamic diameter (AMEAD) were 1.16 and 0.84, respectively. Death occurred in 10/20 (50%) test animals treated with ancymidol + acetone. Other signs of toxicity included: hypoactivity, labored breathing, gasping, poor grooming, prostration, ataxia, and kyphosis. Based on the results of this study, the median lethal concentration (LC_{50}) for a 4-hour exposure was estimated to be 0.59 mg ancymidol/L of air which places ancymidol in Toxicity Category III. This study is classified as Core Supplementary and does not satisfy the requirements for an acute inhalation toxicity study in rats. It may be upgraded upon submission of missing clinical observations and pathology information. This information has been requested from the registrant.

In a primary eye irritation study [MRID#41937902], 63 mg (0.1 ml) of ancymidol was placed into the conjunctival sac of one eye of each of 6 New Zealand white rabbits (three of each sex) for several seconds. Within one hour post-treatment, iritis, conjunctivitis and slight corneal dullness was observed in one rabbit. By Day 4, the irritation had cleared. The remaining 5 animals developed very slight redness with 4/5 showing very slight chemosis. These signs cleared by Day 3. Corneal damage in 3/6 test animals was indicated by positive responses to the sodium fluorescein stain 24 hours post-treatment. This had resolved by Day 4. There were no adverse effects on body weight during the study. The results of this study indicate that ocular irritation was cleared by Day 4 or less in

all test animals. Ancymidol was determined to be a mild ocular irritant with a Toxicity Category of III. This study satisfies data requirements for a primary eye irritation study in rabbits.

In a dermal sensitization study (modified Buehler method, 1965) [MRID#: 419137-02], 12 female Hartley albino guinea pigs were exposed to 50 mg doses of ancymidol at 6 hour intervals, three times a week for 2 weeks, then challenged with the same dose 10 days later. All test animals survived to the end of the study period. There were no adverse effects on body weight during the study. Based on the results of this study, dermal sensitization or irritation was not evident in animals induced and challenged with ancymidol at a dose of 50 mg. This study satisfies the guideline requirement for a dermal sensitization study in guinea pigs.

b. Subchronic Toxicity

In a 21-Day subchronic dermal toxicity study [MRID#: 421212-01], the systemic toxicity and dermal irritation potential of ancymidol were evaluated in 5 male and 5 female New Zealand White rabbits. None of the treated animals exhibited any dermal irritation or systemic toxicity after repeated exposure to 1000 mg/kg (limit dose) of ancymidol for 21 days. This study satisfies the requirement for a repeat dose [21-day] dermal toxicity study on the skin of rabbits.

c. Developmental Toxicity

In a developmental toxicity study [MRID#: 42480602], ancymidol was administered to pregnant CD [Crl:CD (SD)] rats at doses of 0, 50, 200, or 800 mg/kg/day on gestation days 6-17. Treatment-related maternal findings included decreases in body weight gain and food consumption at 200 mg/kg/day. The maternal no observed effect level (NOEL) was 50 mg/kg/day. The maternal lowest observed effect level (LOEL) was determined to be 200 mg/kg/day, based on decreased body weight gain and food consumption.

Developmental toxicity findings worthy of note included extra or rudimentary thoracic ribs and increased number of presacral vertebrae. The levels of extra or rudimentary thoracic ribs were outside of historical control ranges and demonstrated a treatment-related response. It was concluded that there was evidence of developmental alterations of rib development (e.g., rudimentary cervical and thoracic ribs, extra ribs, wavy ribs) with some vertebral changes (e.g., extra cervical vertebrae) at 800 mg/kg/day. Alterations in rib development (e.g., extra and rudimentary thoracic rib) were also seen at 200 mg/kg/day. The data suggested a dose

response in the incidence of rib anomalies, but this was not supported statistically. Based on these findings, the no observed effect level (NOEL) for developmental toxicity was determined to be 50 mg/kg/day and the lowest observed effect level (LOEL) for developmental toxicity was determined to be 200 mg/kg/day. This study satisfies the requirements for a developmental toxicity study in rats.

d. Mutagenicity

Ancymidol was evaluated in a forward gene mutation study [MRID#: 470105-08] at the thymidine kinase locus in mouse L5178Y $TK^{+/-}$ cells in culture. The cells were exposed to ancymidol at concentrations of 10, 50, 100, 200, 400, 600, 800, or 1000 μg/ml in the absence of exogenous metabolic activation system and to 0.1, 1, 10, 100, 200, 400, 600 or 800 μg/ml in the presence of an exogenous metabolic activation system. Ancymidol was tested to a sufficiently high concentration based on reduced cell growth in suspension. All cells were killed by 1000 μg/ml in the presence of S9 mix in the preliminary cytotoxicity assay. Positive and solvent control values were adequate. No evidence was seen of mutagenicity at any concentration of ancymidol with or without exogenous metabolic activation. This study is classified as an acceptable study that satisfies the requirements for an in vitro mammalian cell gene mutation study.

In a Salmonella/microsome plate incorporation assay [MRID#: 470105-10] strains TA98, TA100, TA1535, TA1537, and TA1538 were exposed to ancymidol at concentrations of 250, 500, 1000, 2500 or 5000 μg/plate, with and without exogenous metabolic activation. In the absence of cytotoxicity or solubility limitations, ancymidol was tested to a maximum concentration of 5000 μg/plate. There was no evidence of induced mutant colonies over background at any dose tested, either with or without exogenous metabolic activation. This study satisfies the guideline requirements for a gene mutation study.

In an unscheduled DNA synthesis (UDS) assay [MRID#: 470105-12], cultures of primary hepatocytes from a male Fischer 344 rat were exposed to ancymidol at concentrations of 0.5, 1, 5, 10, 50, 100, 500 or 1000 μg/ml. Two assays were performed, each using hepatocytes from a separate rat. The test compound was delivered in DMSO and the cells exposed to the test material for 20 hours. Ancymidol was excessively cytotoxic in both assays at 1000 μg/ml, precluding evaluation of the cells for UDS induction at this concentration. Some cytotoxicity was apparent at 500 μg/ml778778 but surviving cells were suitable for evaluation. All other doses were non-cytotoxic. No induction of UDS occurred at any

concentration of ancymidol evaluated in either assay. This is an acceptable study for other genotoxic effects.

e. Other Toxic Endpoints

Based on the use pattern for ancymidol as a non-food use pesticide, the RfD Committee of the Office of Pesticide Programs decided not to establish an RfD for this chemical. There has been no review by the Food and Agricultural Organization/World Health Organization (FAO/WHO) Joint Committee on Pesticide Residues (JMPR) for this pesticide.

2. Exposure Assessment - Occupational and Residential

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to either handlers (mixers, loaders, applicators) during use of the chemical or to persons entering treated sites after application is complete. At this time there are no products containing ancymidol intended for residential use. Therefore, the Agency did not conduct a residential exposure assessment.

Mixer/Loader/Applicator Exposure

Since ancymidol is used as a plant growth regulator for commercial purposes, the potential exposure for handlers is significant. Based on the pattern of use, several exposure scenarios are plausible depending on the type of application equipment and procedures employed. The current label (EPA. Reg.No. 67690-2) indicates that three kinds of application methods are available: bench area sprays; soil drench treatments; and foliar spray application methods. Handlers using open spray application methods (hand-held and tank-type sprayers) have potential for respiratory, dermal, and eye exposure when using ancymidol.

Post-Application Exposures

Based on the existing use patterns of ancymidol, post-application dermal (including contact with foliage) and inhalation exposures exist.

