United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA 738-R-98-023 December 1998

Reregistration Eligibility Decision (RED)

Hydramethylnon

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 Pyridinone which includes the active ingredients Hydramethylnon. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998 contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

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

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 Cynthia Williams at (703) 308-8195. Address any questions on required generic data to the Special Review and Reregistration Division representative Dean Monos at (703) 308-8074.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

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

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

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

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-605-6000).

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

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

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

e. **Certification With Respect to Citation of Data and Data Matrix**. Complete and sign EPA forms 8570-34 and 8570-35 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

HYDRAMETHYLNON

LIST B

CASE 2585

TABLE OF CONTENTS

HYDRAMETHYLNON REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Steve Nako	Economic Analysis Branch
Doug Sutherland	Herbicide and Insecticide Branch
Richard Peacock	Science Information Analysis Branch

Environmental Fate and Effects Risk Assessment

Arnet Jones	Environmental Risk Branch 1
Gail Maske	Environmental Risk Branch 1
Ed Odenkirchen	Environmental Risk Branch 1
Mary Frankenberry	Environmental Risk Branch 1

Health Effects Risk Assessment

David Hrdy	Chemistry and Exposure Branch 2
Steve Knizer	Risk Characterization and Analysis Branch
Jack Arthur	Chemistry and Exposure Branch 2
Ken Dockter	Reregistration Branch 2
John Whalen	Toxicology Branch 2

Registration Support Risk Assessment

Richard Gebken	Insecticide Branch
Marion Johnson	Insecticide Branch

Risk Management

Tom Luminello	Reregistration Branch 3
Dean Monos	Reregistration Branch 3
Steve Morrill	Product Reregistration Branch
Cynthia Williams	Product Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ANSI	American National Standard Institute
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	GENeric Expected Environmental Concentration. A surface water computer model.
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
HPLC	High Pressure Liquid Chromatography. A type of residue analytical method
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
LOAEL	Lowest Observed Adverse Effect Level
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
µg/L	Micrograms per Liter

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.
MTD	Maximum Tolerated Dose
N/A	Not Applicable
NOAEL	No Observed Adverse Effect Level
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NPDES	National Pollutant Discharge Elimination System
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
POTW	Publicly Owned Treatment Works
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
ppt	Parts Per Trillion
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SCI-GROW	A new groundwater detection screening model for vulnerable sites
SLN	Special Local Need (Registrations Under Section 24 C of FIFRA)
Tc	Transfer coefficients. An exposure parameter.
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.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency (hereafter referred to as "the Agency") has completed its reregistration eligibility decision of the pesticide active ingredient tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone(3-(4-(trifluoromethyl)phenyl)-1-(2-(4-(trifluoromethyl)phenyl)ethenyl)-2-propenylidene)hydrazone, also known as hydramethylnon. This decision includes a comprehensive reassessment of the required data and the use patterns of all currently registered products.

Hydramethylnon is the active ingredient in the end use products *Amdro*, *Combat*, *Maxforce*, *Sensible*, and *Siege*, which are sold in the United States by the basic producer, American Cyanamid Company. These products are slow-acting toxicants used primarily to control ants in grasses and rangelands and other non-crop lands such as lawns, turf, and non-bearing nursery stock. Hydramethylnon is also registered for the control of household ant species and cockroaches in non-food use areas in and around domestic dwellings and commercial establishments. The registered granular formulation may be applied via broadcast or individual mound treatment for imported fire ant control. For the control of ants and cockroaches in dwellings, the impregnated formulation may be applied as a bait or as a crack and crevice treatment.

The product *Sensible* is a subterranean termiticide bait containing 0.3% hydramethylnon and is intended for use by professional pest control operators as supplemental or alternative treatments for controlling termites in and around buildings, decks, walls, fences, utility poles, or other wooden structures which can be attacked by termites. The baits may be placed in or around the structure to be protected, and may also be placed in the soil beneath concrete slabs, asphalt, paving stones, landscaping timbers, or other ground coverings.

On August 3, 1996, the President signed the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food Drug and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Among other things, the FQPA requires the Agency to consider the special sensitivity of infants and children to a pesticide, aggregate exposure of a pesticide from dietary, drinking water and non-occupational exposures, and cumulative effects from other compounds with a common mode of toxicity when establishing or reassessing tolerances.

Hydramethylnon has established tolerances from use on grasses in pastures and rangeland and the Agency is proposing to raise the tolerances. However, hydramethylnon is almost completely metabolized within the body of ruminants and there are no detectable residues in meat, milk, or meat byproducts. Therefore, per 40 CFR §180.6(a)(3), tolerances are not required for these commodities even though hydramethylnon is considered a food use pesticide for the purposes of reregistration and tolerance reassessment.

The Agency has not yet made a determination regarding the common mode/mechanism of toxicity of hydramethylnon and whether it is appropriate to consider exposure from hydramethylnon with other compounds in order to address potential cumulative effects. However, based on the negligible residues from the grass and rangeland use, the unlikelihood of residues in drinking water,

and minimal residential and occupational exposure, the Agency believes that the contribution of hydramethylnon exposure to the exposure of other chemicals with a common mode/mechanism of toxicity is likely to be minimal.

The Agency has also concluded that risk to freshwater and terrestrial nontarget organisms and water resources will be minimal since hydramethylnon degrades rapidly in water and is of low acute toxicity to terrestrial non-target species. Therefore, the insecticide uses of hydramethylnon have been determined to be eligible for reregistration. Certain confirmatory data are being required of the registrant including a reproductive test in birds.

Before reregistering the products containing hydramethylnon, the Agency is requiring that product specific data, confirmatory ecological effects and environmental fate 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 these products.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. There are five phases to that 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 reregistration requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (hereafter 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 ingredients 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.

The Food Quality Protection Act of 1996 (FQPA) amended both the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. Because hydramethylnon is an insecticide that has tolerances on grasses, it is considered a food use.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of hydramethylnon. The document consists of six sections. Section I is the introduction. Section II describes hydramethylnon, 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 hydramethylnon. Section V discusses the reregistration requirements for hydramethylnon. And, Section VI contains the Appendices which support this Reregistration Eligibility Decision document. 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:** Hydramethylnon (ANSI)
- **Chemical Name:** Tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone [3-[4-(trifluoromethyl)phenyl]-1-[2-[4-trifluoromethyl)phenyl]ethenyl]-2-propenylidene]hydrazone (CAS)
- **Chemical Family:** amidinohydrazone
- **CAS Registry Number:** 67485-29-4
- **OPP Chemical Code:** 118401
- **Empirical Formula:** $C_{25}H_{24}F_6N_4$
- **Trade and Other Names:** *Amdro, Combat, Maxforce, Sensible, Siege*
- **Basic Manufacturer:** American Cyanamid Company

B. Use Profile

Hydramethylnon is the active ingredient in the end use products, *Amdro, Combat, Maxforce*, *Sensible,* and *Siege* and sold in the United States by the basic producer, American Cyanamid, which developed the chemical compound in 1977. Hydramethylnon is a slow activating stomach toxicant registered for the control of ants in grasses and non-crop lands such as lawns, turfs, and non-bearing nursery stocks. It is also registered for the control of ants and cockroaches in non-food use areas in domestic dwellings and commercial establishments. Hydramethylnon is also registered for control of imported fire ants in areas of the southern United States where infestations occur. The registered granular formulation may be applied via broadcast or to individual mounds for ant control. The impregnated formulation may be applied as a bait to control household ants and cockroaches. Hydramethylnon is also used for control of subterranean termites in a bait package that is sold to and only for use by certified Pest Control Operators (PCOs).

Although the Agency no longer differentiates between pasture and rangeland (Chemistry Science Advisory Council meeting of September 17, 1997) tolerances are established for residues of the insecticide in or on grass and grass hay (pasture and rangeland

grasses) at 0.05 ppm (40 CFR § 180.395). Hydramethylnon is formulated as a bait for control of imported fire ants, harvester ants, and leafcutting ants in rangeland and pastures. The maximum registered application rate is 0.0176 lb ai/A.

The following is information on the registered ant, cockroach, and termite uses with an overview of use sites and application methods. A more detailed table describing the use parameters is found in Appendix A.

For **Hydramethylnon:**

Type of Pesticide: Insecticide

Use Sites:
Food: Rangeland grasses, hay and forage.

Nonfood: Indoor and outdoor residential and agricultural areas (including in and around homes, on lawns, in and around outside buildings/barns, right-of-ways/fencerows/hedgerows, and uncultivated areas), agricultural crops/soils, indoor and outdoor commercial/industrial or institutional premises and equipment (including food handling establishments), golf courses, ornamental sod farms, wood or wood structure treatments. Nonagricultural uncultivated areas (paths/patios, private roads/sidewalks), ornamental herbaceous plants, ornamental woody shrubs and vines, ornamental and/or shade trees. Forest trees. Sewage systems (bottom of manhole cover). Refuse/solid waste containers, commercial transportation facilities, aircraft or railroad cars (food/feed empty). Animal sleeping quarters/kennels, poultry houses, eating establishments non-food areas (non-food contact crack and crevice treatment only), hospitals/medical institutions non critical premises. Indoor residential, bathroom premises/hard surfaces, households/domestic dwellings.

Target Pests:
ANTS:
Acrobat, Argentine, Bigheaded, Black, Black Carpenter, Black Imported Fire, Carpenter, Cornfield, Crazy, Grease-Eating, False Honey, Field, Fire, Florida Carpenter, Ghost, Harvester, Honey, Leafcutting, Little black, Odorous house, Pavement, Pharoah, Pyramid, Red imported fire, Sweeteating,Thief, Texas leafcutting

Cockroaches: Brownbanded, Wood, Asian, German, American, Smoky Brown, Oriental

Termites: Termites, Subterranean Termites(Coptoermes, Heterotemes, Reticulatehermes)

Other insects: crickets, silverfish, Palmetto Bugs,Waterbugs

Mode of Action: Slow Acting Poison

C. Regulatory History

Hydramethylnon was first registered in the United States in August 1980 for use as an insecticide. There is one (1) technical registration and twenty eight (28) end-use products currently registered with the Agency.

When the accelerated reregistration program started after the revisions of FIFRA in 1988, the Agency issued the Phase 2 Data Call-In. The Phase 2 Data Call-In of 1989 focused largely on obtaining additional toxicology and environmental fate and effects data. In response, the registrant cited existing data and indicated that certain data requirements were inapplicable.

In April 1991, in response to the correspondence and data citations or submissions from American Cyanamid , the Agency issued the Phase 3 Data Call-In. This Call-In required new or additional product chemistry data; a reduced set of ecological effects and environmental fate data; toxicology; residue chemistry and worker exposure data to satisfy the basic reregistration database.

The comprehensive Outdoor Residential (Turf) and Agricultural Reentry Data Call-Ins were issued in March and October 1995, respectively. This Data Call-In required submission of studies to satisfy the following guideline requirements: foliar residue dissipation, dermal passive dosimetry exposure, and inhalation passive dosimetry exposure studies. American Cyanamid is a member of the task force created to submit these data.

American Cyanamid commited to amend their product labels to comply with State restrictions as outlined in Section V of this RED. The Agency has reviewed these labels and approved the amended labels on September 30, 1998. American Cyanamid commited to utilize these new labels on all product produced after December 1998.

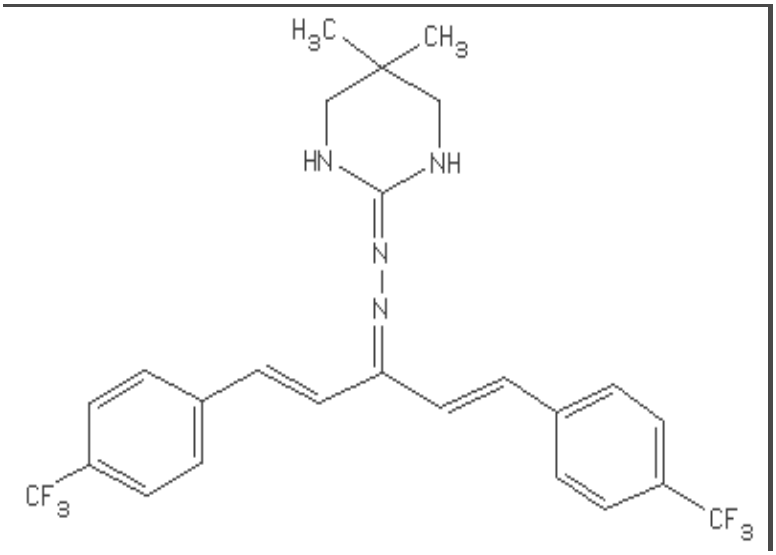
This RED will discuss and propose for reregistration only currently approved uses. Additional generic and product-specific data are required for hydramethylnon. In addition to submitting the required data, the registrants must certify that the suppliers of beginning chemical materials and the manufacturing processes for the hydramethylnon products have not changed since the last comprehensive product chemistry review. Alternatively, the registrants may elect to submit complete updated product chemistry data packages for their products. The Agency considers these data to be confirmatory and does not expect them to alter the risk eligibility decision for hydramethylnon presented herein. Appendix B includes all data requirements identified by the Agency to support reregistration.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

IDENTIFICATION OF ACTIVE INGREDIENT

Hydramethylnon:



Empirical Formula:	$C_{25}H_{24}F_6N_4$
Molecular Weight:	494.50
CAS Registry No.:	67485-29-4
Shaughnessy No.:	118401

Technical hydramethylnon is a yellow to tan crystalline solid with a characteristic vegetable oil odor and melting point of 189-191° C. It is insoluble in water, slightly soluble in alcohols, and soluble in acetone, chlorobenzene, and 1,2-dichloroethane. The vapor pressure is $2x10^{-8}$ mm of Hg @ 25^{O} C. The average partition coefficient (Kow) of hydramethylnon between n-octanol and water was determined to be 27,965 (Log Kow = 4.45) in MRID 416125-02.

There is one registered hydramethylnon manufacturing-use product (MP) as described in MRID 416125-01. The registrant is American Cyanamid Company and the product is a 95% technical formulation (241-270) called *Amdro Technical Insecticide.*

PRODUCT CHEMISTRY

All pertinent generic and product-specific product chemistry data requirements are satisfied for the American Cyanamid 95% manufacturing use (technical) product. New data, guideline requirement 830.7050 (ultra violet/visible absorption for the pure active ingredient)

is being called-in with this RED.

The generic product chemistry data base will be satisfied if the registrant either certifies suppliers of beginning materials and manufacturing process for the hydramethylnon TGAI have not changed since the last comprehensive product chemistry reviews or submits a complete updated product chemistry data package.

B. Human Health Assessment

1. Hazard Assessment

The toxicology studies reviewed in performing this human health risk assessment satisfy established guideline requirements for the registration of a food use pesticide. The hydramethylnon toxicology database is complete and all requirements are satisfied.

a. Acute Toxicity

The Agency has evaluated the acute toxicology data base. The observed effects are categorized from one to four, with toxicity category one being the most acutely toxic effect and category four being the least toxic. Table 1 summarizes the results of the acute toxicity studies for hydramethylnon:

TABLE 1: ACUTE TOXICITY OF HYDRAMETHYLNON TGAI

Guideline	Study Type Formulation	MRID	Results	Toxicity Category
81-1	Acute Oral, Rats 95% A.I.	41612503	LD_{50} = 817 mg/kg (M), 1502 mg/kg (F), 1146 mg/kg (combined) Clinical signs included decreased activity, diuresis, anorexia, ataxia, epistaxis, chromo dacryorrhea and salivation.	III
81-2	Acute Dermal, Rabbits 95% A.I.	41612504	LD_{50} >2000 mg/kg (limit test) There was no evidence of toxicity.	III
81-3	Acute Inhalation, Rats 98.2% A.I.	42871101	2.9 mg/L (combined); 4-hour analytical, whole-body exposure; Clinical signs included labored breathing, eye closure, decreased activity, rales, excessive salivation, yellow material on the fur, and decreased weight gain.	IV
81-4	Primary Eye Irritation, Rabbits 95% A.I.	41612505	Moderate corneal irritant; reversed in ≤7 days Corneal opacity and conjunctival redness, chemosis, and discharge reversed within 7 days. Hydramethylnon is a moderate irritant.	III
81-5	Primary Skin Irritation, Rabbits 95% A.I.	41612506	No irritation, there was no evidence of dermal irritation or systemic toxicity.	IV
81-6	Dermal Sensitization, Guinea Pigs 92% & 3.2% A.I.	00101560	Not a sensitizer.	

b. Subchronic Toxicity

In a 90 day feeding study in rats, MRID 00032641, groups of 20 male and 20 female Sprague-Dawley rats were dosed with hydramethylnon in their feed at 0, 50, 100, 200, or 400 ppm (equivalent to 0, 2.5, 5.0, 10.0 or 20.0 mg/kg/day). Due to significant decreases in body weight gain and food consumption during the first two weeks of the study at the highest dose (400 ppm, 20 mg/kg/day), this dose level was reduced to 25 ppm (1.25 mg/kg/day) on study day 15. Thus, the dose levels tested were 0, 25, 50, 100, or 200 ppm (0, 1.25, 2.5, 5.0, or 10.0 mg/kg/day).

No compound-related clinical signs were observed in any rats. On study day 68, a 50 ppm male was sacrificed moribund, and a 200 ppm (10.0 mg/kg/day) female died. The 200 ppm female had a blood urea nitrogen (BUN) value 4-fold higher than that of the controls on day 45. Histopathologic evaluation of this female revealed nephrocalcinosis and hydronephrosis. The food consumption and body

weight changes in the 400/25 ppm (equivalent to 20.0/1.25 mg/kg/day) group were skewed by the fact that they were initially dosed at 400 ppm for two weeks. Their feed consumption was decreased 27-45% during the first 2 weeks, but soon approached, and then exceeded, control levels. Their body weights were as much as 39% and 28% lower than control levels for the males and females, respectively, during the first weeks of study, with a gradual improvement thereafter.

Compared to controls, food consumption in the 200 ppm (10.0 mg/kg/day) group was reduced as much as 20% in the males and 19% in the females during the first weeks of the study, with improvement as the study progressed. Body weights were as much as 15% lower in males and 13% lower in females. Food consumption and body weights were normal in the 50 and 100 ppm (2.5 and 5.0 mg/kg/day) groups. There were no significant group clinical pathology anomalies. The only dose-related organ weight anomalies were in the testes. Compared to the controls, absolute testicular weights in the 400/25, 50, 100, or 200 ppm males (equivalent to 20.0/1.25, 2.5, 5.0 or 10.0 mg/kg/day) were decreased 34%, 11%, 34%, or 63%. The corresponding relative testicular weight losses were 31%, 5%, 32%, and 56%. The two weeks of dosing at 400 ppm had an effect on the testes in the "low" dose group. There were no gross lesions in any rats. Testicular atrophy incidence in the 0, 400/25, 50, 100, or 200 ppm males (equivalent to 0, 20.0/1.25, 2.5, 5.0 or 10.0 mg/kg/day) was 0/20, 5/20, 1/20, 5/20, or 20/20, respectively. The single incidence of atrophy in the 50 ppm (2.5 mg/kg/day) male was congenital (present before treatment). No other histopathologic lesions were found. The NOAEL was 50 ppm (2.5 mg/kg/day) and the LOAEL was 100 ppm (5.0 mg/kg/day) based on small soft testes, decreased testicular weights, and testicular atrophy in males, (MRID 00032641). This study is classified as acceptable and satisfies guideline requirement 82-1(a) for a 90-day feeding study in rodents.

In a subchronic toxicity study, MRID 00061794, groups of 4 male and 4 female beagles received gelatin capsules containing hydramethylnon at doses of 0, 3.0, 6.0, or 12.0 mg/kg/day for 91 days. None of the control or low-dose dogs died, but 3 males and 3 females in the mid-dose died or were sacrificed moribund between days 27 and 75, and all high-dose dogs were sacrificed moribund between days 27 and 53. The mid and high-dose dogs began refusing their feed after week 2. During the third week, the dry feed was replaced with canned meat in the mid and high-dose groups. Decreased food consumption was most pronounced in females. Body weights in the low, mid, and high-dose groups were decreased as much as 11%, 51%, and 34% in males; and 9%, 42%, and 37% in the females (body weight decreases were greatest in the mid-dose dogs because they survived longer than the high-dose dogs).

At month 2, serum glutamic pyruvic transaminase (SGPT) was increased 4 to 8-fold in the three surviving mid-dose males and 4-fold in 2 of the mid-dose

females, compared to controls. There were no other clinical pathology anomalies. All mid and high-dose dogs were cachectic at necropsy. Compared to controls, the increase in absolute liver weights in the low-dose was 13% in males and 5 % in females. Increase in relative liver weights in the low-dose was 29% in males and 10% in females. Organ weights were not presented for the mid and high-dose dogs. Considering the small changes in organ weight and the absence of confirmatory clinical pathology and histopathology, these weight changes are not considered biologically significant. Microscopic evaluation revealed wasting of muscle and subcutaneous fat, and testicular atrophy in the mid and high-dose dogs, but normal tissues in the controls and low-dose dogs.

The 6 mg/kg/day dose caused lethality, as well as decreased food consumption and body weight gain, increased SGPT, cachexia, wasting of muscle and subcutaneous fat, and testicular atrophy. The LOAEL was 3 mg/kg/day (the lowest does tested) based on decreased food consumption and body weight gain; a NOAEL was not established. This study is classified as acceptable and satisfies guideline requirement 82-1(b) for a 90-day feeding study in non-rodents.

In a 21-day dermal toxicity study in rabbits, MRID 00101559, groups of 10 male and 10 female New Zealand White rabbits received a total of 15 repeated dermal applications of hydramethylnon at doses of 0 (control), 10, 50, or 250 mg/kg/day, 6 hours/day, 5 days/week over a three week period. The occluded doses were on the clipped skin of the dorsal trunk. The skin of half of each group was abraded prior to treatment.

A 10 mg/kg/day male died on study day 12 of unknown causes. Gross skin lesions, which were seen in the control and treated rabbits, included thickening, crusting, matting, and reddening. Food consumption was depressed as much as 38% and 45% in the high-dose males and females, compared to controls. The high-dose males and females weighed as much as 8% and 9% less than the controls. The platelet count in the high-dose females at termination was 54% less than the control count. Absolute organ weight changes observed in the high-dose male and female rabbits included decreased heart weights of 12% and 16% and increased liver weights of 12% and 7%, respectively. Relative organ weight changes observed in the high-dose male and female rabbits included decreased heart weights of 4% and 8% and increased liver weights of 21% and 17%, respectively. There were no corresponding clinical chemistry or histopathologic findings to suggest damage to either of these organs.

Skin lesions observed in the control and treated rabbits included diffuse acanthosis, hyperkeratosis, sloughing of superficial epidermis, acantholysis, inflammatory cell infiltration in the dermis, edema, and acute inflammation of the dermis. These lesions were most frequent in the control rabbits, so a dose-

relationship could not be defined.

Toxicity observed at the highest dose tested (250 mg/kg/day) included decreased food consumption in males and females as well as thrombocytopenia (a persistent decrease in the number of blood platelets that is usually associated with hemorrhagic conditions) in females. Although thrombocytopenia was observed at this dose (250 mg/kg/day), it was not considered to be an adverse, or biologically significant effect because it was seen in the presence of skin irritation in animals having abraded skins. In addition, alterations in hematological parameters are often seen in dermal toxicity studies in the presence of skin irritation. Therefore, the 250 mg/kg/day (the highest dos tested), in spite of the presence of this effect, is considered to be the NOAEL for dermal and systemic toxicity; a LOAEL was not established. MRID 00101559 is classified as acceptable and satisfies guideline requirement 82-2 for a 21-dermal toxicity study in rats.

c. Chronic Toxicity and Carcinogenicity

In a 6-month study, MRID 00035529, groups of 4 male and 4 female beagles dogs received gelatin capsules containing hydramethylnon at doses of 0, 0.33, 1.0, or 3.0 mg/kg/day for 26 weeks. The control group received 120 mg/kg/day of lactose. No dogs died. Dose-related clinical signs included an increase in the incidence of soft stools, mucoid stools, and diarrhea in the high-dose dogs. A high-dose male was removed from the study due to anorexia between study days 42 and 98, and day 120 to termination. Food consumption, body weights, clinical pathology, ophthalmologic examinations, and histopathology were normal. Half of the high-dose dogs had yellow-tinged body fat, but this was not considered to be a toxic effect. The only other dose-related anomalies were increases in absolute and relative liver weights in the high-dose dogs of both sexes. Compared to controls, the increases in absolute liver weights at the mid and high-dose were 7% and 31% in males, and 4% and 11% in females. Compared to controls, the increases in relative liver weights at the mid and high-dose were 2% and 29% in males, and 7% and 16% in females. In the absence of elevated liver enzymes and histopathology, these elevated liver weights are considered to be the compensatory response of healthy livers. The NOAEL was 1.0 mg/kg/day and the LOAEL was 3.0 mg/kg/day, based on increased incidence of soft stools, mucoid stools, and diarrhea. This study is not a guideline requirement but does provide useful scientific data.

In a chronic toxicity/carcinogenicity study, MRID 00101565, groups of 50 male and 50 female Charles River CD rats were fed diets containing hydramethylnon at dose levels of 0, 25, 50, 100, or 200 ppm (0, 1.2, 2.4, 4.9, or 10.0 mg/kg/day in males, and 0, 1.5, 3.0, 6.2, or 12.1 mg/kg/day in females, respectively based on food consumption) for two years. No compound-related clinical signs were observed.

Survival was not affected by treatment. Body weights in the males were as much as 17% less than the controls at 200 ppm, and 5% at 100 ppm. Body weights in the females were as much as 42% less than the controls at 200 ppm, and 22% at 100 ppm. Body weights were comparable in the other groups. Food consumption was reduced an average of 7% in the 200 ppm males, and 16% in the 200 ppm females. The other groups were comparable.

There were no biologically significant clinical pathology anomalies, yet there were dose-related organ weight anomalies. Absolute testicular weights were reduced 59% in the 200 ppm males, and 27% in the 100 ppm males. Relative testicular weights were reduced 51% in the 200 ppm males and 22% in the 100 ppm males. Testicular weights were comparable in the lower doses. The only compound-related gross lesions were small and soft testes in the 100 ppm (19/50) and 200 ppm (42/50) males. Histopathology revealed testicular atrophy in these groups (23/47 and 46/50, respectively). Glomerulonephrosis was greater in the treated males and females than in the controls, but there was no dose-response relationship.

On May 28, 1998, the Agency's Cancer Peer Review Committee concluded that the dose levels of 100 ppm in males, and 50 ppm in females were adequate to assess the carcinogenic potential of hydramethylnon in rats. This conclusion was based on significant decreases in body weight at higher doses. The statistically significant increases in tumors observed in the uterus (adenomatous polyps) and adrenals (medullary adenomas) were not considered to be biologically significant since they were seen at excessive doses (i.e., at 200 ppm).

Under the conditions of this study, the NOAEL was 50 ppm (2.4 mg/kg/day in males, 3.0 mg/kg/day in females), and the LOAEL was 100 ppm (4.9 mg/kg/day in males, 6.2 mg/kg/day in females) based on small, soft testes, decreased testicular weights, and testicular atrophy in males; and decreased body weight gain in females. This study is classified as acceptable and satisfies guideline requirement 83-5 for a chronic feeding/carcinogenicity study in rodents.

In a carcinogenicity study, MRID 00101563, groups of 50 male and 50 female Charles River CD-1 mice received diets containing hydramethylnon at dose levels of 0, 25, 50, 100, or 200 ppm (0, 3.57, 6.93, 14.2, or 28.6 mg/kg/day in males, and 0, 4.45, 6.87, 17.3, or 33.1 mg/kg/day in females, based on food consumption) for 18 months. The 200 ppm males and females were sacrificed after 55 weeks because of high mortality. Survival after 18 months at the 50 and 100 ppm doses was 72% and 46% in males, and 66% and 46% in females (compared to control survival of 86% in males and 76% in females).

Body weights in the 100 and 200 ppm groups were as much as 13% and 23% less than the controls in males, and as much as 6% and 19% less than the

controls in females, respectively. Food consumption was reduced an average of 14% in the 200 ppm males, and 20% in the 200 ppm females. The other groups were comparable. There were no compound-related gross lesions. Histopathologic findings of testicular degeneration in the 50, 100, and 200 ppm males displayed a dose-related pattern of incidence and severity, and included hypospermia, interstitial cell hyperplasia of Leydig cells, and germinal cell degeneration. Dose-related amyloidosis was seen in the kidneys of the 50 and 100 ppm females.

The Cancer Peer Review Committee (CPRC), based on mortality and toxicity, concluded that a dose between 50 and 100 ppm would be adequate to assess the carcinogenic potential of hydramethylon in both sexes of mice. The Committee did not consider the hyperplasia and neoplasia observed in the lungs of males to be toxicologically/biologically significant because they were seen at an excessive dose (i.e., at 200 ppm). The CPRC, however, did consider the statistically significant increases in lung adenomas at 50 and 100 ppm (27% and 27%, respectively) and combined lung adenomas/carcinomas at 25, 50, and 100 ppm observed in females to be treatment-related and classified hydramethylnon to be carcinogenic in female mice. For chronic toxicity, in males, the NOAEL was 25 ppm (3.57 mg/kg/day) and the LOAEL was 50 ppm (6.93 mg/kg/day) based on testicular lesions. In females, the LOAEL was 25 ppm (4.45 mg/kg/day), based on combined lung adenomas and carcinomas; a NOAEL was not established in females. This study is classified as acceptable and satisfies guideline requirement 83-2 for a carcinogenicity study in rodents.

d. Developmental Toxicity

In a prenatal developmental toxicity study, MRID 00061790, groups of 26 pregnant female Sprague-Dawley rats were given oral administration of hydramethylnon at doses of 0, 3, 10, or 30 mg/kg/day on gestation days 6-15. The vehicle controls were dosed with corn oil. The dams were sacrificed and examined on gestation day 20.

There were two maternal deaths in the high-dose, presumably due to intubation error. The mid-dose dams weighed as much as 8% less than the controls, and the high-dose dams weighed as much as 16% less than the controls. Body weight gain during the post-dosing interval (gestation days 15-20) was comparable in all groups. There was an increased incidence of nasal mucus, alopecia, soft stool, and staining of the ano-genital fur in the high-dose dams.

The mean number of corpora lutea and implantation sites was comparable in all groups. The mid-dose dams had slightly more resorption than the other groups. This is not considered a compound-related effect because the resorption rate was within historical limits, and because the high-dose and control dams had

nearly the same resorption rates. At necropsy, several of the mid and high-dose dams had yellowish discoloration of the fat, and several high-dose dams had small thymus.

Mean high-dose fetal weights were reduced 10% for both sexes, but the other groups were comparable. There was no dose-related effect on sex ratios, external malformations, visceral malformations, or skeletal malformations. Skeletal variations were generally comparable in all groups, although the high-dose fetuses had an increase in the incidence of rudimentary structures and \incompletely ossified supraoccipitals.

For maternal toxicity, the NOAEL was 3 mg/kg/day and the LOAEL was 10 mg/kg/day, based on an 8% decrease in body weight and yellowish discoloration of the fat. At 30 mg/kg/day, a 16% decrease in maternal body weight, increased incidence of clinical signs (nasal mucus, alopecia, soft stool, staining of the ano-genital fur), yellowish discoloration of the fat, and small thymus were observed. For developmental toxicity, the NOAEL was 10 mg/kg/day and the LOAEL was 30 mg/kg/day, based on decreased mean fetal weights, increased incidence of rudimentary structures, and increased incidence of incompletely ossified supraoccipital. This study is classified as acceptable and satisfies guideline requirement 83-3(a) for a developmental toxicity study in rats.

In a developmental toxicity study, MRID 00101558, groups of 16 impregnated New Zealand rabbits received oral administration of hydramethylnon at doses of 0, 5, 10, or 20 mg/kg/day on gestation days 6-18. The vehicle controls were dosed with corn oil. The does were sacrificed and examined on gestation day 29.