3. Risk Assessment - Occupational

The most appropriate endpoint for occupational exposure was determined to be from the 21 day dermal toxicity study in rabbits (MRID 421212-01). However, since no systemic effects were seen at doses up to

1000 mg/kg/day in that study, no quantitative occupational or residential risk assessment is necessary.

As noted in Section III.B.1a, "Acute Toxicity", rats treated with ancymidol in an acute inhalation study showed what appeared to be neurotoxic effects. Without additional refined data (i.e., from an acute inhalation neurotoxicity study) the Agency is not able to quantitatively characterize potential risk of this effect from exposure. However, while spray applications may produce significant exposure, concentrations of ancymidol are low in formulated products (0.0264 % a.i.), spray volatility is low, and current usage is very small. In consideration of this, the Agency believes that submission of an acute inhalation neurotoxicity study is unnecessary since the potential risk to applicators is insignificant.

C. Environmental Assessment

Because of the limited acreage anticipated, minor use sites (ornamental flowers and shrubs), and low toxicity cited in all of the submitted studies, the Agency expects minimal adverse effects to birds, mammals, aquatic organisms and non-target plants.

1. Environmental Fate

At this time, all appropriate data requirements in the environmental fate guidelines are fulfilled for ancymidol.

a. Environmental Fate Assessment

Based on the acceptable environmental fate data required (three data requirements) for the limited use pattern, the major route of dissipation of ancymidol in the soil is by microbial metabolism (aerobic half-life = 14.9 days). Based on an acceptable hydrolysis study, ancymidol was stable in sterile aqueous buffer solutions at pH 5.0, 7.0 and 9.0. In an acceptable batch equilibrium study ancymidol was highly mobile with reported K_{ads} values ranging from 0.11 (sand soil) to 0.82 (clay loam soil). In an acceptable leaching soil column study using a sandy loam soil, a total of 8.9 percent of the radioactivity applied to the column was recovered in the combined leachate.

b. Environmental Chemistry, Fate and Transport

(1) Hydrolysis

Ancymidol was reported to be stable to hydrolysis in sterile aqueous buffer solutions at pH 5.0, 7.0 and 9.0 at 25°C for 30

days. The requirement for hydrolysis data has been satisfied. (MRID # 417235-03)

(2) Aerobic Soil Metabolism

Ancymidol, applied at 0.5 ppm, degraded with a half-life of 14.9 days in a sandy loam soil incubated at 25°C. Six unidentified degradates were detected at ≤ 0.01 ppm. Carbon dioxide increased to a maximum of 44.89 percent of the applied by 61 days post treatment and unextracted radioactivity increased to approximately 43 percent at 61 days post treatment. The aerobic soil metabolism data requirement has been fulfilled. (MRID #420530-01)

(3) Leaching and Adsorption/Desorption

Ancymidol was highly mobile with reported Freundlich K_{ads} values ranging from 0.11 (sandy soil) to 0.82 (clay loam soil). In a leaching soil column study, using a sandy loam soil, a total of 8.9 percent of the radioactivity applied to the column was recovered in the combined leachates during the 43 day leaching period. In the original study, the cation exchange capacity was not provided for one of the four soils and was requested. This requested information was provided and was listed as 30.0 meq/100 g. This study is now acceptable and the data requirements fulfilled for a leaching and adsorption/desorption study. (MRID #s 417235-02 and 419137-01)

2. Ecological Effects

The ecotoxicological data base is adequate to characterize the toxicity of ancymidol to nontarget terrestrial and aquatic organisms when used in greenhouses and on limited terrestrial non-food sites.

a. Non- Target Bird Data

In order to establish the toxicity of ancymidol to birds, the following tests may be required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). If the chemical is persistent in the environment, the Agency may also require two avian reproduction studies on mallard duck and bobwhite quail. In this case, due to the limited use sites, only one study is necessary to be evaluated under this topic, the avian

subacute dietary. The study summarized below is acceptable for use in hazard assessment.

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. No wild mammal testing is required for ancymidol.

(1) Avian Acute Toxicity

The requirement for avian acute oral toxicity has been waived because of the low expected exposure to birds. Ancymidol has very limited usage with use sites including greenhouses and bedding areas. In addition, ancymidol was found to be practically nontoxic in the dietary feeding study using bobwhite quail. For these reasons the Agency believes it unnecessary to require avian acute toxicity testing.

(2) Avian Subacute Dietary Toxicity

Table 2: Avian Subacute Dietary Toxicity Findings

Species	% Test Material (TGAI)	LC_{50}	Conclusions
Bobwhite quail	99.9	> 5192 ppm	practically nontoxic

These results show that ancymidol is practically nontoxic to birds with an LC_{50} > 5192 ppm. The guideline requirement for the avian subacute dietary LC_{50} study is fulfilled. (MRID # 416706-02)

(3) Avian Reproduction

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. No avian reproduction studies are required for the current use pattern of ancymidol.

b. Aquatic Data

(1) Freshwater Fish Toxicity

In order to establish the toxicity of a pesticide to freshwater fish, the data which may be required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish), and if persistent in the environment, the fish early life stage study would be required. Based on the limited use sites, only one study is necessary to be evaluated under this topic.

Table 3: Freshwater Fish Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Rainbow trout	99.9	> 100 ppm	practically nontoxic

The results of the rainbow trout 96-hour acute toxicity study indicates that ancymidol is practically nontoxic to cold water fish. The guideline requirement for acute toxicity testing of the technical on freshwater fish is fulfilled. (MRID # 416706-03)

(2) Freshwater Invertebrate Toxicity

Testing which may be required to assess the hazard of a pesticide to freshwater aquatic invertebrates is a test using preferably first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. If the chemical is persistent in the environment, an aquatic invertebrate life cycle may be required.

Based on the limited use sites, only one study is necessary to be evaluated under this topic.

Table 4: Freshwater Invertebrate Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Daphnia magna	99.9	> 100 ppm	practically nontoxic

There is sufficient information to characterize ancymidol as practically nontoxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID #416706-01)

(3) Estuarine/Marine Toxicity

Estuarine studies were not required or submitted for evaluation under this topic since it is assumed that estuarine exposure is minimal.

c. Terrestrial, Semi-Aquatic, and Aquatic Plant Data

In order to establish the toxicity to aquatic plants, an aquatic plant growth study comprising of *Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and freshwater diatom may be required using the technical grade material. In order to establish the toxicity to terrestrial plants, the germination, seedling emergence and vegetative vigor studies may be required using the technical grade material.

Because of the limited acreage anticipated, and minor use sites to be treated (ornamental flowers and shrubs), only two non-target aquatic plant studies using *Selenastrum capricornutum and Lemna gibba* were required. No non-target terrestrial plant toxicity data were required (also because of limited acreage anticipated and minor use sites to be treated). The non-target aquatic plant studies are summarized below and are acceptable for use in hazard assessment.

Table 5: Nontarget Aquatic Plant Toxicity Findings

Species	% A.I.	EC_{50}
Lemna gibba	99.8	0.29 ppm
Selenastrum capricornutum	99.8	26.9 ppm

When considering the environmental fate and ecotoxicological data (Tier I and II effects) in combination with the application methods and rates, the Agency concludes that ancymidol will represent minimal risk to aquatic plant species. Both Tier I and II data requirements have been fulfilled. (MRID # 431405-01 and 431405-02)

d. Non-Target Insects Data

The minimum data required to establish the acute toxicity to honey bees is an acute contact LD_{50} study with the technical material. There is sufficient information to characterize ancymidol as practically nontoxic to bees. The guideline requirement is fulfilled. (MRID # 413405-04)

Table 6: Nontarget Insect Acute Contact Toxicity Findings			
Species	**% Test Material**	**LD_{50}**	**Conclusion**
Apis mellifera	99.8	> 100 μg/bee	practically nontoxic

e. Non-Target Mammal Data

The available mammalian data indicate that ancymidol is slightly toxic to small mammals on an acute basis. This study is discussed in the Human Health Assessment, III. B. 1. a. and presented below (MRID #424806-01)

Table 7: Mammalian Acute Oral Toxicity Findings		
Species	**LD_{50}(mg/kg)**	**Conclusion**
Rat (small mammal surrogate studies)	M = 1721 F = 1016	slightly toxic

3. Ecological Effects Risk Assessment

a. Risk to Terrestrial Animals

The maximum expected residues (ppm) on vegetation immediately after one application of 0.4356 lbs a.i./A (based on Hoerger and Kenaga, 1972) would be 104 ppm. This would be well below the toxicity hazard to birds of 5192 ppm and to mammals (LC_{50}= 4500 ppm in the diet of female rats, based on an oral LD_{50} of 1016 mg/kg and consumption of 31% of their weight in food). Minimal adverse effects are expected to birds and mammals from the use of ancymidol. It also appears likely that there will be minimal adverse effects to beneficial insects (LD_{50} >100 μg/bee) since it is practically nontoxic to honey bees.

b. Risk to Aquatic Animals

A direct application of 0.4356 lbs a.i./A into an acre pond six feet deep would have 27 parts per billion (ppb) of ancymidol. This is well below the toxicity hazard of 100 ppm for fish and aquatic invertebrates. Minimal adverse effects are expected to aquatic animals from the use of ancymidol.

c. Risk to Non-Target Plants

A direct application of 0.4356 lbs a.i./A into an acre pond six feet deep would have 27 parts per billion (ppb) of ancymidol. This is well below the toxicity hazard of 290 ppb for aquatic plants.

Since current application rates and usage are very low and this chemical is a growth regulator for height control of commercially produced ornamental plants and shrubs, very little exposure to terrestrial plants is anticipated. Therefore, minimal adverse effects are expected to terrestrial plants from the labeled use of ancymidol.

d. Risk to Endangered Species

Endangered species are not expected to be affected from the labeled use of ancymidol because of very limited exposure of the chemical to endangered species sites and, triggers for endangered species were not exceeded.

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 ancymidol as the active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing ancymidol. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of ancymidol, and lists the submitted studies that the Agency found acceptable.

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

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

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

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

B. Regulatory Position

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

Worker Protection Requirements

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Covered uses include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turfgrass, flowers, shrubs, ornamental, and seedlings). These include uses on plants, and on the soil or planting medium the plants are (or will be) grown in. Current use of ancymidol on commercially-grown ornamental plants falls within the scope of the WPS. There are no residential uses of ancymidol.

Handler (Mixer, Loader, Applicator) Personal Protective Equipment

The potential for exposure of handlers (mixer, loader, and applicator) to ancymidol exists. For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

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

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

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

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

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

There no are special toxicological concerns about ancymidol that warrant the establishment of active-ingredient-based PPE requirements. Therefore any PPE requirements will be established based on the acute toxicity of the end-use product.

Post-application Entry Restrictions

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

The 12 hour interim restricted entry interval (REI) must be imposed for all uses of ancymidol within the scope of the WPS, based on acute toxicity effects (Category III and IV).

Early Entry PPE-- personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one or two ways.

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based

on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

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

This minimum required early entry PPE appropriate to ancymidol consist of coveralls, chemical-resistant gloves, and shoes plus socks.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of ancymidol for the above eligible uses has been reviewed and determined to be substantially complete. However, the Agency has required the registrant to submit missing clinical observation and pathology information to upgrade the acute inhalation study in rats or to conduct a new study.

2. Labeling Requirements for Manufacturing-Use Products

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

"Only for formulation into a herbicide/plant growth regulator for the following use(s): (fill blank only with those uses that are being supported by MP registrants)."

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

(a) "this product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower

has complied with U.S. EPA submission requirements regarding the supported use(s).

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

The following label statements are required on all end-use products:

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

b. "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) for 12 hours."

c. "PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is coveralls, chemical-resistant gloves, and shoes plus socks."

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

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

SITE Application Type, Application Timing, Application Equipment — Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP									
Soil drench treatment., Containerized., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Cutting., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Plant bed., Sprayer.	SC/L	NA	.01 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			, C46
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: TERRESTRIAL NON-FOOD CROP									
Soil drench treatment., Containerized., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Cutting., Sprayer.	SC/L	NA	.01 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Plant bed., Sprayer.	SC/L	NA	.01 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			, C46

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Restr. Entry Interv (days)	: Restricted Entry Interval (days)
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

SC/L	: SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

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

APPLICATION RATE

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

USE LIMITATIONS CODES

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case ANCYMIDOL covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to ANCYMIDOL in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

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

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Ancymidol

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	162638
61-2A	Start. Mat. & Mnfg. Process	ALL	162638
61-2B	Formation of Impurities	ALL	162638
62-1	Preliminary Analysis	ALL	162638
62-2	Certification of limits	ALL	162638
62-3	Analytical Method	ALL	162638
63-2	Color	ALL	162638
63-3	Physical State	ALL	162638
63-4	Odor	ALL	162638
63-5	Melting Point	ALL	162638
63-6	Boiling Point	ALL	INAPPLICABLE
63-7	Density	ALL	162638
63-8	Solubility	ALL	41723501
63-9	Vapor Pressure	ALL	41821201
63-10	Dissociation Constant	ALL	43140503
63-11	Octanol/Water Partition	ALL	162638
63-12	pH	ALL	162638
63-13	Stability	ALL	43216301

Data Supporting Guideline Requirements for the Reregistration of Ancymidol

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-2A	Acute Avian Diet/Quail	ALL	41670602
72-1C	Fish Toxicity - Rainbow Trout	ALL	41670603
72-2A	Invertebrate Toxicity	ALL	41670601
123-2	Aquatic Plant Growth	ALL	43140501, 43140502
141-1	Honey Bee Acute Contact	ALL	43140504
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	ALL	42480601
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	41937901
81-3	Acute Inhalation Toxicity - Rat	ALL	42130801
81-4	Primary Eye Irritation - Rabbit	ALL	41937902
81-5	Primary Dermal Irritation - Rabbit	ALL	41937901
81-6	Dermal Sensitization - Guinea Pig	ALL	41913702
82-2	21-Day Dermal - Rabbit/Rat	ALL	42121201
83-3A	Developmental Toxicity - Rat	ALL	42480602
84-2A	Gene Mutation (Ames Test)	ALL	47010508
84-2B	Structural Chromosomal Aberration	ALL	47010510
84-4	Other Genotoxic Effects	ALL	47010512

Data Supporting Guideline Requirements for the Reregistration of Ancymidol

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIROMENTAL FATE			
161-1	**Hydrolysis**	**ALL**	**41723503**
162-1	**Aerobic Soil**	**ALL**	**42053001**
163-1	**Leaching and Adsorption/desorption**	**ALL**	**41723502, 41913701**

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92 and 2070-0057 (expiration date 03-31-96). This Notice is divided into six sections and six Attachments. The Notice itself contains information and

instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific

data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item

number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

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

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

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of

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

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 6. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency

or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

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

1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

ANCYMIDOL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Ancymidol. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Ancymidol Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Ancymidol, please contact Rieman Rhinehart at (703) 308-8584.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Veronica Dutch at (703) 308-8585.