Two high-dose does died during the post-treatment period of undetermined causes. Six does aborted, 3 each in the mid and high-dose groups. Dose-related clinical signs seen at the mid and high-dose included soft stool, reduced amount of stool, and ano-genital matting and discharge. The high-dose body weights were as much as 12% less than the controls (gestation day 24). The low and mid-dose body weights were comparable, though slightly less than the controls.

The mean number of implantations, corpora lutea, post-implantation loss, early or late resorptions, viable fetuses, and sex distribution were comparable in all groups. The fetal weights in the low, mid, and high-dose groups were 8%, 16%, and 25% lower than the controls; the low-dose was within historical limits. There were no biologically significant external, visceral, or skeletal malformations, or variations.

For maternal toxicity, the LOAEL was 5 mg/kg/day based upon body weight

loss, soft stool, and reduced amount of stool; a maternal NOAEL was not established. However, the incidence of soft stool, reduced amount of stool, and body weight loss of less than 6%, at the low-dose, were not considered adverse. At 10 mg/kg/day, ano-genital matting and discharge was also observed, and the same findings, with increased severity, were observed at the 20 mg/kg/day dose level. For developmental toxicity, the NOAEL was 5 mg/kg/day and the LOAEL was 10 mg/kg/day, based upon decreased fetal weight (16%) mg/kg/day. The decreased fetal weight observed at the 5 mg/kg/day was not considered to be treatment-related since the incidences were within historical control ranges . This study is classified as acceptable and satisfies guideline requirement 83-3(b) for a developmental toxicity study in rabbits.

e. Reproductive Toxicity

In two-generation reproduction study, MRID 43741501, 98.2% hydramethylnon was administered to Sprague-Dawley rats in their diet at 0, 2, 50, or 75 ppm (0, 1.66, 3.32 or 5.05 mg/kg/day for males and 0, 2.02, 4.13, or 6.19 mg/kg/day for females) for two successive generations. For reproductive toxicity, the NOAEL was 25 ppm (1.66 mg/kg/day for males) and the LOAEL was 50 ppm (3.32 mg/kg/day for males), based upon histological findings in the testes (degeneration of the germinal epithelium and aspermia) and the epididymides (increased cellular debris); also at 75 ppm (5.05 mg/kg/day in males), reproductive performance of the males was decreased, with longer precostal intervals, lower pregnancy rates, reduced gestation weight gain for females, and smaller litters.

For offspring toxicity, the NOAEL was 75 ppm (highest dose tested); a LOAEL was not established. This study is classified as acceptable and satisfies guideline requirement 83-4 for a two-generation reproduction study in rats.

f. Mutagenicity

There are five acceptable mutagenicity (84-2) studies of hydramethylnon. The findings of adverse effects on spermatocyte and/or spermatogonia in the dominant lethal assay are consistent with the results of the 2-generation reproduction study in rats showing that hydramethylnon is a reproductive toxicant which appears to specifically target the germinal cells and/or tissues in the testes. Based on the available toxicology data, there is no concern for mutagenicity at this time. The following studies were evaluated:

Gene Mutations: In a *Salmonella typhimurium/Escherichia coli* reverse gene mutation assay, MRID 42132701, both the spot test assay and the plate incorporation assay are negative up to an insoluble dose (1000 µg/plate with or without S9 activation) in *S.typhimurium* TA1535, TA1537, TA98 and TA100 and

E. coli WP2 uvrA.

In a *Schizosaccharomyces pombe* P1 forward gene mutation assay, MRID 40407603, the test is negative up to the highest assayed levels (12.5 µg/mL -S9; 50 µg/mL +S9).

Chromosome Aberrations - Somatic Cells: The *in vitro* cytogenetic assay, MRID 40422401, in Chinese Hamster Ovary (CHO) cells is negative up to a cytotoxic dose (500 ng/mL -/+S9).

Chromosome Aberrations - Germinal Cells: The rat dominant lethal assay MRID 00035897, is negative in male Sprague-Dawley rats in which hydramethylnon was administered by gavage at doses of 3, 30, or 90 mg/kg/day for 5 days. By week 7 of study, 100% of the high-dose (90 mg/kg/day) males were infertile. Infertility of a few animals was also observed at the mid-dose (30 mg/kg/day). At the high dose, 50% of these infertile males recovered from this effect (two by week 11 of study and 3 more by week 17 of study), and at the mid-dose, all of the males recovered, within 12 weeks. There was no evidence of adverse effects on implantation data in the high-dose group (90 mg/kg/day) through mating week 5. At necropsy (week 17), 80% of the high-dose group had smaller testes and epididymides. There was, however, no indication of a dominant lethal effect at any dose. Overall, these findings suggest an adverse effect on spermatocyte and/or spermatogonia.

It is noted that the findings of the rat dominant lethal study, including the small testes and epididymides at the 90 mg/kg/day dose, are supported by other study results. Testicular atrophy and/or degeneration was also observed in the 3-month subchronic (MRID 00032641) and 2-year chronic feeding (MRIDs 00061768, 00101565, 00126106) studies in rats, the 18-month feeding studies in mice (MRIDs 00035526, 00101563, 40871801), and the 3-month subchronic study in dogs (MRID 00061794). Results of this dominant lethal study support the effects seen in the reproductive toxicity study.

Other Mutagenic Mechanisms: In a *Saccharomyces cerevisiae* D4 mitotic gene conversion assay, MRID 40407602, the test is negative up to the highest dose tested (25 µg/plate +/-S9).

The data shows that hydramethylnon is not genotoxic in microbial test systems or clastogenic in cultured mammalian cells and did not induce dominant lethality in male rat germinal cells. The mutagenicity studies are classified as acceptable and satisfy guideline requirements 84-2(a) and (b) and 84-4 for *in vivo* and *in vitro* studies.

g. Metabolism

In a metabolism study in rats, MRID 42343701, groups of male and female Sprague-Dawley rats were dosed by gavage with hydramethylnon labeled ^{14}C in either the phenyl or pyrimidinyl ring. Rats received either a single low-dose (3 mg/kg), a single high-dose (100 mg/kg), or 14 consecutive doses of 2 mg/kg/day unlabeled test material followed by a single 2 mg/kg dose with the ^{14}C in either ring. Urinary and fecal samples were collected over 7 days.

The majority of the administered dose of phenyl- or pyrimidinyl- ^{14}C-hydramethylnon was recovered in the feces (85-98%). Recovery in the urine was minimal (1-2% of the administered dose). There were no sex or dose-related differences in urinary or fecal elimination. Radiolabel retention in the tissues was somewhat greater in the females. Distribution of the residues retained by all tissues accounted for <10% of the administered dose, with most of the radiolabeled material accumulating in the carcass. Most of the radioactivity (94-99%) in the feces was unchanged parent compound. In contrast, the urine contained traces of parent compound and polar metabolites which may be benzoate, cinnamate, or pyrimidinone derivates. Polar metabolites in the tissue were probably ketone, pyrimidinone, cinnamate, and benzoate derivatives.

h. Neurotoxicity

Neurotoxicity studies are not required since hydramethylnon is neither an organophosphate nor is structurally related to compounds that are known to induce neurotoxicity.

i. Dermal Absorption

There are no acceptable dermal absorption data for the technical product. Dermal absorption studies are available with the formulated gel product.

In one study, MRID 42989101, Sprague-Dawley rats received dermal application of a gel formulation containing 2% a.i. (*Maxforce* Gel). The total dose absorbed after 10 hours was 0.414%). In an another study, MRID 43093901, Sprague-Dawley rats received dermal application of a gel formulation containing 2.16% a.i. (*Siege*). The total dose absorbed after 10 hours was 0.97%.

Based on the results of these two studies, the Toxicology Endpoint Selection Committee determined a dermal absorption factor of 1% for use in risk assessments.

j. Incident Data

There is no verified information available on human incidents related to use of hydramethylnon from any of the available data bases consulted by the Agency. There was a reported incident in 1998 involving the deaths of 17 chickens that may have been caused by hydramethylnon. Like other baits placed inside and outside homes, young children and pets are curious about them and tempted to handle or bite the baits. However, hydramethylnon's relatively low acute toxicity combined with the current voluntary use of child-resistant packaging reduces the hazard to a minimum.

k. Potential Risks to Infants and Children

Hydramethylnon is considered a food use pesticide yet, infants and children have little or no exposure to residues in milk, meat and meat byproducts. Currently, the terminal residue to be regulated in the milk, meat, and meat byproducts of ruminants is hydramethylnon *per se*. The Agency has determined that there is no reasonable expectation of finite hydramethylnon residues of concern in the milk, meat, and meat byproducts of ruminants [40 CFR §180.6(a)(3)] as a result of hydramethylnon use on pastures or rangeland grasses. Hydramethylnon has one non-food aquatic use site but since it rapidly hydrolyzes, drinking water exposure is not likely. Consumer use in residential settings is the greatest source of possible exposure to children, which as discussed above, is expected to be minimal.

2. Dose Response Assessment

a. Determination of Susceptibility to Infants and Children

The Reference Dose Committee made the following FQPA recommendations and conclusions:

The Agency has reviewed an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. There are no data gaps for the assessment of pre- and/or postnatal toxicity in rats or rabbits.

The data provided no indication of increased sensitivity in rats or rabbits to pre- and/or postnatal exposure to hydramethylnon. In the two-generation reproduction study in rats, no toxicity to the offspring was observed at any dietary level tested, while reproductive toxicity was produced in the parental animals at dietary levels as low as 3.32 mg/kg/day. In the prenatal developmental toxicity studies in rats and rabbits, gavage doses of hydramethylnon during the major period of organogenesis resulted in delays in fetal development (retardation in skeletal ossification and/or decreased fetal body weight). However, these effects were seen only at doses which were maternally toxic (as evidenced by body weight loss and

clinical signs of toxicity).

There is no evidence in the prenatal developmental toxicity studies in either rats or rabbits of alterations to central nervous system development, nor is there any indication of neurotoxicity in the other short or long-term oral studies in rats, mice, or dogs. This chemical is a male reproductive toxicant which appears to specifically target the germinal cells and/or tissues in the testes.

The data base for developmental and reproductive toxicity is largely complete. An assessment of these data did not reveal evidence of an increased sensitivity of perinatal animals to pre- and/or postnatal exposure to hydramethylnon. **Therefore, the 10x safety factor for protection of infants and children, as required by FQPA, is not warranted and has been removed.**

b. Toxicological Endpoints Selected for Risk Assessment

Acute Dietary

An acute dietary risk assessment is not required because studies indicate an insignificant toxicological result from acute exposure to hydramethylnon. In addition, no appropriate endpoint attributable to a single exposure (dose) could be ascertained from the available oral toxicity studies, as determined in the July 7, 1993, Toxicology Endpoint Selection document.

Chronic Reference Dose

The Reference Dose Committee recommended that a Reference Dose (RfD) for hydramethylnon be established on the basis of the chronic toxicity study in dogs, MRID 00035529, and the two generation reproduction study in rats MRID 43741501.

The NOAEL for systemic toxicity in the chronic dog study was 1 mg/kg/day based on an increased incidence of soft stool, mucoid stool, and diarrhea observed at 3 mg/kg/day. The NOAEL for reproductive toxicity in the 2-generation rat reproduction study was 25 ppm (1.66 mg/kg/day for males), and the reproductive LOAEL was 50 ppm (3.32 mg/kg/day for males), based upon histological findings in the testes (degeneration of the germinal epithelium and aspermia) and the epididymides (increased cellular debris). At 75 ppm (5.05 mg/kg/day in males), reproductive performance of the males was decreased, with longer precoital intervals; and, there were lower pregnancy rates, reduced gestation weight gain for females, and there were smaller litters.

An uncertainty factor of 100 was applied to account for interspecies

extrapolation (10) and intra species variability (10). On this basis the RfD was calculated to be 0.01 mg/kg/day.

Short Term Occupational and Residential (1-7 days)

The NOAEL established in the 21-day dermal toxicity study in rabbits, MRID 00101559, will be used for this risk assessment.

A NOAEL of 250 mg/kg/day was established, based on nonadverse decreased food consumption in males and females, and thrombocytopenia in females. Although thrombocytopenia was observed at this dose (250 mg/kg/day), it was not considered to be an adverse, or biologically significant, effect because it was seen in the presence of skin irritation in animals having abraded skins. In addition, alterations in hematological parameters are often seen in dermal toxicity studies in the presence of skin irritation. Therefore, this dose, in spite of the presence of this effect, is considered to be the NOAEL.

Intermediate Term Occupational and Residential (1 week to several months)

The NOAEL of 250 mg/kg/day in a 21-day dermal toxicity study in rabbits, MRID 00101559, will be used for this risk assessment. Effects observed at the NOAEL included decreased food consumption in males and females, and thrombocytopenia in females; however, this latter effectis not considered to be adverse or biologically significant as previously stated.

Long-Term Occupational and Residential (several months to lifetime)

Based on the current use pattern the Agency does not believe chronic exposure is likely. However, the Reference Dose Committee recommended the use of a NOAEL of 1 mg/kg/day in the event that there is chronic exposure. The use of a dermal absorption factor of 1% is necessary for this assessment since an oral NOAEL was selected. This NOAEL was used to derive the Reference Dose.

Dermal Absorption

There are no dermal absorption data for the technical product. As discussed earlier, a dermal absorption of 1% was estimated based on the results of two dermal absorption studies with a formulation product.

Inhalation Exposure (any time period)

The acute 4-hour whole-body LC_{50} in rats is 2.9 mg/L for the combined sexes (Table 1). This exceeds the limit concentration of 2 mg/L, and places

hydramethylnon into Toxicity Category IV. Therefore, a risk assessment for the inhalation route of exposure is not required. In addition, based on the low toxicity, minimal use (maximum of 4 applications per year) and the methods of application, there is negligible concern for potential exposure. Therefore an inhalation risk assessment.

Classification of Carcinogenic Potential

The Cancer Peer Review Committee determined that hydramethylnon should be classified as a Group C carcinogen, a possible human carcinogen, and recommended that, for the purpose of risk characterization, the Reference Dose approach should be used for quantification of human risk. This classification was based upon statistically significant increases in lung adenomas at 50 and 100 ppm (27% and 27%, respectively) and combined lung adenomas/carcinomas at 25, 50, and 100 ppm (32%, 40%, and 35%, respectively) in female mice. The MTD is between 50 ppm and 100 ppm in both sexes of mice.

Based on the Agency's Cancer Peer Review Committee recommendation that the RfD approach be used, a quantitative dietary cancer risk assessment was not performed. Dietary risk concerns due to long-term consumption of hydramethylnon residues are adequately addressed by the Dietary Risk Evaluation System (DRES) chronic exposure analysis using the RfD.

3. Dietary Exposure, Risk Assessment and Characterization

a. Dietary Exposure from Food Sources

GLN 860.1200: Directions for Use

The reregistration of hydramethylnon in the United States is being supported by American Cyanamid Company. An Agency database search identified five end-use products (EPs) with food/feed uses registered to American Cyanamid Company. The sole hydramethylnon food site being supported for reregistration is use on grass in pastures and rangelands. The application of hydramethylnon as a bait in domestic dwellings and commercial establishments has been determined to be a non-food use.

The conclusions regarding the reregistration eligibility decision of hydramethylnon food/feed uses are based on the use patterns registered by the basic producer/technical registrant, American Cyanamid Company.

GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are fulfilled. An acceptable study, MRID 437445-01, depicting the qualitative nature of the residue in grasses has been submitted and evaluated. The Agency's Metabolism Committee has determined that hydramethylnon is the terminal residue (the final residue of concern) to be regulated in/on plants. The current tolerance values for grasses must be amended due to the zero day pre-grazing interval because hydramethylnon is used on grasses for forage or hay.

GLN 860.1300: Nature of the Residue - Animals

The reregistration requirements for animal metabolism are fulfilled. An acceptable ruminant metabolism study, MRID 428711-02, has been submitted and evaluated. The terminal residue to be regulated in the milk, meat, and meat byproducts of ruminants is hydramethylnon *per se*. The Metabolism Committee previously determined that there is no reasonable expectation of finite hydramethylnon residues of concern in the milk, meat, and meat byproducts of ruminants [40 CFR §180.6(a)(3)] as a result of hydramethylnon use on grasses. Therefore, tolerances for these animal commodities need not be established. A poultry metabolism study is not required at this time because there are no poultry feed items associated with grasses.

GLN 860.1340: Residue Analytical Method

The reregistration requirements for residue analytical methods are fulfilled. Adequate methodology determined in MRIDs 00034020, 00034021 and 00034025, is available for the enforcement of tolerances for residues of hydramethylnon *per se* in/on plant commodities.

The Pesticide Analytical Manual (PAM) Vol. II lists a gas liquid chromatography method with electron capture detection (GLC/ECD) for the analysis of hydramethylnon residues in/on grass commodities (Pesticide Reg. Sec 180.395). The PAM Vol. II method, designated as Method I, has a detection limit of 0.05 ppm. The Agency has forwarded to FDA a confirmatory high pressure liquid chromatography (HPLC) method (American Cyanamid Method M2334) for inclusion in PAM Vol. II as a lettered method. Method M2334 determines residues of hydramethylnon *per se* in/on grass commodities, and has a detection limit of 0.05 ppm. Method M2334 has undergone successful independent laboratory validation.

GLN 860.1340: Residue Analytical Method-Animals

Tolerances for animal commodities are not needed at this time. Therefore, no analytical methodology is required for the determination of hydramethylnon residues to be regulated in animal commodities.

GLN 860.1360: Multi-residue Method

The FDA PESTDATA database of January 1994 (PAM Volume I, Appendix I) indicates that recovery of hydramethylnon using multi-residue methods is unlikely.

GLN 860.1380: Storage Stability

The reregistration requirements for storage stability data are fulfilled. The available storage stability data, MRIDs 428711-02, 434852-01, 436367-02, 437445-01, indicate that fortified residues of hydramethylnon *per se* are stable in/on grass forage and hay for up to 24 months of frozen storage. Field trial samples of grass forage and hay were stored frozen for up to 19 months.

GLN 860.1400: Water, Fish, and Irrigated Crops

Hydramethylnon is presently not registered for direct use on potable water and aquatic food and feed crops. Therefore, residue chemistry data are not required under these guideline topics.

GLN 860.1460: Food-Handling

The Agency has determined that the registered crack and crevice treatment of hydramethylnon for the control of cockroaches in residential settings and food-handling establishments is a non-food use. Therefore, data depicting magnitude of the residue in food-handling establishments are not required for reregistration purposes. Hydramethylnon is relatively non-volatile and is used only in enclosed bait stations, therefore, the likelihood of residue transfer to food is low.

GLN 860.1480: Meat, Milk, Poultry, and Eggs

The reregistration requirements for data on magnitude of the residue in animals are fulfilled. An acceptable cattle feeding study is available. However, the Agency's Metabolism Committee has determined that from the currently registered uses there are no reasonable expectations of finite hydramethylnon residues of concern in milk, meat, and meat byproducts of ruminants [40 CFR §180.6(a)(3)]. Therefore, tolerances for these animal commodities need not be established. A poultry feeding study is not required at this time because there are no poultry feed

items associated with grasses.

GLN 860.1500: Crop Field Trials

Adequate grass field trial data for the areas infested by the imported fire ants (Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia) have been submitted and evaluated. Use on pastures and rangelands are permitted in these states only. These data indicate that residues of hydramethylnon *per se* will exceed the established tolerance following applications of a representative granular formulation according to the parameters of use patterns which the registrant wishes to support. Therefore, the tolerance levels are being increased. The reregistration requirements for magnitude of the residue in/on grass forage and hay will be considered fulfilled pending compliance by the registrant with the recommended label amendments and tolerance proposals.

GLN 860.1520: Processed Food/Feed

Table 1, "Raw Agricultural and Processed Commodities and Feedstuffs Derived From Crops," of OPPTS GLN 860.1000, states that there are no processed commodities associated with grasses. Therefore, hydramethylnon processing data are not required for reregistration. There is no need for an anticipated residue calculation at this time.

GLNs 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

Grasses are not typically rotated. Therefore, no residue chemistry data are required under these guideline topics.

b. Dietary Exposure from Drinking Water

The Agency has considered registered uses and the available data on hydramethylnon persistence and mobility. The Agency has determined, through a qualitative risk assessment, that hydramethylnon will not significantly impact water resources through labeled uses. In addition, hydramethylnon's physical and chemical characteristics (i.e., insoluble in water, volatile, etc.) are such that it is unlikely to impact water resources. In light of these findings, the Agency does not believe that hydramethylnon poses a threat to human health through drinking water and that a quantitative drinking water risk assessment is not warranted for this pesticide.

c. Dietary Risk Assessment and Characterization

The food crop use which is being supported for reregistration is grasses rangeland forage and hay. These uses have all been designated as food uses, based on the application methods and OPPTS policy GLN 180.1000, and have tolerances.

Since these crops are not direct human foods and no dietary consumption is expected there is no likelihood of residues of hydramethylnon being found through transfer of residues on grasses to meat and milk. Therefore, a dietary risk assessment is not necessary.

4. Occupational and Residential Exposure and Risk Assessment and Characterization

a. Occupational and Residential Exposure

Summary of Use Patterns and Formulations

Formulation: Hydramethylnon, is an insecticide used to control various ant species, cockroaches, and subterranean termites. It is the active ingredient in end-use products formulated as a granular (concentration ranging from 0.73% to 1.0%), liquid-ready-to-use gel (concentration ranging from 2.00% to 2.15%), and solid bait (concentration ranging from 0.5% to 2.0%). Hydramethylnon end-use products are employed in the following uses/sites:

Occupational and residential: Indoor residential use includes inside domestic dwellings, including use on bathroom hard surfaces, garbage cans, and other solid waste refuge sites within the dwellings. An indoor use on medical institution premises also exists.

Outdoor residential use includes the following uses on and around domestic dwellings, including garbage cans; ornamental trees, plants, lawns, shrubs and vines; patios; sidewalks; and private roads. Terrestrial feed crops include grasses. Terrestrial non-food crops include use on agricultural crops/soils; uncultivated areas; golf course turf; outside commercial, institutional and industrial premises; protection of seasoned forest products; ornamental trees, plants, lawns, shrubs and vines; sod farm turf; patios; paved roads; sidewalks; and recreational areas. Aquatic non-food industrial use includes use in sewage systems.

Occupational use and/or residential use products: End-use products containing the active ingredient hydramethylnon are marketed for both occupational and residential use. Occupational use can range from large scale aerial application of granular formulations for imported fire ant control to application of small dabs of a ready-to-use gel injected into cracks and crevices for cockroach treatment.

Residential use can take the form of small scale application of the granular formulation with a hand held or push-type spreader, spoon, or scoop, or the application of gel to cracks and crevices. Residential use also commonly includes the strategic placement of hydramethylnon in self-contained, enclosed-bait discs around the residence. The gel formulation is also used on the bottoms of man hole covers.

Handler exposures and assumptions: The Agency has determined that there is potential for exposures to loaders, applicators, and other handlers during usual occupational and residential use-patterns associated with hydramethylnon. Based on currently registered use patterns, eight major exposure scenarios were identified for hydramethylnon handlers: 1) loading granular for aerial application; 2) application of granular by fixed-wing aircraft; 3) flagging for granular aerial application; 4) loading and application of granular by tractor-drawn, drop-type spreader; 5) hand distribution of granular bait; 6) loading and application of granular by hand-held rotary spreader; 7) loading and application of granular by push-type spreader; and, 8) hand application of gel from syringe-type container/applicator. A ninth exposure scenario for the occupational and residential handling of self-contained, child-resistant ant and roach bait discs was not included because negligible exposure was expected from this activity. A tenth exposure scenario for the occupational handling of tamper-proof termite bait stations (product is labeled for sale to PCOs only) is also not included. The exposure from handling this solid product is considered negligible with much less potential exposure than the handling of granular products under scenario 5 (above).

b. Post-Application Exposures and Assumptions

Occupational and Residential Risk Assessment/Characterization

Risk from Dermal and Inhalation Exposures

Risk from Handler Exposure

Short-term and intermediate-term dermal exposure assessments using the Pesticide Handlers Exposure Database (PHED) Version 1.1 surrogate data and baseline risk calculations for occupational handlers are presented in Table 2. Applicable exposure scenarios for residential handlers are represented by scenarios 5, 6, and 7 in Table 2 and scenario 8 as described below. Table 2 summarizes the parameters specific to each exposure scenario and corresponding risk assessment.

Table 2. EXPOSURE SCENARIO DESCRIPTIONS FOR USES OF HYDRAMETHYLNON

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Loader Descriptors			
Loading Granular Formulations (1)	PHED V1.1	300 acres for aerial applications	**Baseline:** "Best Available" grades: Hands = all grades; dermal = ABC grades. Hands = 10 replicates; Dermal = 33 to 78 replicates. Low confidence in dermal data. PHED data used for baseline, no Protection Factors (PFs) were necessary.
Applicator Descriptors			
Apply Granular Bait by Fixed-wing Aircraft (Enclosed Cockpit) (2)	PHED V1.1	300 acres	**Engineering Controls:** "Best Available" grades: Hands = all grades; dermal = C grade. Hands = 4 replicates; dermal = 0 to 13 replicates. Low confidence in dermal data. A 50% Protection Factor (PF) was applied to the total deposition data to represent a single layer of clothing.
Flagger Descriptors			
Flagging for Aerial Application of Granular Bait (3)	PHED V1.1	300 acres	**Baseline:** "Best Available" grades: Hands all grades; dermal = ABC grades. Hands = 4 replicates; Dermal = 16 to 20 replicates. Low confidence in dermal data. A 50% PF was applied to the total deposition data to represent single layer of clothing.
Loader/Applicator Descriptors			

Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Load/Apply Granular Bait Using Drop-Type Tractor-Drawn Spreader (4)	PHED V1.1	100 acres	**Baseline Granular Loader:** "Best Available" grades: Hands all grades; dermal = ABC grades. Hands = 10 replicates; Dermal = 33 to 78 replicates. Low confidence in dermal data. PHED data used for baseline, no PFs were necessary. Note: The loader data were combined with the applicator data for a combined exposure. **Baseline Granular Spreader:** "Best Available" grades: Hands and dermal acceptable grades. Hands = 5 replicates; Dermal = 1 to 5 replicates. Low confidence in dermal data. PHED data used for baseline, no PFs were necessary. Note: The applicator data were combined with the loader data for a combined exposure.
Hand Apply Granular Bait (5)	PHED V1.1	(R) 1,000 ft^2 (O) 5,000 ft^2	**Baseline:** "Best Available" grades: Hand and dermal ABC grades. Hands = 15 replicates; Dermal = 16 replicates. Low confidence in dermal data. A no glove hand exposure value was back-calculated from the glove data for baseline dermal exposure.
Load/Apply Granular Bait Using Handheld Rotary Spreader (6)	PHED V1.1	(R) 1 acre (O) 1 acre	**Baseline:** "Best Available" grades: Hands and dermal = ABC grades. Hands = 23 replicates; dermal = 29 to 45 replicates. Medium confidence in dermal data. PHED data used for baseline, no PFs were necessary.
Load/Apply Granular Bait Using Push-Type Granular Spreader (7)	PHED V1.1	(R) 1 acre (O) 5 acres	**Baseline:** "Best Available" grades: Hands and dermal = ABC grades. Hands = 15 replicates; dermal = 0 to 15 replicates. Low confidence in dermal data. PHED data used for baseline, no PFs were necessary.
Hand Apply Gel by Syringe (8)	No Data	No Data	No Data

(R) Residential (O) Occupational

[a] Standard Assumptions based on an 8-hour work day as estimated by the Agency, except for scenarios 1 through 4. Assumptions for scenarios 1 through 4 are from information supplied to the Agency by the registrant. Baseline dermal exposure is based on the worker wearing long pants, long sleeve shirt, and no gloves; and, if applicable, employing open loading techniques and an open cab tractor. Where indicated, for some PHED data, correction factors have been applied to arrive at these baseline scenarios.

[b] "Best Available" grades are defined by the Agency for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:
High = grades A and B and 15 or more replicates per body part.
Medium = grades A, B, and C and 15 or more replicates per body part.
Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates.

Table 3: BASELINE SHORT-TERM AND INTERMEDIATE-TERM EXPOSURE AND RISK ASSESSMENTS FOR HYDRAMETHYLNON

Exposure Scenario	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Maximum Application Rate (lb ai/acre)[b]	Maximum Acres/Day[c]	Daily Dermal Exposure (mg ai/day)[d]	Daily Dermal Dose (mg ai/kg/day)[e]	Dermal MOE[f]
Loader Exposure						
1. Load Granular Bait for Aerial Application	0.0084	0.018	300	0.045	0.0006	420,000
Applicator Exposure						
2. Apply Granular Bait by Fixed-wing Aircraft	0.0024	0.018	300	0.013	0.0002	1,250,000
Flagger Exposure						
3. Flagging for Aerial Application of Granular Bait	0.003	0.018	300	0.016	0.0002	1,250,000
Applicator Exposure						
4. Load/Apply Granular Bait Using Drop-type Tractor-Drawn Spreader (Open Cab)[g]	0.018	0.018	100	0.032	0.0005	500,000
5. Hand Apply Granular Bait[h]	103.8	0.018	(R) 1,000 ft^2 (0.023 A)	0.043	0.0006	420,000
			(O) 5,000 ft^2 (0.11 A)	0.21	0.003	83,000

Table 3: BASELINE SHORT-TERM AND INTERMEDIATE-TERM EXPOSURE AND RISK ASSESSMENTS FOR HYDRAMETHYLNON

Exposure Scenario	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Maximum Application Rate (lb ai/acre)[b]	Maximum Acres/Day[c]	Daily Dermal Exposure (mg ai/day)[d]	Daily Dermal Dose (mg ai/kg/day)[e]	Dermal MOE[f]
6. Load/Apply Granular Bait Using Handheld Rotary Spreader	10.4	0.018	(R) 1	0.19	0.003	83,000
			(O) 1	0.19	0.003	83,000
7. Load/Apply Granular Bait Using Push-Type Granular Spreader	2.9	0.018	(R) 1	0.052	0.0007	360,000
			(O) 5	0.26	0.004	62,000
8. Hand apply Gel by Syringe	See Page 32	N\A	N\A	26.7	0.38	660

(R) Residential (O) Occupational

a Baseline dermal unit exposure, taken from PHED Version 1.1, represents long pants, long sleeve shirt, no gloves, open loading, open cab tractor (unless otherwise indicated). Note that for some PHED data correction factors were applied to arrive at the baseline scenario.

b Application rate comes from maximum rates found in the hydramethylnon labels.

c Daily acres treated values are from Agency estimates of acreage that could be treated in a single day for each exposure scenario of concern. Assumptions for scenarios 1 through 4 are from information supplied to the Agency by the registrant.

d Daily Dermal Exposure (mg ai/day) = Unit exposure (mg/lb ai) x Application Rate (lbs ai/acre) x Acres Treated.

e Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/70 kg

f Dermal Margin of Exposure (MOE) = NOAEL (250 mg/kg/day)/Daily Dermal Dose (mg/kg/day)

g Unit exposure is sum of unit exposures for loading granular and applying granular with solid broadcast spreader, open cab.

h Unit exposure from PHED is for individuals wearing gloves. Estimate entered here has been corrected by back calculation to present the unit exposure for un-gloved hands, using a 90% protection factor for gloves.