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

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

RE: **ANCYMIDOL**

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

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

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

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

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is

committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

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

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING ANCYMIDOL 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 end-use products containing the active ingredient ancymidol, the Agency considered batching end-use 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.).

However, batching of end-use products containing ancymidol was not possible after considering the available information described above. Table I lists all the end-use products containing ancymidol. These products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Registrants must generate all the required acute toxicological studies for each of their 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 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). Since the end-use products containing ancymidol could not be batched, registrants cannot choose from the remaining options: Cost sharing (Option 2) or Offers to Cost Share (Option 3).

Table I. End-Use Products Containing Ancymidol

EPA Reg. No.	% of ancymidol	Formulation Type
67690-2	0.0264	Soluble Concentrate
67690-5	98	Technical

INSERT LIST OF REGISTRANTS GENERATED BY THE PRODUCT SPECIFIC DCI IN PLACE OF THIS PAGE.

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

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

EPA	United States Environmental Protection Agency Washington, DC 20460 CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents related to ancymidol. 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 ancymidol 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. Ancymidol RED Fact Sheet

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

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

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-027 June 1995

R.E.D. FACTS

Ancymidol

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3017, ancymidol.

Use Profile

Ancymidol is a plant growth regulator registered for treating container-grown herbaceous plants, ornamental woody shrubs, and bedding plants grown in greenhouses and other plant bedding areas for commercial production. Growth regulator effects produced by ancymidol are the result of inhibition of gibberellin biosynthesis. Since gibberellin promotes growth, treatment with ancymidol induces a more compact growth form by suppressing growth between nodes. The amount of active ingredient required for an optimum growth response depends on pot size, stage of growth, method of application, season, and varietal response.

Regulatory History

Ancymidol was first registered as a pesticide in the U.S. in 1973.

In 1993 the Agency issued a Data Call-in (DCI) to the registrant for submission of additional data on ancymidol to support reregistration.

Currently there are two registered products, a technical formulation for manufacturing-use only and an end-use product containing 0.0264% ancymidol.

Human Health Assessment

Toxicity

Testing of ancymidol for acute toxicity on animals indicates that when inhaled, ingested, or applied to eyes, ancymidol is considered slightly acutely toxic (Toxicity category III). When applied to skin, it is practically non-toxic (Toxicity category IV). A subchronic 21-day toxicity study on rabbits showed no dermal irritation or systemic toxicity at the limit dose (1000 mg/kg) when applied dermally. A developmental toxicity study in rats did not indicate that ancymidol is a developmental toxicant. From that study, a lowest observed effect level for non-developmental toxic effects was determined to be 200 mg/kg/day, based on decreased body-weight gain and food consumption; while the no-effect level was considered to be 50 mg/kg/day. Finally, a battery of mutagenicity studies were negative for ancymidol. Long-term chronic toxicity testing of ancymidol has not been conducted but is not required since it is not found in food and other potential exposure to humans is very limited.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of ancymidol since no food or feed uses are registered.

Occupational and Residential Exposure

Since ancymidol is used as a plant growth regulator for commercial purposes, there is potential exposure to pesticide handlers during use of the chemical and to persons entering treated sites after application is complete. At this time there are no products containing ancymidol intended for residential use. Therefore, the Agency did not conduct a residential risk assessment.

Human Risk Assessment

Since ancymidol has no food or feed uses, dietary risk is not expected. An acute toxicity inhalation study in rats treated with ancymidol shows what appeared to be neurotoxic effects. However, while spray applications may produce significant exposure, concentrations of ancymidol are low in formulated products (0.0264% a.i.), spray volatility is low, and current usage is very small. In consideration of this, the Agency believes that the potential risk to applicators is insignificant.

Ecological Effects Risk Assessment

Because environmental exposure to ancymidol is very limited and low toxicity is cited in all of the submitted studies, the Agency expects minimal adverse effects to birds, mammals, aquatic organisms and non-target plants.

Additional Data Required

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

Product Labeling Changes Required

All end-use products containing ancymidol must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the ancymidol RED document.

Regulatory Conclusion

The use of currently registered products containing ancymidol in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

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

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for ancymidol during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

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

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

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

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

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case [enter case name here] which includes the active ingredients [enter chemical names here]. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative [enter your name and phone number here].

Sincerely yours,

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

Enclosures

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

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

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

ANCYMIDOL

LIST C

CASE 3017

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

TABLE OF CONTENTS

ANCYMIDOL REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Steve Jarboe	**Biological Analysis Branch**
Eric Maurer	**Economic Analysis Branch**

Environmental Fate and Effects Division

Linda Kutney	**Science Analysis and Coordination Staff**
Renee Costello	**Science Analysis and Coordination Staff**
Mike Davy	**Ecological Effects Branch**
George Tompkins	**Environmental Fate and Groundwater Branch**

Health Effects Division

Paula Deschamp	**Chemical Coordination Branch**
Winston Dang	**Occupational and Residential Exposure Branch**
Sanyvette Williams-Foy	**Toxicology Branch II**

Registration Division

Bipin Gandhi	**Registration Support Branch**
James Stone	**Fungicide-Herbicide Branch**

Special Review and Reregistration Division

Rieman Rhinehart	**Accelerated Reregistration Branch**
Bruce Sidwell	**Accelerated Reregistration Branch**

Office of General Counsel:

Kevin Lee	**Pesticide Branch**

Office of Compliance Monitoring

Amar Singh	**Pesticide Enforcement Policy Branch**

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision (RED) addresses the eligibility for reregistration of pesticide products containing the active ingredient ancymidol (alpha-cyclopyl-alpha-(4-methoxyphenyl) -5-pyrimidinemethanol). Ancymidol is a plant growth regulator used in commercial production of ornamental plants. It is used to treat herbaceous plants and ornamental woody shrubs and vines. It acts by inhibiting gibberellin biosynthesis. Two products containing ancymidol are currently registered.

The Agency has completed its review of the target database for ancymidol and has determined that the uses of ancymidol as labeled and specified in this RED will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. No additional data on the generic active ingredient is needed to confirm this reregistration eligibility decision.

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

I. INTRODUCTION

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

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

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

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Ancymidol

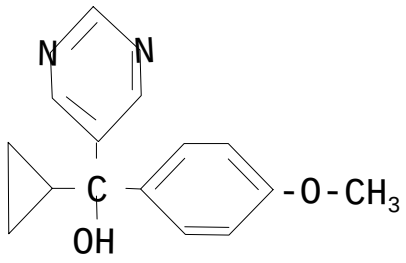
- **Chemical Name:** Alpha-cyclopropyl-alpha-(4-methoxyphenyl)-5-pyrimidinemethanol

- **CAS Registry Number:** 12771-68-5

- **OPP Chemical Code:** 108601

- **Empirical Formula:** $C_{15}H_{16}N_2O_2$

- **Structural Formula:**



- **Trade and Other Names:** Ancymidol, "A-Rest"

- **Basic Manufacturer:** Sepro Corporation

B. Use Profile

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

Ancymidol is a plant growth regulator registered for treating container-grown herbaceous plants, ornamental woody shrubs, and bedding plants grown in greenhouses and other plant bedding areas for primarily commercial production. Growth regulator effects produced by ancymidol are the result of inhibition of gibberellin biosynthesis. It produces a more compact growth form by suppressing internode elongation. The amount of active ingredient required for an optimum growth response depends on pot size, stage of growth, method of application, season, and varietal response.