Formulas for determining dermal exposure and risk to handlers are as follows:

Daily Exposure (mg ai/day) =
Unit Exposure (mg ai/lb ai) x Use Rate (lb ai/acre) x Maximum Area Treated (acres/day)

Daily Dermal Dose (mg ai/kg bw/day) =
Daily Exposure (mg ai/day) / Body Weight (kg)

Margin of Exposure (MOE) =
NOAEL (mg/kg/day) / Daily Dermal Dose (mg/kg/day)

The following are important assumptions used in the occupational and residential exposure

assessments:

- Assume exposed adult's body weight is 70 kg;

- Assume exposed child's body weight is 10 kg;

- Inhalation exposure is assumed to be negligible for all exposure scenarios due to the low vapor pressure of the active ingredient ($2x10^{-8}$ mm of Hg at 25^{o} C), the size of the granules (no free particles below 140 microns), and the oily nature of the granular bait products (17 to 26% soybean oil). For this reason and the lack of a toxicity concern for this route, inhalation exposure is not figured into any of the exposure calculations for handlers;

- Assume that the tractor drawn drop-type spreader equipment would result in a reasonable surrogate exposure scenario for the blower or rotary spreader that are sometimes actually used for this granular product; and,

- Assume that the unit exposures for the loader is additive with the unit exposure for the applicator using the tractor drawn, drop-type spreader.

- In addition, other assumptions are listed in Table 2.

c. Occupational Handler Exposures

Table 2 contains the results of exposure assessment calculations for the occupational handler scenarios associated with hydramethylnon. Because neither actual data nor routine methods for using surrogate information exist to evaluate gel formulations, the Agency utilized the methodology and approach which had been submitted by the registrant and accepted by the Agency. Exposure scenario 8 (hand application of gel in cracks and crevices by syringe applicator) is described below.

d. Residential Handler Exposures

Common residential handler exposures would be described by scenarios 5, 6, and 7 (in Table 2) as well as scenario 8 (described separately below due to lack of PHED data). For handler exposure scenario 8 (for both occupational and residential use) hand application of gel by syringe applicator assume:

- Repeated inadvertent exposure to dispenser and treated surfaces results in uniform layer of gel on exposed hand surface.

- Exposure to half of the surface area of a hand using maximum values for hands as 1130 cm^2. Therefore, 0.5 x 1130 cm^2 = 622.5 cm^2

! Diffusion of the active ingredient through the gel layer will be limited due to matrix effects and high molecular weight of the active ingredient, so that multiple contacts during the day, beyond those necessary to establish a uniform layer on the exposed skin will provide no additional absorbed dose. The dermal dose is then calculated as follows:

Daily Dermal Dose = (weight fraction a.i.) x (density of formulation - assumed to be same as water) x (film thickness) x (skin surface area) x (1/body weight) =

(0.0215) x (1 g/cm^3) x (10^3 mg/g) x (2 x 10^{-3} cm) x (622.5 cm^2)/ 70 kg =
0.38 mg a.i./kg/day

MOE = NOAEL = (250 mg/kg/day)/(0.38 mg/kg/day) **= 658** (rounded to 660)

Post-Application Exposures and Assumptions

Occupational Post-Application Exposures

The potential for post-application occupational exposure exists. For example, potential exposures would be expected for golf-course maintenance workers and for harvesters and mowers on sod farms and to persons in buildings following indoor applications. There are no chemical-specific data to use in assessing these potential exposures, therefore, a range finder post-application exposure and risk assessment was performed (Table 4). This assessment uses typical transfer coefficients (Tc) for low crops and/or low exposure activities (1,000 cm^2/hr) and for high crops and/or high exposure activities (10,000 cm^2/hr) and dislodgeable foliar residues (DFR) derived from the application rate and an estimated 20 percent of rate available as dislodgeable. The Agency believes that exposures following applications to crops are likely to represent a reasonable worse-case post-application exposure to occupational workers. Post-application occupational exposures following applications of the gel to crack and crevices are expected to be minimal.

TABLE 4: SURROGATE POSTAPPLICATION RANGE-FINDER ASSESSMENT

DAT [a]	Age Group	Surrogate DFR (g/cm^2)[b]	Dermal Dose (mg/kg/day)[c]	MOE[d]
Low Exposure Activities (Tc = 1,000 cm^2/hr)[e]				
zero	Adult	0.040	0.005	54,000
zero	Child	0.040	0.032	7,800
High Exposure Activities (Tc = 10,000 cm^2/hr)[f]				
zero	Adult	0.040	0.046	5,400
zero	Child	0.040	0.32	780

a DAT is days after treatment based on an application rate of 0.018 lb ai/acre.

b Surrogate DFR (g/cm^2) = Rate (lb ai/A) x [(11.2 g/cm^2)/(1 lb ai/A) conversion factor] x percent (20 percent assumed) of rate available as dislodgeable

c Dermal Dose (mg/kg/day) = [DFR (g/cm^2) x Tc (cm^2/hr) x (1 mg/1,000 g unit conversion) x 8 hours/day] / Body Weight (70 kg)

d MOE = NOAEL (250 mg/kg/day)/Dermal Dose (mg/kg/day)

e Low exposure crops/activities include crops, such as low-growing ornamentals and established turf (other than sod-farm turf), and activities such as scouting and crop-advising.

f High exposure crops/activities including crops, such as ornamental trees, plants, shrubs, and vines and sod farm turf, and activities such as harvesting, transplanting, and pruning.

Residential Post-Application Exposures

The potential exists for post-application residential exposure to adults and children. For example, potential exposures would be expected following applications to lawns, and ornamental gardens, and to indoor (in-home) sites. There are no chemical-specific data to use in assessing these potential exposures, therefore, a range finder post-application exposure and risk assessment was performed (Table 4). The assessment uses typical transfer coefficients (Tc) for low crops and/or low exposure activities (1,000 cm^2/hr), and for high crops and/or high exposure activities (10,000 cm^2/hr) and dislodgeable foliar residues (DFR) derived from the application rate and an estimated 20 percent of rate available as dislodgeable. The Agency believes that exposures following applications to plants, such as lawn-turfgrass, are likely to represent a reasonable upper bound post-application exposure to residents. However, the Agency also estimated the post-application residential exposure following applications of the gel to cracks and crevices.

Post-application dermal exposure to the gel product

The following evaluation is based on a methodology and approach which had been submitted by the registrant, and accepted by the Agency in a previous waiver request evaluation. Assume:

! Exposure to lower surface of hands and forearms. Using half of the maximum values for

hands (1130 cm^2) and forearms (1360 cm^2), the total surface area exposed becomes: (0.5 x 1130 cm^2) + (0.5 x 1360 cm^2) = 1245 cm^2

- Maximum use-rate of 2.4 g/m^2 of a 2.15% active ingredient formulation; and,

- Five contact events per day

Calculate the amount contacted per event as:

(2.4 g/m^2) x (0.0215 a.i.) x ($m^2/10^4$ cm^2) x (1000mg/g) x (1245 cm^2) =
6.4 mg a.i./event

Calculate the post-application exposure as:

Daily Exposure = (5 events/day) x (6.4 mg a.i./event) = 32 mg a.i./day

Daily Dermal Dose (DDD)= (32 mg a.i./day) / 70 kg = 0.46 mg a.i./kg/day

MOE = NOAEL/DDD = (250 mg/kg/day)/(0.46 mg/kg/day) = **540**

Risk from Handler Exposures

The calculations for short-term and intermediate-term handler risk indicate that the MOEs for handlers are much greater than 100 at baseline for all scenarios. It should be noted that the PHED data for aerial fixed-wing application are used with enclosed cockpits. Data do not exist in PHED for unit exposures from aerial application without this engineering control. The current label for this use does not require this engineering control. However, because the MOE for this scenario is much larger than 100 (1,250,000), even use of enclosed cockpits is unnecessary.

Risk from Post-Application Exposures

Post-application risk from use of the gel product would be primarily to the adult resident. Children are expected to be less at risk than adults because the gel is likely to be applied in inaccessible and untraveled areas. Assessment of potential risk, using upper bound assumptions for body area exposed, result in a MOE of 540.

The range-finder calculations for short-term and intermediate-term post-application risk from use of the granular formulation indicate that the MOEs from post-application exposures to occupational workers and to residents (both adults and children) are much greater than 100 for risk using the short term endpoint for exposures estimated immediately following application.

These assumptions reflect an upper bound estimate of exposure and hazard and, therefore, reflect upper bound risk from handler and post-application exposure.

Additional Occupational/Residential Exposure Studies

Handler Studies

There are data gaps for baseline and PPE data for applying granular formulations with fixed-wing aircraft. However, because the toxicity of this substance is sufficiently low, the Agency is not requiring studies for these scenarios at this time.

Post-Application Studies

No studies are required at this time.

5. Other Exposure and Risk Considerations

The Food Quality Protection Act (FQPA) of 1996 amends both FFDCA and FIFRA by setting a new safety standard for the establishment of tolerances. In determining whether or not a tolerance meets the new safety standard, FQPA directs EPA to consider information concerning: the susceptibility of infants and children to residues of the pesticide in food; the potential for aggregate exposure from dietary as well as non-occupational sources, such as pesticides used in and around the home; and the potential for cumulative effects from a pesticide and other substances that have a common mechanism of toxicity.

Because the use of hydramethylnon on grass in pastures and rangelands is considered a food use and a tolerance has been established for hydramethylnon on grass and grass hay (i.e., pasture and rangelands), certain determinations outlined in FQPA were required for this chemical. A tolerance has been established for hydramethylnon on grass forage and grass hay. However, no finite residues are anticipated in meat, milk, or meat byproducts. Therefore, the Agency has not undertaken a dietary risk assessment because no dietary exposure is anticipated.

The Agency has completed an aggregate risk assessment from the other potential exposure pathways (e.g. non- occupational sources). With regard to cumulative risk, hydramethylnon is structurally similar to some other amidinohydrazone compounds; however, the Agency has not made a determination regarding a cumulative risk assessment. For the purposes of this Reregistration Eligibility Decision document, the Agency has considered only risks from hydramethylnon. However, the contribution of hydramethylnon exposure to the exposure from other chemicals with a common mode of toxicity is likely to be minimal since the MOEs are so high. If required, cumulative risks will be assessed when methodologies for determining common mode of toxicity and for performing cumulative risk assessment are finalized.

C. Environmental Assessment

The environmental fate and effects database on hydramethylnon is adequate and will support reregistration eligibility. To support broadcast applications, an avian reproduction (GLN 71-4) study is required for confirmatory data purposes.

1. Ecological Effects

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) was conducted to establish the toxicity of hydramethylnon to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this study are tabulated below.

Table 5: Avian Acute Oral Toxicity

Species	% ai	LD50 (mg/kg)	Toxicity Category	MRID	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	92%	1828	Slightly toxic	00064576	Acceptable
Mallard duck *(Anas platyrhynchos)*	92%	2510	Practically non-toxic	00064575	Acceptable

Since the LD50 falls in the range of 1828-2510 mg/kg, hydramethylnon is slightly toxic to practically non-toxic to avian species on an acute oral basis. The guideline requirement (71-1a) is fulfilled.

Two subacute dietary studies using the TGAI were conducted to establish the toxicity of hydramethylnon to birds. These studies were performed on the preferred test species, mallard duck and bobwhite quail. Results of these tests are tabulated below.

Table 6: Avian Subacute Dietary Toxicity

Species	% ai	5-Day LC50 (ppm)[1]	Toxicity Category	MRID	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	92%	1136	Slightly toxic	00064577	Core
Mallard duck *(Anas platyrhynchos)*	92%	4355	Slightly toxic	00085931	Core

[1] Test organisms observed an additional three days while on untreated feed.

Since the LC50 falls in the range of 1136-4355 ppm, hydramethylnon is slightly toxic to avian species on a subacute dietary basis. Guideline requirements (71-2 a and b) are fulfilled.

(2) Birds, Chronic

No avian reproduction data are available for hydramethylnon. Observation of reproductive effects in mammals suggests that oral exposure of other organisms to hydramethylnon may result in chronic reproductive effects. In the absence of toxicological data to the contrary, the Agency assumes that hydramethylnon has a potential to cause chronic reproductive effects in avian species. Uncertainties regarding the potential for adverse reproductive effects in birds would be reduced if avian reproduction toxicity data were available for the compound. Avian-specific toxicity thresholds for reproductive effects would allow a more accurate comparison between bait concentrations and toxicological effects thresholds. The Agency has requested such studies for other pesticides including when (1) birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season; (2) the pesticide is stable in the environment to the extent that potentially toxic amounts may persist in animal feed; (3) the pesticide is stored or accumulated in plant or animal tissues; and/or (4) information derived from mammalian reproduction studies indicates reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the product. Because hydramethylnon meets condition (1), (2) and (4) above, the Agency requires that avian reproduction data be submitted or that use patterns resulting in potential chronic exposures be eliminated.

(3) Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's files substitute for wild mammal testing. These toxicity values are reported below.

Table 7: Mammalian Toxicity

Species	% ai	Test Type	Toxicity Value	Toxicity Category	MRID
Norway Rat *(Rattus norvegicus)*	95%	LD50	(m) 817 (f) 1502 combined: 1146 mg/Kg	Slightly Toxic	416125-03
Norway Rat *(Rattus norvegicus)*	92%	Reproduction (3 generation)	NOEL= 50 ppm LOEL= 100 ppm	Male infertility was noted at 100 ppm	35525 35526 101575

The results indicate that hydramethylnon is slightly toxic to small mammals on an acute oral basis. Reproductive effects (male infertility) occurred at 100 ppm (NOEL= 50 ppm).

In a two generation study (MRID 43741501), 98.2% hydramethylnon was administered to Sprague-Dawley rats. The reproductive NOAEL was 25 ppm and the reproductive LOEL was 50

ppm based on histological findings in the testes and the epididymides. At 75 ppm, reproductive performance of the males was decreased. As noted above, these findings are suggestive of the potential for reproductive effects in other organisms including birds.

(4) Insects

A honey bee acute contact study using the TGAI was required for hydramethylnon because its outdoor use may result in honey bee exposure. Results of this test are tabulated below.

Table 8: Nontarget Insect Acute Contact Toxicity

Species	% ai	LD_{50} (g/bee)	Toxicity Category	MRID	Study Classification
Honey bee *(Apis mellifera)*	96.8	68.0	Practically non-toxic	416078-01	Acceptable

The results indicate that hydramethylnon is practically non-toxic to bees on an acute contact basis. The guideline (141-1) is fulfilled.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of hydramethylnon to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

Table 9: Freshwater Fish Acute Toxicity

Species/ (Flow-through or Static)	% ai	96-hour LC_{50} (ppm)*	Toxicity Category	MRID	Study Classification
Rainbow trout *(Oncorhynchus mykiss)*	92%	0.15	Highly toxic	00052857	Acceptable
Bluegill sunfish *(Lepomis macrochirus)*	92%	1.7	Moderately toxic	00061708	Acceptable
Channel catfish *(Ictalurus punctatus)*	92%	0.09	Very highly toxic	00061707	Acceptable

*Note: LC_{50} concentrations exceed the water solubility of hydramethylnon. These concentrations were achieved through the use of dimethyl formalin as a co-solvent.

Because the LC_{50} falls in the range of 0.09-1.7 ppm, hydramethylnon is moderately to very highly toxic to freshwater fish on an acute basis. It should be noted that these LC50 values exceed

the aqueous solubility of hydramethylnon and are therefore not likely to be of environmental significance. The guideline requirement 72-1 is fulfilled.

(2) Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI may be required for hydramethylnon because the end-use product may be transported to water from the intended use site, and conditions are met with regard to the chemical's toxicity and expected environmental concentration. This test would normally be required for hydramethylnon due to the compound's high toxicity (LC_{50}< 1 mg/L) in rainbow trout and channel catfish. The preferred test species in this case would be the channel catfish, as it is the freshwater species tested that is most sensitive to hydramethylnon. Water solubility of hydramethylnon is 0.005 to 0.007 ppm (The Agrochemicals Handbook, Royal Chemistry Society, 1987), an order of magnitude lower than the catfish LC_{50} of 0.09 ppm. In addition, hydramethylnon photodegrades in water with a half-life of under one hour. In this case, under natural conditions, susceptible species are not expected to be exposed to the chemical. This study is not needed at this time, but may be required for future new uses. The guideline requirement 72-4 is reserved.

(3) Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of hydramethylnon to aquatic invertebrates. Results of this test are tabulated below.