Type of Pesticide: Plant growth regulator

Use Sites: Terrestrial nonfood (greenhouses and other plant bedding areas.)

Container-grown ornamental herbaceous plants, ornamental woody shrubs and bedding plants

Target Pests: none

Formulation Types Registered:

Single Active Ingredient (AI) Products
Soluble concentrate/liquid--0.0264%
Technical/solid--98%

Method and Rates of Application:

Soluble concentrate/liquid
At containerized stage, apply soil drench treatment at 15.6mg (0.0000344 lb) ai/gal to 4" pots (0.21 lb ai/A of bench area) or 6" pots (0.19 lb ai/gal of bench area). At cutting, foliar, or plant bed stage, spray by backpack or tank-type sprayer at 0.0011 lb ai/gal or 0.022 lb ai/A.

Use Practice Limitations:

Do not apply through any type of irrigation system.

C. Data Requirements

The Agency required data to support reregistration through a Data Call-In Notice (2/18/93) for ancymidol. Requirements included studies on ecological effects, product chemistry, environmental fate, and toxicology.

These data were required to assess the potential risk from uses identified on current labels. Appendix B includes all data requirements, identified by the Agency for currently registered uses, needed to support reregistration.

D. Regulatory History

The first pesticide product containing ancymidol as an active ingredient was registered by the Agency in 1973. Currently, there are two registered products, a technical formulation for manufacturing-use only and a 0.0264% end-use product. In 1993 the Agency issued a Data Call-in requiring the registrant to provide appropiate chemistry, toxicological and environmental fate data on this active ingredient to support reregistration.

III. SCIENCE ASSESSMENT

Below is a summary of the physical chemistry data bases reviewed by the Agency for the purpose of determining the physical and chemical properties of ancymidol. The specific studies reviewed for guidelines 61-1 through 63-13 are referenced in Appendix B.

A. Physical Chemistry Assessment

- **Color:** white to buff
- **Physical State:** crystalline granular
- **Odor:** Slightly aromatic
- **Melting Point:** 111-112 °C.
- **Boiling Point:** Not Required for a Solid
- **Density :** Loose 0.418 g/ml
  Settled 0.510 g/ml
- **Solubility:**

Solvent	gms/100 ml
Water	0.065
Acetone	>25
Acetonitrile	7
Benzene	3.7
Chloroform	>50
Hexane	0.019
Methanol	>25
Methyl Cellosolve	>25

- **Vapor Pressure:** 2 X 10^{-7} Torr at 25°C.

- **Octanol/Water Partition Coefficient:** Log K=1.91
- **pH:** 7.06 for 10% slurry in deionized water
- **Stability:** Stable in glass or fiber drums

B. Human Health Assessment

Below is a summary of the toxicology and exposure data bases reviewed by the Agency for the purpose of determining the potential risk to human health from the use of ancymidol.

1. Toxicology Assessment

a. Acute Toxicity

Table 1 describes the acute toxicity of ancymidol.

Table 1: ACUTE TOXICITY DATA

TEST	RESULTS	CATEGORY
Oral LD_{50} - rat	1721 mg/kg M; 1016 mg/kg F	III
Dermal LD_{50} - rabbit	LD_{50} = >5000 mg/kg (limit dose)	IV
Inhalation LC_{50} - rat	LC_{50} = 0.59 mg/l	III
Ocular irritation - rabbit	mild irritant	III
Primary dermal irritation - rabbit	Primary Irritation Index (P.I.I.) = 0.0	IV
Dermal sensitization - guinea pig	Non-sensitizer	

* Note: Data pertaining to primary eye irritation, primary dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

In an acute oral toxicity study [MRID#: 424806-01], male and female Fischer 344 rats were administered ancymidol at doses of 0, 750, 1375, or 2500 mg/kg/day. The LD_{50} for males and females was 1721 and 1016 mg/kg, respectively. Treatment-related signs included decreased body weight gain, hypoactivity, tremors, ataxia, lethargy, chromodacryorrhea and a minimal decrease in testicular size. Based on these results, ancymidol was determined to have an acute oral Toxicity Category of III. This study satisfies data requirements for an acute oral toxicity study in rats.

The acute dermal toxicity (LD_{50}) and primary dermal irritation potential [MRID#: 419379-01] of ancymidol was evaluated in 5 male and 5 female New Zealand White rabbits. The "limit dose" of 5000 mg/kg was applied topically and occluded for 24-hours after which it was removed. The rabbits remained on study for 14 days and were sacrificed. There were no treatment-related clinical findings upon observation of test animals. All animals survived to the end of the study period. There was no dermal irritation on any animal. Based on the results of this study, the dermal LD_{50} for ancymidol is >5000 mg/kg (limit dose) and the primary irritation index (P.I.I.) = 0.0; ancymidol is not considered to be a dermal irritant. Both acute dermal toxicity and primary dermal irritation studies were determined to indicate a Toxicity Category of IV. This study satisfies the requirements for an acute dermal (LD_{50}) toxicity study and a primary dermal irritation study in rabbits.

In an acute inhalation toxicity study [MRID# 42130801], groups of Fischer 344 rats [10/sex/group] were exposed for a 4-hour "nose only" period to a liquid droplet aerosol containing 7.5% ancymidol + acetone or acetone alone. The total gravimetric exposure concentration was 0.63 mg/l of air and the activity concentration was 0.59 mg ancymidol/L of air. The mass median equivalent aerodynamic diameter (MMEAD) and the activity median equivalent aerodynamic diameter (AMEAD) were 1.16 and 0.84, respectively. Death occurred in 10/20 (50%) test animals treated with ancymidol + acetone. Other signs of toxicity included: hypoactivity, labored breathing, gasping, poor grooming, prostration, ataxia, and kyphosis. Based on the results of this study, the median lethal concentration (LC_{50}) for a 4-hour exposure was estimated to be 0.59 mg ancymidol/L of air which places ancymidol in Toxicity Category III. This study is classified as Core Supplementary and does not satisfy the requirements for an acute inhalation toxicity study in rats. It may be upgraded upon submission of missing clinical observations and pathology information. This information has been requested from the registrant.

In a primary eye irritation study [MRID#41937902], 63 mg (0.1 ml) of ancymidol was placed into the conjunctival sac of one eye of each of 6 New Zealand white rabbits (three of each sex) for several seconds. Within one hour post-treatment, iritis, conjunctivitis and slight corneal dullness was observed in one rabbit. By Day 4, the irritation had cleared. The remaining 5 animals developed very slight redness with 4/5 showing very slight chemosis. These signs cleared by Day 3. Corneal damage in 3/6 test animals was indicated by positive responses to the sodium fluorescein stain 24 hours post-treatment. This had resolved by Day 4. There were no adverse effects on body weight during the study. The results of this study indicate that ocular irritation was cleared by Day 4 or less in

all test animals. Ancymidol was determined to be a mild ocular irritant with a Toxicity Category of III. This study satisfies data requirements for a primary eye irritation study in rabbits.