Table 10: Freshwater Invertebrate Acute Toxicity

Species/(Static)	% ai	48-hour LC_{50}/ EC_{50} (ppm)	Toxicity Category	MRID	Study Classification
Waterflea *(Daphnia magna)*	92%	1.14	Moderately toxic	00035877	Acceptable

Since the LC_{50}/EC_{50} is 1.14 ppm, hydramethylnon is moderately toxic to aquatic invertebrates on an acute basis. The guideline requirement 72-2 is fulfilled.

(4) Freshwater Invertebrate, Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI is not required at this time for hydramethylnon because of the very low aqueous solubility in water, its brief half-life there, and the limited opportunity for residues to reach surface water for current use patterns. Any expansion of the current use patterns may trigger the need for these data.

c. Toxicity to Aquatic Plants

Currently, aquatic plant testing is not required for pesticides other than herbicides and fungicides, except on a case-by-case basis (e.g., labeling bears phytotoxicity warnings, incident data

or literature that demonstrate phytotoxicity). The Agency does have data from 96 hour studies (MRID 40098001) conducted with 96.2 % technical hydramethylnon indicating that hydramethylnon is very highly toxic to aquatic plants as indicated by the following toxicity (EC50) levels: green algae species (5-18 ppb); a marine haptophyte (2.9 ppb); and, marine diatoms (0.24-0.26 ppb).

d. Environmental Fate Data

This environmental fate assessment of hydramethylnon is based on both acceptable (hydrolysis, photo degradation on soil, aerobic soil metabolism, anaerobic aquatic metabolism, unaged mobility, and accumulation in fish) and supplemental data (photo degradation in water and terrestrial field dissipation) submitted for reregistration since 1989. Although some environmental fate data requirements remain unfulfilled at this time, the available data provide enough information to conduct a risk assessment for the parent compound. This is possible for aquatic exposure scenarios because the observed toxic thresholds for parent hydramethylnon exceed solubility and information on individual degradate identities is not likely to significantly alter risk calculations. For terrestrial receptors, risks are based on exposures to parent hydramethylnon at concentrations measured in baits. The Agency's conservative assumption of potential exposure levels expressed in terms of parent compound is likely to, at worst, remain unchanged or be reduced if full information on individual degradates becomes available.

e. Environmental Fate Assessment

Laboratory data indicate that the major routes of hydramethylnon dissipation on the soil surface are abiotic photolysis and soil binding. Hydramethylnon's photolytic half-life in water is less than or equal to 1 hour, while its photolysis on soil is biphasic, with half-lives of 4 days for the first phase and in about 30 days for the second phase. Parent hydramethylnon was reported to adsorb strongly to soils: loamy sand, sandy loam, loam, and silt loam soils with reported Kds of 1039-1782 mL/g. The reported Kd values ranged from 3330 to 8667 mL/g. In addition, hydramethylnon appears to dissipate very slowly by biotic processes (half-lives for aerobic soil metabolism were 385 days, and for anaerobic aquatic metabolism 445 to 552 days). It is stable to hydrolysis at pH 5, pH 7, and pH 9.

Field data appear to confirm the laboratory data. Half-lives of 3 days and 55 days were reported for Florida and Texas field plots with no detections reported below the 0-6 inch soil depth. Therefore, based on the low application rate hydramethylnon of hydramethylnon (0.0176 lb a.i./A), rapid photolysis, low soil mobility, and low solubility in water (7 to 9 ppb), hydramethylnon on soil surfaces appears to be non-persistent and immobile. However, below the soil surface hydramethylnon appears to be more persistent and immobile. Due to the lack of movement of hydramethylnon in the soil profile under most conditions, hydramethylnon appears to have a low potential for groundwater contamination, but may move horizontally on the soil surface through soil erosion.

During aqueous photolysis, a major degradate, (4H-pyrimido [2-1-c]as-triazio-4-one-1,6,7,8-tetrahydro-7,7-dimethyl-3-[p-(trifluoromethyl)-styryl], represented 25.2% and 30.5% of the recovered ^{14}C-phenyl and ^{14}C-pyrimidine radioactivity, respectively. A second major degradate, 1,5-bis(alpha, alpha, alpha-trifluoro-p-tolyl)-1,4-pentadien-3-one, represented 28.0% of recovered phenyl labeled material. In addition, five unidentified compounds were discernible in the 2-pyrimidine radio labeled and the phenyl radio labeled samples, ranging from 29.6% to 7.6% of recovered radioactivity. Further analysis of these unknown degradates was either inconclusive and/or indicated they were formed by specific conditions of confirmation analysis or rate of formation and decline analysis. Two unidentified degradates in the hydramethylnon soil photolysis data, which were found to make up 10% of the applied radioactivity, were determined to be comprised of a mixture of products. Epoxide and ketone compounds of hydramethylnon comprised the major degradates in these mixtures.

Hydramethylnon showed some tendency to accumulate in fish tissues with reported bioconcentration factors of 1300X in whole fish, 780X in fillet, and 1900X in viscera. Slow depuration (48 to 63% of residues depurated after a 14-day clearance period) was observed. The current limited outdoor use patterns of hydramethylnon combined with its low aqueous solubility, tendency to photodegrade in water, and high soil sorption affinity suggest low potential for bioaccumulation in the environment.

f. Environmental Fate and Transport

(1) Degradation

Hydrolysis One guideline hydrolysis study (MRID 42194701) was submitted to the Agency. This study was found to be acceptable to fulfill the data requirement (161-1). Hydramethylnon was reported to be stable to hydrolysis at pH5, pH 7, and pH 9. In addition, the stability of hydramethylnon does not appear to be affected by type or concentration of buffer at pH 7.

Photodegradation in water Photodegradation in water data submitted were found to be supplemental but did not fulfill the data requirement (161-2). Two degradates were present at concentrations of 29.6% and 15.6% of recovered radioactivity, but were not identified. In addition, confirmatory analyses by LC/MS were inconclusive (MRIDs 42238201 and 42473301).

The photodegradation in water data indicate that hydramethylnon rapidly photodegrades in pH 7 buffer solutions (half-life of $\leq$1 hour). Hydramethylnon was stable in the dark control treatment.

A major photodegradate, 4H-pyrimido [2-1,c]as-triazio-4-one-1,6,7,8-tetrahydro-7,7-dimethyl-3-[p-(trifluoromethyl)-styryl], represented 25.2% and 30.5% of the recovered ^{14}C-phenyl and ^{14}C-pyrimidine radioactivity, respectively. A second major degradate, 1,5-bis(alpha, alpha, alpha-trifluoro-p-tolyl)-1,4-pentadien-3-one, represented 28.0% of recovered phenyl labeled material. In addition, five unidentified compounds (Unknowns 1, 2, 3, 4, and 5) were discernible

in test samples. Unknowns 1, 4, and 5 were detected in the 2-pyrimidine radiolabeled samples and reached concentrations of 9.5, 29.6, and 7.7% of recovered radioactivity, respectively. Unknowns 3 and 5 were detected in the phenyl radiolabeled samples and reached concentrations of 7.6 and 15.6% of recovered radioactivity, respectively. Unknown 2 did not appear in the HPLC analyses of the confirmatory samples, but was observed in the rates of formation and decline analyses. Attempts to identify these unknowns by LC/MS indicated that Unknowns 1 and 2 were formed by specific conditions of confirmatory analysis or of the rate of formation and decline analysis. In addition, after further analysis of Unknown 3, the study authors believed that it was formed by specific conditions of analysis, and/or is an insignificant degradate of hydramethylnon in photolysis. Furthermore, additional analysis by LC/MS of Unknowns 4 and 5 was inconclusive. However, these data did indicate that aqueous photolysis is a route of degradation for hydramethylnon.

The status of the photodegradation in water data is supplemental and cannot be used to fulfill the data requirement (161-2). The study does not fulfill the guideline requirement because 1) photodegradation is a route of dissipation; 2) the structures of Unknowns 4 and 5 were not identified; and, 3) these compounds were present at concentrations of 29.6% and 15.6% of recovered radioactivity, respectively. However, this risk assessment is based on parent compound and since the toxic effect concentrations of parent exceed aqueous solubility, risk to aquatic organisms is not expected.

Photodegradation on soil One guideline photodegradation on soil study, MRID 42353801, was submitted to the Agency. Although problems with the study were identified (test soil was sieved to 1 mm, removing the very coarse sand fraction thereby increasing the surface area and potentially affecting the rate of photo degradation), it can be used to fulfill the data requirement (161-3) at this time. Additional data may be needed to support additional outdoor uses of hydramethylnon.

Photodegradation of hydramethylnon on loam (called sandy loam by author) soil did not follow linear first order kinetics. Rapid degradation over the first 3 days was observed, which was followed by a slower degradation rate. The half-life for the initial (rapid) phase was approximated at 4 days (based on 24 hours light exposure) using first-order kinetics. The second (longer) phase was reported to have a half-life of approximately 30 to 35 days (based on 24 hours light exposure) using first order kinetics. This difference may be due to the light contact on the soil surface and rapid adsorption of hydramethylnon to the soil. Hydramethylnon was stable in the dark control treatment.

Two unidentified peaks, which comprised 10% of the applied radioactivity, were determined to be a mixture of compounds. Hydramethylnon epoxide and ketone compounds comprised the major degradates detected in these mixtures. The control samples were reported to show <10% degradation during the testing period.

Aerobic metabolism in soil One guideline aerobic soil metabolism study, MRID 42320801, was submitted to the Agency. Hydramethylnon appears to degrade relatively slowly under aerobic

conditions when applied to sandy loam soil at an exaggerated application rate (0.095 ppm, or 6 times the normal rate). After 1 year of aerobic incubation, first-order half-lives of 375 and 391 days for the ^{14}C-phenyl and ^{14}C-pyrimidine labeled hydramethylnon were reported, respectively. One unidentified degradate, which HPLC analysis indicated to contain both labels and be more polar than the parent compound, was detected at concentrations of 15.6 and 16.8% of applied radioactivity in the ^{14}C-phenyl and pyrimidine labeled samples, respectively. The study author believes that formation of this degradate was partially due to the soil extraction and analytical methodology of the extracts and that it is unstable. Further attempts to identify this degradate by LS/MS were unsuccessful. In addition, up to 18 minor degradates, all at concentrations <0.004 ppm, were discernible in the soil extracts. Additional information on the identities of the 18 minor degradates is not needed at present because of the low rate of occurrence of these compounds in the study. This study was found acceptable to fulfill data requirement 162-1. Because of the relatively high occurrence of the unidentified polar compound, expanded outdoor uses of hydramethylnon, may necessitate additional information on this compounds identity and subsequent revision of the exposure assessments.

Anaerobic aquatic metabolism One guideline anaerobic soil metabolism study, MRID 42320801, was submitted to the Agency and will fulfill guideline requirement 162-2.

Hydramethylnon appears to be relatively persistent under anaerobic conditions. Half-lives of 552 and 455 days were calculated for the phenyl and pyrimidine labeled hydramethylnon samples, respectively. The concentration of ^{14}C-phenyl and ^{14}C-pyrimidine decreased from 90.7% and 82.6% to 50.4% and 57.4%, respectively, of applied radioactivity by termination of testing period (1 yr).

Two additional peaks were discernible in test samples. Peak A was discernible at maximum concentrations of 15 to 8.8% at 9 and 12 months post-treatment for phenyl and pyrimidine labeled samples, respectively. Peak A was determined by HPLC and Thin Layer Chromatography (TLC) to be mainly parent hydramethylnon. Peak B was determined to be a photolytic product formed during sample analysis. Since Peaks A and B generated multiple peaks during HPLC and liquid-liquid chromatography, they could not be identified. Peak B was reported to reach a maximum concentration of 12.7% and 9.2% of applied radioactivity at 3 and 4 months post-treatment samples in the phenyl and pyrimidine labeled test samples, respectively.

(2) Mobility

Leaching, adsorption/desorption Two guideline mobility studies were submitted to the Agency. One of these is an unaged adsorption/desorption study, MRID 41888302, and the other is a TLC study, MRID 41888301. Both studies are considered scientifically valid. However, the Agency does not accept soil TLC mobility data to fulfill the mobility data requirement (163-1) (aged or unaged). The unaged data requirement is fulfilled by adsorption/ desorption mobility data, MRID 41888302. Therefore, no further unaged mobility data for hydramethylnon are needed at this time. Because the current risk assessment is based on parent alone, no additional information on aged mobility are needed at this time. However, since photolysis appears to be a major route of

degradation, aged mobility data for photodegradation products may be needed to support any additional uses of hydramethylnon.

Hydramethylnon appears to be relatively non-mobile (Kd values ranged from 1039-1782 mL/g). In addition, hydramethylnon was reported to be stable since only one major spot, which co-chromatographed with non-labeled hydramethylnon, was discernible on the normal phase assays. Soil TLC results indicate that hydramethylnon is relatively non-mobile in loamy sand, sandy loam, loam, and clay loam soils.

(3) Accumulation

One guideline study, MRID 00101611, was submitted to the Agency. This study was found to be acceptable to fulfill the guideline requirement 164-5. Hydramethylnon showed some tendency to accumulate in fish tissues with reported bioconcentration factors of 1300X in whole fish, 780X in fillet, and 1900X in viscera. Slow depuration (48 to 63% of residues depurated after a 14-day clearance period) was observed. The current limited outdoor use patterns of hydramethylnon combined with its low aqueous solubility, tendency to photodegrade in water, and high soil sorption affinity suggest low potential for bioaccumulation in the environment.

(4) Field Dissipation

Terrestrial field dissipation Two studies, MRIDs 43293101 and 43293102, were submitted to the Agency for guideline requirement 164-1. However, these data are supplemental since two major photo degradation products were identified (4H-pyrimido [2-1,c]as-triazio-4-one-1,6,7,8-tetrahydro-7,7-dimethyl 3-[p-(tri-fluoromethyl)-styryl] at 25.2% and 30.5% of the recovered ^{14}C-phenyl and ^{14}C-pyrimidine labeled material respectively, and 1,5-bis(alpha, alpha, alpha-tri-fluoro-p-tolyl)-1,4-pentadien-3-one at 28.0% of recovered phenyl labeled material). These degradation products were not analyzed for in these two terrestrial field dissipation studies.

In addition, two unidentified photolysis products reached concentrations >10% of applied. Major photo degradation (>10% of applied) and metabolism products should be analyzed for in terrestrial field dissipation studies. Because the current risk assessment is limited to parent hydramethylnon, no further testing is required at this time. However, since photolysis appears to be a route of dissipation, additional field data on degradation products may be needed to evaluate any additional uses of hydramethylnon in the future.

Hydramethylnon appeared to dissipate in Florida sand soil with a calculated half-life of 3 days. Average residues above the analytical detection limit (0.010 ppm) were not detected below the 0-6 inch soil depth level. Hydramethylnon residues ranged from 115 ppb at immediately after treatment (0.01 day test interval) to <10 ppb at 14 days post-treatment. There were no degradation products identified during analysis of test samples for the entire testing period (152 days).

Hydramethylnon appeared to dissipate in Texas sandy loam soil with a calculated half-life

of 55 days. Average residues above the analytical detection limit (0.010 ppm) were not detected below the 0-6 inch soil depth level. Hydramethylnon residues ranged from 114 ppb at immediately after treatment (0.01 day test interval) to <10 ppb at 148 days post-treatment. There were no degradation products identified during analysis of test samples for the entire testing period (148 days).

Laboratory data indicated that hydramethylnon had a biphasic photodegradation pattern. The first and most rapid phase of photodegradation may have been reflected in the Florida field test study on sandy soil where a half-life of 3 days was reported . It is reasonable to assume that the field dissipation half-life can range from 3 to 55 days, depending on the availability of residues to photodegradation. It is not possible to confirm the role of photodegradation in this field study, because photodegradates were not identified.

(5) Spray Drift

American Cyanamid is a member of the Spray Drift Task Force and are able to cite those data. Although there are aerial broadcast application uses, the granular formulation is of a particle size that would not be expected to drift during typical application.

g. Water Resources

The Agency does not believe that surface water or ground water resources will be affected by the labeled use of hydramethylnon.

(1) Ground Water

No data on hydramethylnon residues in ground water are readily available. Hydramethylnon is not included in the Pesticides in Ground Water Database, and it was not an analyte in the National Pesticide Survey. A search of the World Wide Web provided no further environmental fate data for hydramethylnon. No Maximum Contamination Limit (MCL) or Health Advisory (HA) has been established for hydramethylnon residues in drinking water.

Due to the high binding affinity of hydramethylnon, it is not likely to contaminate ground water. When a chemical has a K_{oc} of greater than 9,995, the SCI-GROW screening model provides a default estimate of 0.006 ppb in groundwater. In addition, there are limited data on the mobility of hydramethylnon degradation products at this time.

The Agency notes there is uncertainty with surface and ground water assessments, because the environmental fate data for hydramethylnon do not include the major photo transformation products [e.g., (4H-pyrimido [2-1,c]as-triazio-4-one-1,6,7,8-tetrahydro-7,7-dimethyl-3-[p-(trifluoromethyl)-styryl] and 1,5-bis (alpha, alpha, alpha-tri-fluoro-p-tolyl)-1,4-pentadien-3-one]. Additionally, the surface water assessment for bait uses was not evaluated because this type of use does not constitute direct environmental exposure. Although there is uncertainty in the surface

water assessment, the GENeric Expected Environmental Concentration Program (GENEEC) estimated environmental concentration (EEC) for hydramethylnon is expected to be a conservative estimate of the impact on surface water quality.

(2) Surface Water

The Agency uses a computer model to calculate expected environmental concentrations (EECs) of pesticides using the GENEEC program. The EECs are used for assessing the surface water concentrations of a chemical, and the acute and chronic risks to aquatic organisms.

GENEEC uses basic environmental fate data and pesticide label application information to estimate the expected EECs following treatment of 10 hectares. The model calculates the concentration (i.e. EEC) of a pesticide in a one-hectare, two meter deep pond, taking into account the following: (1) adsorption to soil or sediment; (2) soil incorporation; (3) degradation in soil before washoff to a water body; and (4) degradation within the water body. The model also accounts for direct deposition of spray drift into the water body (assumed to be 1% and 5% of the application rate for ground and aerial applications, respectively). When multiple applications are permitted, the interval between applications is included in the calculations. The environmental fate parameters used in the model and calculated EECs for this pesticide are tabulated in the tables below.

The peak GENEEC estimated environmental concentration (EEC) of hydramethylnon in surface water is 15 parts per trillion (ppt). This estimate is based on a maximum application rate of 0.0176 lb ai/acre. Hydramethylnon is persistent ($t_{1/2}$= 385 days) and immobile (K_{oc}= 217,442 ml/g) in terrestrial environments. Hydramethylnon dissipation appears to be dependent on photo degradation and soil binding. Since hydramethylnon has a high binding affinity, it is expected to move into surface waters on entrained sediments. Once in surface waters, hydramethylnon is expected to be associated predominantly with the sediment.

Table 11: GENEEC EECs (µg/L)

Crops	PEAK		4 DAYS		21 DAYS		56 DAYS	
	Air Applied	Ground Applied	Air Applied	Ground Applied	Air Applied	Ground Applied	Air Applied	Ground Applied
Pasture land	.014	.015	.004	.004	.0008	.0008	.0003	.0003

Table 12: GENEEC Environmental Fate Input Parameters

DATA	VALUE	DATA ASSESSMENT	SOURCE
Hydrolysis	Stable	Acceptable	MRID 42194701
Photo degradation in Water	$t_{1/2}$ = < 1 hour	Supplemental	MRID 42238201
Aerobic Soil Metabolism	$t_{1/2}$ = 385 days	Acceptable	MRID 42320801
Aerobic Aquatic Metabolism	Probably Stable	No Data Available	No Data Available
Batch Equilibrium (Koc)	217,442 ml/g (mean)	Acceptable	MRID 41888302

(3) Drinking Water

The Agency believes that hydramethylnon should not pose a major threat to surface and ground water quality, because it has a high binding affinity (Kd>1039 ml/g) on soil, and the outdoor (non-bait) use is limited. However, the impact of hydramethylnon photo transformation products on surface and ground-water quality cannot be assessed due to insufficient data. If new uses or sites are added to label, additional mobility data would be required to assess the environmental fate of photo transformation products.

The peak GENEEC estimated environmental concentration (EEC) of hydramethylnon in surface water is 0.015 ppb. Drinking water exposure through ground water is estimated to be the SCI-GROW default value of 0.006 ppb.

2. Exposure and Risk Characterization

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

RQ = EXPOSURE/TOXICITY

RQs are then compared to levels of concern (LOCs) determined by the

Agency. These LOCs are the criteria used by the Agency to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) acute high, potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification; (2) acute restricted use, the potential for acute risk is high, but this may be mitigated through restricted use classification; (3) acute endangered species, the potential for acute risk to endangered species is high, regulatory action may be warranted; and, (4) chronic risk, the potential for chronic risk is high, regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds); (2) LD50 (birds and mammals; (3) EC50 (aquatic plants and aquatic invertebrates); and, (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates); (2) NOEC (birds, fish, and aquatic invertebrates); and, (3) MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement end point is production of offspring or survival. Risk presumptions, along with the corresponding RQs and LOCs, are tabulated below.

TABLE 13: Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Wild Mammals and Birds		
Acute High Risk	EEC[1]/LC50 or LD50/sqft[2] or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1

TABLE 14: Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOEC	1

[1] EEC = (ppm or ppb) in water

TABLE 15: Risk Presumption for Plants

Risk Presumption	RQ	LOC
Terrestrial and Semi-Aquatic Plants		
Acute High Risk	EEC[1]/EC25	1
Acute Endangered Species	EEC/EC05 or NOEC	1
Aquatic Plants		
Acute High Risk	EEC[2]/EC50	1
Acute Endangered Species	EEC/EC05 or NOEC	1

[1] EEC = lbs ai/A

[2] EEC = (ppb/ppm) in water

a. Ecological Exposure and Risk Characterization

Hydramethylnon is expected to have minimal acute impact other than on the intended target pest. However, available mammalian reproduction data suggest a potential for reproduction effects in terrestrial wildlife species.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Birds may be exposed to granular/bait pesticides such as hydramethylnon by ingesting granules when foraging for food or grit. Hydramethylnon is formulated as a granular bait utilizing soybean oil as the attractant for ants on various inert corn grit carriers. Birds also may be exposed by other routes, such as by walking on exposed granules or drinking water contaminated by granules. The number of lethal doses (LD50s) that are available within one square foot immediately after application ($LD50s/ft^2$) is used as the risk quotient for granular/bait products. Risk quotients are calculated for two separate weight

class of birds: 1200 g (e.g., waterfowl), and 200 g (e.g., upland gamebird).

The acute risk quotients for broadcast applications of granular/bait products are tabulated below.

TABLE 16: Avian Risk Quotients for Granular Products (Broadcast) Based on a quail LD50 of 1828 mg/kg and a mallard duck LD50 of 2510 mg/kg.

Site/ Application Method/Rate in lbs ai/A	% (decimal) of Pesticide Left on the Surface	Body Weight (grams)	LD50 (mg/kg)	Acute RQ[1] (LD50/ft^2)
Granular (Broadcast) 0.0176 lbs ai/A	1.0	200	1828	0.00
Rangeland/Turf/Recreation areas/Nonbearing nursery stock/Nonagricultural uncultivated areas/Terrestrial feed crop (pastures) 0.0176 lbs ai/A	1.0	1200	2510	0.00

[1] RQ = $\frac{\text{App. Rate (lbs ai/A)} * (453{,}590 \text{ mg/lbs}/43{,}560 \text{ ft}^2/\text{A})}{\text{LD50 mg/kg} * \text{Weight of Animal (g)} * 1000 \text{ g/kg}}$

The results indicate that for broadcast applications of granular products, avian acute high risk, restricted use, and endangered species levels of concern are not exceeded at registered maximum single application rates of 0.0176 lbs ai/A.

The lack of avian reproduction data for hydramethylnon precludes a quantitative assessment of chronic risks of hydramethylnon baits to birds. However, the Agency assumes, in the absence of data to the contrary, that avian reproductive endpoints may be as sensitive as mammalian endpoints. Because the concentrations of hydramethylnon in baits (0.88 to 1.65 percent) exceeds the dietary NOAEL (50 ppm) and the LOAEL (100 ppm) for mammalian reproductive effects, the Agency's position is that outdoor uses of hydramethylnon baits may pose a reproductive risk to avian species.

(b) Mammals

Birds and mammals have similar responses to xenobiotics, their differences being more quantitative than qualitative. Birds have lower hepatic microsomal mono-oxygenase and A-esterase activity than do mammals. Therefore, birds are more susceptible than mammals to many pesticides in general. Since hydramethylnon does not present an acute risk to endangered birds, mammals are also presumed to be protected from acute risks.

Mammalian species also may be exposed to granular/bait pesticides by ingesting granules. They also may be exposed by other routes, such as by walking on exposed granules and drinking water contaminated by granules. The number of lethal doses (LD50's) that are available within one square foot immediately after application can be used as a risk quotient (LD50's/ft^2) for the various types of exposure to bait pesticides. Risk quotients are calculated for three separate weight classes of mammals: 15 g, 35 g and 1000 g.

The acute risk quotients for broadcast applications of granular products are tabulated below.

TABLE 17: Mammalian Acute Risk Quotients for Granular Products (Broadcast) Based on Rat LD50 of 817 mg/kg.

Rate in lbs ai/A	Amount of Pesticide Left on the Surface	Body Weight (g)	Rat LD50 (mg/kg)	Acute RQ[1] (LD50/ft^2)
0.0176	1.0%	15	817	0.00
0.0176	1.0%	35	817	0.00
0.0176	1.0%	1000	817	0.00

[1] RQ = $\frac{\text{App. Rate (lbs ai/A)} * (453{,}590 \text{ mg/lbs}/43{,}560 \text{ ft}^2/\text{A})}{\text{LD50 mg/kg} * \text{Weight of Animal (g)} * 1000 \text{ g/kg}}$

The results indicate that for broadcast granular products, mammalian acute high risk, restricted use, and endangered species levels of concern are not exceeded at a registered maximum application rate $\leq$ 0.0176 lb/ai/A.

Presently, the Agency has no standardized method for estimating small terrestrial mammal chronic oral exposures to pesticides, like hydramethylnon, incorporated into bait formulations. However, available information indicates that hydramethylnon concentrations in baits range from 0.88 to 1.65 percent active ingredient. This range in bait concentrations exceeds the mammalian reproductive NOEC of 50 ppm, and encompasses the 100 ppm LOEC for male rat infertility. These findings suggest a potential reproduction risk to terrestrial small mammals in areas of bait application.

(c) Insects

Currently, the Agency does not assess risk to nontarget insects. Results of acceptable studies are used for recommending appropriate label precautions. As hydramethylnon is practically non-toxic to honeybees, label precautions are not needed.

(2) Exposure and Risk to Nontarget Aquatic Animals

As noted above, the Agency calculates EECs using the GENeric Expected Environmental Concentration Program (GENEEC). The EECs are used for assessing surface water concentrations

and for assessing acute and chronic risks to aquatic organisms. Acute risk assessments are performed using peak EEC values for single and multiple applications. Chronic risk assessments are performed using the 21-day EECs for invertebrates and 56-day EECs for fish. EEC values were presented in the Surface Water Assessment section of this document.

(3) Freshwater Fish

Acute risk quotients are tabulated below.

TABLE 18: Risk Quotients for Freshwater Fish

Site/ Application Method/ Rate in lbs ai/A (No. of Apps.)	LC50 (ppm)	NOEC/ MATC (ppm)	EEC Initial/Peak (ppm)	EEC 56-day avg. (ppm)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
Ag areas/aerial 0.0176 (1)	0.09	NA	0.000015	-----	0.00	N/A
Ag areas/ground unincorp. 0.0176 (1)	0.09	NA	0.000015	-----	0.00	N/A

The results indicate that no aquatic acute levels of concern are exceeded for freshwater fish at any registered single application rate ($\leq$0.0176 lb ai/A).

Hydramethylnon appears to bioaccumulate in fish. Bioconcentration factors of 1300X in whole fish, 780X in fillet, and 1900X in viscera have been reported (MRID 00101611). The chemical was observed to depurate slowly. The binding of hydramethylnon to soil may decrease its bioavailability to aquatic organisms, however.

(a) Freshwater Invertebrates

The acute risk quotients are tabulated below.

TABLE 19: Risk Quotients for Freshwater Invertebrates

Site/ Application Method/ Rate in lbs ai/A (No. of Apps.)	LC50 (ppm)	NOEC/ MATC (ppm)	EEC Initial/ Peak (ppm)	EEC 21-Day Average	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
Ag areas/aerial 0.0176 (1)	1.14	NA	0.000015	-----	0.00	??

TABLE 19: Risk Quotients for Freshwater Invertebrates

Site/ Application Method/ Rate in lbs ai/A (No. of Apps.)	LC50 (ppm)	NOEC/ MATC (ppm)	EEC Initial/ Peak (ppm)	EEC 21-Day Average	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
Ag areas/ground unincorp. 0.0176 (1)	1.14	NA	0.000015	-----	0.00	NA

The results indicate that no aquatic acute levels of concern are exceeded for freshwater invertebrates at any single registered application rate (≤0.0176 lb ai/A). There are no data available to assess chronic risk.

The only aquatic use hydramethylnon has is a non-food industrial use in sewage systems. To simulate direct exposure to aquatic organisms, a worst case direct application to water during aerial applications to terrestrial sites was used. For such a case, the Agency assumes simple dilution of the amount applied to a surface acre of water at depths varying from 6 inches to 6 feet. The resulting EECs ranged from 0.0015 ppm to 0.009 ppm (note 0.009 ppm is consistent with the registrant's estimate of water solubility and slightly exceeds published solubility maximum of 0.007 ppm). Since this worst case scenario of direct aerial application to a body of water results in such a low estimate of exposure, the Agency estimates that the exposure of aquatic organisms from use in sewer systems will be far less.

(4) Endangered Species

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

b. Environmental Risk Characterization

Hydramethylnon is an insecticide used to control imported fire ants, harvester ants, big-headed ants, and cockroaches indoors; on agricultural crops, pastures, and rangeland; ornamental and shade trees; ornamental herbaceous plants; and ornamental lawns and turf. In addition, hydramethylnon has been used in sewage systems to coat the backs of manhole

covers. Agency data show that approximately 95% of the chemical's limited usage in pounds per active ingredient is in non-agricultural use, such as homeowner bait use and professional pest control application. About 5% of the total amount used may be in agriculture, primarily on pastures and rangeland. Hydramethylnon is applied in bait boxes or by ground, air, or by hand. The maximum application rate, formulated as a granular bait, is 0.0176 lb a.i./A.

Environmental Fate Summary

Laboratory data indicate that the major routes of hydramethylnon's dissipation on the soil surface are abiotic photolysis and soil binding. The major route of dissipation below the soil surface appears to be soil binding. Hydramethylnon appears to dissipate very slowly by biotic processes. It is stable to hydrolysis at pH 5, pH 7, and pH 9. Furthermore, soil TLC results indicate that hydramethylnon is immobile, and field data appear to confirm the laboratory data as well.

Toxicity Summary

The available acute toxicity data on the TGAI indicate that hydramethylnon is slightly toxic to practically non-toxic to birds, slightly toxic to small mammals, practically non-toxic to bees, and moderately to very highly toxic to freshwater organisms. Hydramethylnon induces male infertility in laboratory mammals. The exact mechanism for these effects is not known at this time. However, hydramethylnon inhibition of electron transport at site II (cytochrome *b-C1* complex) may contribute to direct cellular or tissue toxicity, or may result in some disruption of hormonally-mediated processes.

Risk Assessment/Characterization

For mammals, no acute risks are evident. However, there is a potential for chronic risks to terrestrial mammals consuming hydramethylnon baits. Concentrations of hydramethylnon in bait formulations exceed the mammalian reproduction NOEC and encompass the LOEC. It is therefore possible that dietary incorporation of baits in the field may result in oral exposures approximating reproductive toxicity thresholds in mammalian wildlife. In addition, the Agency does have adverse incident data from the use of hydramethylnon, although the certainty of the incidents is unknown at present.