In a dermal sensitization study (modified Buehler method, 1965) [MRID#: 419137-02], 12 female Hartley albino guinea pigs were exposed to 50 mg doses of ancymidol at 6 hour intervals, three times a week for 2 weeks, then challenged with the same dose 10 days later. All test animals survived to the end of the study period. There were no adverse effects on body weight during the study. Based on the results of this study, dermal sensitization or irritation was not evident in animals induced and challenged with ancymidol at a dose of 50 mg. This study satisfies the guideline requirement for a dermal sensitization study in guinea pigs.

b. Subchronic Toxicity

In a 21-Day subchronic dermal toxicity study [MRID#: 421212-01], the systemic toxicity and dermal irritation potential of ancymidol were evaluated in 5 male and 5 female New Zealand White rabbits. None of the treated animals exhibited any dermal irritation or systemic toxicity after repeated exposure to 1000 mg/kg (limit dose) of ancymidol for 21 days. This study satisfies the requirement for a repeat dose [21-day] dermal toxicity study on the skin of rabbits.

c. Developmental Toxicity

In a developmental toxicity study [MRID#: 42480602], ancymidol was administered to pregnant CD [Crl:CD (SD)] rats at doses of 0, 50, 200, or 800 mg/kg/day on gestation days 6-17. Treatment-related maternal findings included decreases in body weight gain and food consumption at 200 mg/kg/day. The maternal no observed effect level (NOEL) was 50 mg/kg/day. The maternal lowest observed effect level (LOEL) was determined to be 200 mg/kg/day, based on decreased body weight gain and food consumption.

Developmental toxicity findings worthy of note included extra or rudimentary thoracic ribs and increased number of presacral vertebrae. The levels of extra or rudimentary thoracic ribs were outside of historical control ranges and demonstrated a treatment-related response. It was concluded that there was evidence of developmental alterations of rib development (e.g., rudimentary cervical and thoracic ribs, extra ribs, wavy ribs) with some vertebral changes (e.g., extra cervical vertebrae) at 800 mg/kg/day. Alterations in rib development (e.g., extra and rudimentary thoracic rib) were also seen at 200 mg/kg/day. The data suggested a dose

response in the incidence of rib anomalies, but this was not supported statistically. Based on these findings, the no observed effect level (NOEL) for developmental toxicity was determined to be 50 mg/kg/day and the lowest observed effect level (LOEL) for developmental toxicity was determined to be 200 mg/kg/day. This study satisfies the requirements for a developmental toxicity study in rats.

d. Mutagenicity

Ancymidol was evaluated in a forward gene mutation study [MRID#: 470105-08] at the thymidine kinase locus in mouse L5178Y $TK^{+/-}$ cells in culture. The cells were exposed to ancymidol at concentrations of 10, 50, 100, 200, 400, 600, 800, or 1000 μg/ml in the absence of exogenous metabolic activation system and to 0.1, 1, 10, 100, 200, 400, 600 or 800 μg/ml in the presence of an exogenous metabolic activation system. Ancymidol was tested to a sufficiently high concentration based on reduced cell growth in suspension. All cells were killed by 1000 μg/ml in the presence of S9 mix in the preliminary cytotoxicity assay. Positive and solvent control values were adequate. No evidence was seen of mutagenicity at any concentration of ancymidol with or without exogenous metabolic activation. This study is classified as an acceptable study that satisfies the requirements for an in vitro mammalian cell gene mutation study.

In a Salmonella/microsome plate incorporation assay [MRID#: 470105-10] strains TA98, TA100, TA1535, TA1537, and TA1538 were exposed to ancymidol at concentrations of 250, 500, 1000, 2500 or 5000 μg/plate, with and without exogenous metabolic activation. In the absence of cytotoxicity or solubility limitations, ancymidol was tested to a maximum concentration of 5000 μg/plate. There was no evidence of induced mutant colonies over background at any dose tested, either with or without exogenous metabolic activation. This study satisfies the guideline requirements for a gene mutation study.

In an unscheduled DNA synthesis (UDS) assay [MRID#: 470105-12], cultures of primary hepatocytes from a male Fischer 344 rat were exposed to ancymidol at concentrations of 0.5, 1, 5, 10, 50, 100, 500 or 1000 μg/ml. Two assays were performed, each using hepatocytes from a separate rat. The test compound was delivered in DMSO and the cells exposed to the test material for 20 hours. Ancymidol was excessively cytotoxic in both assays at 1000 μg/ml, precluding evaluation of the cells for UDS induction at this concentration. Some cytotoxicity was apparent at 500 μg/ml778778 but surviving cells were suitable for evaluation. All other doses were non-cytotoxic. No induction of UDS occurred at any

concentration of ancymidol evaluated in either assay. This is an acceptable study for other genotoxic effects.

e. Other Toxic Endpoints

Based on the use pattern for ancymidol as a non-food use pesticide, the RfD Committee of the Office of Pesticide Programs decided not to establish an RfD for this chemical. There has been no review by the Food and Agricultural Organization/World Health Organization (FAO/WHO) Joint Committee on Pesticide Residues (JMPR) for this pesticide.

2. Exposure Assessment - Occupational and Residential

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to either handlers (mixers, loaders, applicators) during use of the chemical or to persons entering treated sites after application is complete. At this time there are no products containing ancymidol intended for residential use. Therefore, the Agency did not conduct a residential exposure assessment.

Mixer/Loader/Applicator Exposure

Since ancymidol is used as a plant growth regulator for commercial purposes, the potential exposure for handlers is significant. Based on the pattern of use, several exposure scenarios are plausible depending on the type of application equipment and procedures employed. The current label (EPA. Reg.No. 67690-2) indicates that three kinds of application methods are available: bench area sprays; soil drench treatments; and foliar spray application methods. Handlers using open spray application methods (hand-held and tank-type sprayers) have potential for respiratory, dermal, and eye exposure when using ancymidol.

Post-Application Exposures

Based on the existing use patterns of ancymidol, post-application dermal (including contact with foliage) and inhalation exposures exist.

3. Risk Assessment - Occupational

The most appropriate endpoint for occupational exposure was determined to be from the 21 day dermal toxicity study in rabbits (MRID 421212-01). However, since no systemic effects were seen at doses up to

1000 mg/kg/day in that study, no quantitative occupational or residential risk assessment is necessary.

As noted in Section III.B.1a, "Acute Toxicity", rats treated with ancymidol in an acute inhalation study showed what appeared to be neurotoxic effects. Without additional refined data (i.e., from an acute inhalation neurotoxicity study) the Agency is not able to quantitatively characterize potential risk of this effect from exposure. However, while spray applications may produce significant exposure, concentrations of ancymidol are low in formulated products (0.0264 % a.i.), spray volatility is low, and current usage is very small. In consideration of this, the Agency believes that submission of an acute inhalation neurotoxicity study is unnecessary since the potential risk to applicators is insignificant.

C. Environmental Assessment

Because of the limited acreage anticipated, minor use sites (ornamental flowers and shrubs), and low toxicity cited in all of the submitted studies, the Agency expects minimal adverse effects to birds, mammals, aquatic organisms and non-target plants.

1. Environmental Fate

At this time, all appropriate data requirements in the environmental fate guidelines are fulfilled for ancymidol.

a. Environmental Fate Assessment

Based on the acceptable environmental fate data required (three data requirements) for the limited use pattern, the major route of dissipation of ancymidol in the soil is by microbial metabolism (aerobic half-life = 14.9 days). Based on an acceptable hydrolysis study, ancymidol was stable in sterile aqueous buffer solutions at pH 5.0, 7.0 and 9.0. In an acceptable batch equilibrium study ancymidol was highly mobile with reported K_{ads} values ranging from 0.11 (sand soil) to 0.82 (clay loam soil). In an acceptable leaching soil column study using a sandy loam soil, a total of 8.9 percent of the radioactivity applied to the column was recovered in the combined leachate.

b. Environmental Chemistry, Fate and Transport

(1) Hydrolysis

Ancymidol was reported to be stable to hydrolysis in sterile aqueous buffer solutions at pH 5.0, 7.0 and 9.0 at 25°C for 30

days. The requirement for hydrolysis data has been satisfied. (MRID # 417235-03)

(2) Aerobic Soil Metabolism

Ancymidol, applied at 0.5 ppm, degraded with a half-life of 14.9 days in a sandy loam soil incubated at 25°C. Six unidentified degradates were detected at ≤ 0.01 ppm. Carbon dioxide increased to a maximum of 44.89 percent of the applied by 61 days post treatment and unextracted radioactivity increased to approximately 43 percent at 61 days post treatment. The aerobic soil metabolism data requirement has been fulfilled. (MRID #420530-01)

(3) Leaching and Adsorption/Desorption

Ancymidol was highly mobile with reported Freundlich K_{ads} values ranging from 0.11 (sandy soil) to 0.82 (clay loam soil). In a leaching soil column study, using a sandy loam soil, a total of 8.9 percent of the radioactivity applied to the column was recovered in the combined leachates during the 43 day leaching period. In the original study, the cation exchange capacity was not provided for one of the four soils and was requested. This requested information was provided and was listed as 30.0 meq/100 g. This study is now acceptable and the data requirements fulfilled for a leaching and adsorption/desorption study. (MRID #s 417235-02 and 419137-01)

2. Ecological Effects

The ecotoxicological data base is adequate to characterize the toxicity of ancymidol to nontarget terrestrial and aquatic organisms when used in greenhouses and on limited terrestrial non-food sites.

a. Non- Target Bird Data

In order to establish the toxicity of ancymidol to birds, the following tests may be required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). If the chemical is persistent in the environment, the Agency may also require two avian reproduction studies on mallard duck and bobwhite quail. In this case, due to the limited use sites, only one study is necessary to be evaluated under this topic, the avian

subacute dietary. The study summarized below is acceptable for use in hazard assessment.

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. No wild mammal testing is required for ancymidol.

(1) Avian Acute Toxicity

The requirement for avian acute oral toxicity has been waived because of the low expected exposure to birds. Ancymidol has very limited usage with use sites including greenhouses and bedding areas. In addition, ancymidol was found to be practically nontoxic in the dietary feeding study using bobwhite quail. For these reasons the Agency believes it unnecessary to require avian acute toxicity testing.

(2) Avian Subacute Dietary Toxicity

Table 2: Avian Subacute Dietary Toxicity Findings

Species	% Test Material (TGAI)	LC_{50}	Conclusions
Bobwhite quail	99.9	> 5192 ppm	practically nontoxic

These results show that ancymidol is practically nontoxic to birds with an LC_{50} > 5192 ppm. The guideline requirement for the avian subacute dietary LC_{50} study is fulfilled. (MRID # 416706-02)

(3) Avian Reproduction

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. No avian reproduction studies are required for the current use pattern of ancymidol.

b. Aquatic Data

(1) Freshwater Fish Toxicity

In order to establish the toxicity of a pesticide to freshwater fish, the data which may be required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish), and if persistent in the environment, the fish early life stage study would be required. Based on the limited use sites, only one study is necessary to be evaluated under this topic.

Table 3: Freshwater Fish Acute Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Rainbow trout	99.9	> 100 ppm	practically nontoxic

The results of the rainbow trout 96-hour acute toxicity study indicates that ancymidol is practically nontoxic to cold water fish. The guideline requirement for acute toxicity testing of the technical on freshwater fish is fulfilled. (MRID # 416706-03)

(2) Freshwater Invertebrate Toxicity

Testing which may be required to assess the hazard of a pesticide to freshwater aquatic invertebrates is a test using preferably first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. If the chemical is persistent in the environment, an aquatic invertebrate life cycle may be required.

Based on the limited use sites, only one study is necessary to be evaluated under this topic.

Table 4: Freshwater Invertebrate Toxicity Findings			
Species	**% Test Material (TGAI)**	**LC_{50}**	**Conclusions**
Daphnia magna	99.9	> 100 ppm	practically nontoxic

There is sufficient information to characterize ancymidol as practically nontoxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID #416706-01)

(3) Estuarine/Marine Toxicity

Estuarine studies were not required or submitted for evaluation under this topic since it is assumed that estuarine exposure is minimal.

c. Terrestrial, Semi-Aquatic, and Aquatic Plant Data

In order to establish the toxicity to aquatic plants, an aquatic plant growth study comprising of *Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and freshwater diatom may be required using the technical grade material. In order to establish the toxicity to terrestrial plants, the germination, seedling emergence and vegetative vigor studies may be required using the technical grade material.

Because of the limited acreage anticipated, and minor use sites to be treated (ornamental flowers and shrubs), only two non-target aquatic plant studies using *Selenastrum capricornutum and Lemna gibba* were required. No non-target terrestrial plant toxicity data were required (also because of limited acreage anticipated and minor use sites to be treated). The non-target aquatic plant studies are summarized below and are acceptable for use in hazard assessment.

Table 5: Nontarget Aquatic Plant Toxicity Findings

Species	% A.I.	EC_{50}
Lemna gibba	99.8	0.29 ppm
Selenastrum capricornutum	99.8	26.9 ppm

When considering the environmental fate and ecotoxicological data (Tier I and II effects) in combination with the application methods and rates, the Agency concludes that ancymidol will represent minimal risk to aquatic plant species. Both Tier I and II data requirements have been fulfilled. (MRID # 431405-01 and 431405-02)

d. Non-Target Insects Data

The minimum data required to establish the acute toxicity to honey bees is an acute contact LD_{50} study with the technical material. There is sufficient information to characterize ancymidol as practically nontoxic to bees. The guideline requirement is fulfilled. (MRID # 413405-04)

Table 6: Nontarget Insect Acute Contact Toxicity Findings			
Species	**% Test Material**	**LD_{50}**	**Conclusion**
Apis mellifera	99.8	> 100 μg/bee	practically nontoxic

e. Non-Target Mammal Data

The available mammalian data indicate that ancymidol is slightly toxic to small mammals on an acute basis. This study is discussed in the Human Health Assessment, III. B. 1. a. and presented below (MRID #424806-01)

Table 7: Mammalian Acute Oral Toxicity Findings		
Species	**LD_{50}(mg/kg)**	**Conclusion**
Rat (small mammal surrogate studies)	M = 1721 F = 1016	slightly toxic

3. Ecological Effects Risk Assessment

a. Risk to Terrestrial Animals

The maximum expected residues (ppm) on vegetation immediately after one application of 0.4356 lbs a.i./A (based on Hoerger and Kenaga, 1972) would be 104 ppm. This would be well below the toxicity hazard to birds of 5192 ppm and to mammals (LC_{50}= 4500 ppm in the diet of female rats, based on an oral LD_{50} of 1016 mg/kg and consumption of 31% of their weight in food). Minimal adverse effects are expected to birds and mammals from the use of ancymidol. It also appears likely that there will be minimal adverse effects to beneficial insects (LD_{50} >100 μg/bee) since it is practically nontoxic to honey bees.

b. Risk to Aquatic Animals

A direct application of 0.4356 lbs a.i./A into an acre pond six feet deep would have 27 parts per billion (ppb) of ancymidol. This is well below the toxicity hazard of 100 ppm for fish and aquatic invertebrates. Minimal adverse effects are expected to aquatic animals from the use of ancymidol.

c. Risk to Non-Target Plants

A direct application of 0.4356 lbs a.i./A into an acre pond six feet deep would have 27 parts per billion (ppb) of ancymidol. This is well below the toxicity hazard of 290 ppb for aquatic plants.

Since current application rates and usage are very low and this chemical is a growth regulator for height control of commercially produced ornamental plants and shrubs, very little exposure to terrestrial plants is anticipated. Therefore, minimal adverse effects are expected to terrestrial plants from the labeled use of ancymidol.

d. Risk to Endangered Species

Endangered species are not expected to be affected from the labeled use of ancymidol because of very limited exposure of the chemical to endangered species sites and, triggers for endangered species were not exceeded.

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 ancymidol as the active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing ancymidol. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of ancymidol, and lists the submitted studies that the Agency found acceptable.

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

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

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

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

B. Regulatory Position

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

Worker Protection Requirements

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Covered uses include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turfgrass, flowers, shrubs, ornamental, and seedlings). These include uses on plants, and on the soil or planting medium the plants are (or will be) grown in. Current use of ancymidol on commercially-grown ornamental plants falls within the scope of the WPS. There are no residential uses of ancymidol.

Handler (Mixer, Loader, Applicator) Personal Protective Equipment

The potential for exposure of handlers (mixer, loader, and applicator) to ancymidol exists. For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

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

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

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

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

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

There no are special toxicological concerns about ancymidol that warrant the establishment of active-ingredient-based PPE requirements. Therefore any PPE requirements will be established based on the acute toxicity of the end-use product.

Post-application Entry Restrictions

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

The 12 hour interim restricted entry interval (REI) must be imposed for all uses of ancymidol within the scope of the WPS, based on acute toxicity effects (Category III and IV).

Early Entry PPE-- personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one or two ways.

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based

on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

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

This minimum required early entry PPE appropriate to ancymidol consist of coveralls, chemical-resistant gloves, and shoes plus socks.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of ancymidol for the above eligible uses has been reviewed and determined to be substantially complete. However, the Agency has required the registrant to submit missing clinical observation and pathology information to upgrade the acute inhalation study in rats or to conduct a new study.

2. Labeling Requirements for Manufacturing-Use Products

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

"Only for formulation into a herbicide/plant growth regulator for the following use(s): (fill blank only with those uses that are being supported by MP registrants)."

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

(a) "this product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower

has complied with U.S. EPA submission requirements regarding the supported use(s).

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

The following label statements are required on all end-use products:

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

b. "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) for 12 hours."

c. "PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is coveralls, chemical-resistant gloves, and shoes plus socks."

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

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

SITE Application Type, Application Timing, Application Equipment — Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP									
Soil drench treatment., Containerized., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Cutting., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Plant bed., Sprayer.	SC/L	NA	.01 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			, C46
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: TERRESTRIAL NON-FOOD CROP									
Soil drench treatment., Containerized., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Cutting., Sprayer.	SC/L	NA	.01 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			, C46
Spray., Plant bed., Sprayer.	SC/L	NA	.01 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS			, C46

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Restr. Entry Interv (days)	: Restricted Entry Interval (days)
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

SC/L	: SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS

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

APPLICATION RATE

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

USE LIMITATIONS CODES

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case ANCYMIDOL covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to ANCYMIDOL in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

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

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Ancymidol

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	162638
61-2A	Start. Mat. & Mnfg. Process	ALL	162638
61-2B	Formation of Impurities	ALL	162638
62-1	Preliminary Analysis	ALL	162638
62-2	Certification of limits	ALL	162638
62-3	Analytical Method	ALL	162638
63-2	Color	ALL	162638
63-3	Physical State	ALL	162638
63-4	Odor	ALL	162638
63-5	Melting Point	ALL	162638
63-6	Boiling Point	ALL	INAPPLICABLE
63-7	Density	ALL	162638
63-8	Solubility	ALL	41723501
63-9	Vapor Pressure	ALL	41821201
63-10	Dissociation Constant	ALL	43140503
63-11	Octanol/Water Partition	ALL	162638
63-12	pH	ALL	162638
63-13	Stability	ALL	43216301

Data Supporting Guideline Requirements for the Reregistration of Ancymidol

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-2A	Acute Avian Diet/Quail	ALL	41670602
72-1C	Fish Toxicity - Rainbow Trout	ALL	41670603
72-2A	Invertebrate Toxicity	ALL	41670601
123-2	Aquatic Plant Growth	ALL	43140501, 43140502
141-1	Honey Bee Acute Contact	ALL	43140504
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	ALL	42480601
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	41937901
81-3	Acute Inhalation Toxicity - Rat	ALL	42130801
81-4	Primary Eye Irritation - Rabbit	ALL	41937902
81-5	Primary Dermal Irritation - Rabbit	ALL	41937901
81-6	Dermal Sensitization - Guinea Pig	ALL	41913702
82-2	21-Day Dermal - Rabbit/Rat	ALL	42121201
83-3A	Developmental Toxicity - Rat	ALL	42480602
84-2A	Gene Mutation (Ames Test)	ALL	47010508
84-2B	Structural Chromosomal Aberration	ALL	47010510
84-4	Other Genotoxic Effects	ALL	47010512

Data Supporting Guideline Requirements for the Reregistration of Ancymidol

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIROMENTAL FATE			
161-1	**Hydrolysis**	**ALL**	**41723503**
162-1	**Aerobic Soil**	**ALL**	**42053001**
163-1	**Leaching and Adsorption/desorption**	**ALL**	**41723502, 41913701**

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

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

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

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

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92 and 2070-0057 (expiration date 03-31-96). This Notice is divided into six sections and six Attachments. The Notice itself contains information and

instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific

data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item

number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

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

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

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of

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

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 6. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency

or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

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

1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

ANCYMIDOL DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Ancymidol. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Ancymidol Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Ancymidol, please contact Rieman Rhinehart at (703) 308-8584.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Veronica Dutch at (703) 308-8585.

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

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

RE: **ANCYMIDOL**

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

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

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

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

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is

committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

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

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

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

EPA'S DECISION NOT TO BATCH END-USE PRODUCTS CONTAINING ANCYMIDOL 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 end-use products containing the active ingredient ancymidol, the Agency considered batching end-use 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.).

However, batching of end-use products containing ancymidol was not possible after considering the available information described above. Table I lists all the end-use products containing ancymidol. These products were either considered not to be similar for purposes of acute toxicity or the Agency lacked sufficient information for decision making purposes. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product.

Registrants must generate all the required acute toxicological studies for each of their 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 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). Since the end-use products containing ancymidol could not be batched, registrants cannot choose from the remaining options: Cost sharing (Option 2) or Offers to Cost Share (Option 3).

Table I. End-Use Products Containing Ancymidol

EPA Reg. No.	% of ancymidol	Formulation Type
67690-2	0.0264	Soluble Concentrate
67690-5	98	Technical

INSERT LIST OF REGISTRANTS GENERATED BY THE PRODUCT SPECIFIC DCI IN PLACE OF THIS PAGE.

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

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

EPA	United States Environmental Protection Agency Washington, DC 20460 CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents related to ancymidol. 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 ancymidol 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. Ancymidol RED Fact Sheet

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

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