No avian acute risks are evident. No toxicological data are available to quantitatively assess chronic risks to avian species. However, observation of reproductive effects in mammals suggest that oral exposure of other organisms to hydramethylnon may result in chronic reproductive effects. In the absence of toxicological data to the contrary, the Agency assumes that hydramethylnon has a potential to cause chronic reproductive effects in avian species at concentrations representative of hydramethylnon use in bait formulations. On the basis of this assumption, it is therefore possible that outdoor uses of

hydramethylnon baits may pose a risk to avian wildlife.

No acute LOCs are exceeded for freshwater fish or invertebrates. Chronic risks cannot be evaluated at the present due to lack of data. With regard to plants, aquatic plant testing is not currently required for pesticides other than herbicides and fungicides, except on a case-by-case basis.

The Agency has considered the importance of the mammalian and avian wildlife risk assumptions with respect to the likelihood for terrestrial wildlife exposure. Such a consideration is also useful in evaluating the importance of addressing the current avian reproductive toxicity data gap. Available information indicates that agricultural uses of hydramethylnon encompass approximately 60,000 acres and involve the use of less than 1,000 pounds of active ingredient. In addition, non-agricultural uses, which may account for an additional 21,500 to 36,000 pounds of hydramethylnon, may also include outdoor uses which may result in exposure to terrestrial organisms.

Although the future geographic extent of hydramethylnon usage is uncertain, the Agency believes that the number of acres treated increases the potential for localized wildlife effects. Therefore, the Agency requires that avian reproduction data be submitted to more clearly define toxicological thresholds for such species or that measures be taken to significantly reduce or eliminate the outdoor uses of hydramethylnon.

Drinking Water Assessment

The Agency believes that hydramethylnon should not pose a major threat to surface and ground water quality because it has a high binding affinity (Kd>1039 ml/g) on soil and the outdoor (non-bait) use is limited. However, the impact of hydramethylnon phototransformation products on surface and ground-water quality cannot be assessed due to insufficient data. Additional mobility data are needed to assess the environmental fate of phototransformation products.

The peak GENEEC estimated environmental concentration of hydramethylnon in surface water is 0.015 ppb. Drinking water exposure through ground water is estimated to be the SCI-GROW default value of 0.006 ppb.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing

hydramethylnon. 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 hydramethylnon. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of hydramethylnon and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of hydramethylnon, and to determine that hydramethylnon can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing hydramethylnon 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 hydramethylnon 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 hydramethylnon, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

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

2. Eligible and Ineligible Uses

The Agency has determined that all hydramethylnon uses as previously described are eligible for reregistration.

The Agency has determined that registrants may distribute and sell hydramethylnon products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks

requirements applicable to products they sell or distribute.

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

3. Tolerance Reassessment

Existing tolerances of 0.05 ppm are currently established for the insecticide hydramethylnon in or on grasses, forage (pasture and rangeland) and grasses, hay (pasture and rangeland), respectively (40 CFR §180.395). The Agency no longer distinguishes between rangeland and pastures. The Agency recommends that the grass forage tolerance be increased to 2.0 ppm and the grass hay tolerance be increased to 0.1 ppm. These tolerances have been corrected to a zero day (0-day) post harvest interval (PHI). The Agency no longer allows a PHI restriction for use on grass. There is a 7-day baling restriction for grass hay. The meat, milk, and meat byproducts tolerance will remain in a 40 CFR § 180.6(a)3 status.

4. Tolerance Revocations and Import Tolerances

As part of EPA's reregistration eligibility decision for hydramethylnon, the existing tolerances on grasses (pasture and rangeland) will be amended. If a pesticide use is no longer registered in the United States, the related pesticide residue tolerance and/or food/feed additive regulation generally is no longer needed. It is EPA's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. EPA has the responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke a tolerance/regulation on the grounds that the Agency cannot conclude that the tolerance/regulation is protective of the public health.

The Agency recognizes, however, that interested parties may want to retain a tolerance and/or food/feed additive regulation in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, EPA requires the same technical chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. See 40 CFR Part 158 for EPA's data requirements to support domestic use of a pesticide and establishment and maintenance of a tolerance and/or food/feed regulation. In addition, EPA requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that EPA requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation. Additional guidance on the Agency's import tolerance policy will be published in an upcoming *Federal Register* Notice.

Codex Harmonization

No Codex Maximum Residue Levels (MRLs) have been established for hydramethylnon; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

5. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

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

For hydramethylnon, there is little likelihood of residues in water or food items and non-accidental residential exposure will be minimal. Therefore, no acute or chronic dietary, or drinking water risk assessments were conducted and aggregate risk assessments are not necessary for hydramethylnon at this time.

The Agency has not yet made a determination regarding the common mode/mechanism of toxicity of hydramethylnon and whether it is appropriate to consider exposure from hydramethylnon with other compounds in order to address cumulative effects. In general, after EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier. However, with respect to hydramethylnon tolerance reassessment, any future cumulative risk determination regarding other chemicals that have a common mode of toxicity with hydramethylnon will not include the uses of hydramethylnon discussed in this document because the exposures from hydramethylnon use as described in this RED are so unlikely. For the purposes of this reregistration decision, all hydramethylnon tolerances are assumed to be reassessed.

However, based on the high MOEs for hydramethylnon and its negligible dietary sources, drinking water and non-occupational exposures, the contribution of hydramethylnon exposures to the risks of other compounds with a common mode/mechanism of toxicity is likely to be minimal.

b. Determination of Safety for Infants and Children

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

The Agency does not believe that exposure from the accidental ingestion of baits should be used in making the tolerance safety finding under FQPA. These exposures are accidental in nature and should not be considered as part of the FQPA calculus for non-occupational exposure. In addition, the dietary and drinking water contributions from hydramethylnon are negligible.

In determining whether infants and children are particularly susceptible to the toxic effects from hydramethylnon residues, EPA considers the completeness and reliability of the toxicity data base, the nature of the effects observed in toxicity studies, and other information. The Agency evaluated a two-generation reproduction study in rats and a prenatal developmental toxicity study in rats and rabbits. There was no evidence of pre or post natal sensitivity in any of these studies. The developmental effects and effects on offspring occurred at dose levels that were equal to or greater than the maternal NOAELs. Thus, the Agency has concluded that there is no special sensitivity to infants and children from hydramethylnon exposure.

In addition, the Agency believes there is little likelihood of direct exposure to infants and children since hydramethylnon has one food use and will not result in drinking water exposure. Any residential exposures are expected to be minimal and within safe MOEs. The Agency does not have concerns for prenatal exposures based on the adequate MOEs, the highest risk users, and the lack of increased susceptibility seen in the developmental and reproduction studies.

In examining aggregate exposure, EPA takes into account available information concerning exposures from dietary sources, drinking water and non-occupational sources. As noted in the preceding paragraph, the primary source of hydramethylnon exposure is occupationally related.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementations, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of

FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

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

6. Occupational Labeling Rationale/Risk Mitigation

Hydramethylnon pesticide products that are intended for occupational use are within the scope of the Worker Protection Standard.

The Worker Protection Standard (WPS)

On August 21, 1992, the Agency issued worker protection regulations affecting all pesticide products whose labeling reasonably permits use in the production of agricultural plants on any farm, forest, nursery or greenhouse. In general, products within the scope of the Worker Protection Standard (WPS) had to bear complying labeling when sold or distributed by the registrant after April 21, 1994.

The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted entry intervals (REI), and notification are interim. The interim WPS handler PPE requirements are based solely on the acute dermal and inhalation toxicity and skin and eye irritation potential of the end-use product. The interim WPS restricted-entry intervals for agricultural workers are based solely on the acute dermal toxicity and skin and eye irritation potential of the active ingredient. The interim WPS "double" notification requirement is imposed if the active ingredient is classified as toxicity category I for acute dermal toxicity or skin irritation potential. "Double" notification is the statement on the labels of some pesticide products requiring employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The WPS retained more stringent PPE, REI, and notification requirements from existing labeling. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes. During reregistration, the Agency reviews risks resulting from WPS uses as well as from all other occupational and residential uses.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators)

Occupational handler exposures and risks are evaluated jointly. As a result of the reregistration evaluation of the acute and other adverse effects of hydramethylnon, the Agency has determined that risks to handlers do not warrant the establishment of active-ingredient-based minimum personal protective equipment or engineering-control

requirements that would apply to all hydramethylnon end-use products. The risks to handlers are adequately mitigated with the addition of water resistant gloves for most handler scenarios. Therefore, the Agency is requiring that all handlers wear water- resistant gloves.

Worker Notification

Hydramethylnon is not classified as toxicity category I for select acute dermal toxicity or skin irritation potential and is not classified as a severe skin sensitizer. EPA has no special concerns about hydramethylnon for adverse effects where a single exposure can trigger the effect and EPA has not established an unusually long restricted-entry interval. Therefore, at this time, EPA is not requiring a WPS "double" notification statement on the labeling of hydramethylnon end-use products.

7. Endocrine Disruptor Effects

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

8. Environmental Assessment

Based upon available data, the Agency concludes that risk to freshwater and terrestrial organisms and water resources will be minimal. No additional label statements are required. Certain additional confirmatory data are being required.

9. Restricted Use Classification

Hydramethylnon does not require and is not being considered for restricted use.

10. Endangered Species Statement

The Agency has developed a program (the “Endangered Species Protection Program”) to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, l989), and is providing information

to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

The Agency will consult with the Fish and Wildlife Service and/or the National Marine Fisheries Service if necessary to determine if steps need to be taken to protect newly listed species or from proposed new uses of these hydramethylnon.

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 hydramethylnon has been reviewed and determined to be substantially complete. All product chemistry data requirements will be satisfied when the registrant certifies that suppliers of beginning materials and the manufacturing process for hydramethylnon have not changed since the last comprehensive product chemistry review. The following guideline studies are new requirements are now being called in:

GLN 71-4 Avian Reproduction
GLN 830.7050 UV/visible absorption for PAI

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the labeling contained in Table 20.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made.

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

The reregistration of hydramethylnon in the United States is being supported by American Cyanamid Company. Agency records identified five end-use products (EPs) with food/feed uses registered to American Cyanamid Company. The only hydramethylnon food use being supported for reregistration is grass forage and grass hay. The application of hydramethylnon as a bait in domestic dwellings and commercial establishments has been determined to be a non-food use.

2. Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. All end-use product labels [e.g. multiple active ingredient (MAI) labels, SLN's, and products subject to generic data exemption] must be amended such that they are consistent with the basic producer labels. End use product labels must also bear labeling as specified in Table 20.

Table 20: Summary of Required Labeling Changes for Hydramethylnon		
Description	**Required Labeling**	**Placement on**
Manufacturing Use		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into a insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
End Use Products Intended for Occupational Use (WPS and Non-WPS))		
Minimum (Baseline) PPE Requirements	"Personal Protective Equipment (PPE) Applicators and other handlers must wear: Long-sleeve shirt and long pants Water-resistant gloves Shoes plus socks."	Precautionary Statements: Hazards to Humans and Domestic Animals

User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls	"Engineering Controls When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4.6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Hazards to Humans and Domestic Animals (Must be placed in a box.) (Immediately following Engineering Controls)

Restricted-Entry Interval (required by Supplement Three of PR Notice 93-7)	A 12-hour restricted entry interval (REI) is required.	Directions for Use, Agricultural Use Requirements Box
Personal protective equipment required for early entry	"The PPE required for early entry is: Coveralls, Water resistant gloves, and Shoes plus socks."	
Application Restrictions	"Do not apply this product by any method not specified on this label." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use

The following language must be placed on each product that can be applied aerially:	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1.The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2.Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." **"INFORMATION ON DROPLET SIZE"** "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use

The following language must be placed on each product that can be applied aerially:	**"CONTROLLING DROPLET SIZE"** "**!** Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. **!** Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. **!** Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. **!** Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. **!** Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"BOOM LENGTH"** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use

The following language must be placed on each product that can be applied aerially:	**"APPLICATION HEIGHT"** "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"WIND"** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE AND HUMIDITY**" "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use

The following language must be placed on each product that can be applied aerially:	**"TEMPERATURE INVERSIONS"** "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"SENSITIVE AREAS"** "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use
Application Restrictions for all products with uses on rangeland and pasture (grass forage).	The label must state for use on grass forage. The terms "pasture" and "rangland grasses" are no longer acceptable and must be removed from the label. Post harvest inervals on grass forage must be removed.	Directions For Use
Products used to control imported fire ants.	"This product may only be used in the following States: AL, AR, FL, GA, LA, MS, NC, OK, SC, TN, TX, and VA.	Directions For Use
Products used on non-bearing nursery stocks.	Labeling must be submitted restricting harvesting of food/feed within one year of application on non-bearing nursery stocks.	Directions For Use
All Residential/Consumer/ Homeowner Use Products		

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

C. Tolerance Adjustments

Tolerances and labels for hydramethylnon on grasses should be adjusted so as to permit use on grass forage (both pasture and rangeland grasses). The Agency no longer differentiates between these sites. Tolerances for hydramethylnon on grass forage should be corrected to a 0-day post harvest interval (PHI). The Agency publish a Federal Register Notice that announces the amended tolerances. The labels should remove any PHI on grass forage as the Agency no longer permits this restriction. Hydramethylnon as an imported fire ant bait on grasses is restricted to the following states where infestation has been documented and supporting data is in place: Alabama, Arkansas, Florida, Georgia, Louisana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Restrict against harvesting of food/feed within one year of application on non-bearing nursery stocks.

D. Existing Stocks

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

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

VI. APPENDICES

Appendix A is 26 pages long and is not being included in this RED. Copies of Appendix A are available upon request per the instructions in Appendix E.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 2585 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Hydramethylnon 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) 605-6000.

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 Hydramethylnon (118401)

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
61-1	**Chemical Identity**		ALL	41612501
61-2A	**Start. Mat. & Mnfg.**	**Process**	ALL	41612501
61-2 B	**Formation of Impurities**		ALL	41612501
62-1	**Preliminary Analysis**		ALL	41612502
63-2	**Color**		ALL	41612502
63-3	**Physical State**		ALL	41612502
63-4	**Odor**		ALL	41612502
63-5	**Melting Point**		ALL	41612502
63-7	**Density**		ALL	41612502
63-8	**Solubility**		ALL	41612502
63-9	**Vapor Pressure**		ALL	41612502
63-10	**Dissociation Constant**		ALL	41612502
63-11	**Octanol/Water Partition**		ALL	41612502
63-12	**pH**		ALL	41612502
63-13	**Stability**		ALL	41612502

Data Supporting Guideline Requirements for the Reregistration of Hydramethylnon (118401)

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1	**Acute Avian Oral - Quail/Duck**	BC	64575, 64576
71-2A	**Avian Dietary - Quail**	BC	64577, 98982
71-2B	**Avian Dietary - Duck**	BC	85931, 98982
72-1A	**Fish Toxicity Bluegill**	BC	52858
72-1B	**Fish Toxicity Rainbow Trout**	BC	35279
72-2	**Invertebrate Toxicity**	BC	99779
141-1	**Honey Bee Acute Contact**	BC	41607801
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	ALL	41612503
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	ALL	41612504
81-3	**Acute Inhalation Toxicity - Rat**	ALL	42871101
81-4	**Primary Eye Irritation - Rabbit**	ALL	41612505
81-5	**Primary Dermal Irritation - Rabbit**	ALL	41612506
81-6	**Dermal Sensitization - Guinea Pig**	ALL	101560
82-1A	**90-Day Feeding - Rodent**	BC	32641
82-1B	**90-Day Feeding - NonRodent**	BC	61794

Data Supporting Guideline Requirements for the Reregistration of Hydramethylnon (118401)

REQUIREMENT		USE PATTERN	CITATION(S)
82-2	**21-Day Dermal - Rabbit**	BC	101559
83-1A	**Chronic Feeding Toxicity - Rodent**	BC	**61768, 101565, 126106**
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	BC	61794, 35529
83-2A	**Oncogenicity - Rat**	**BC**	126106
83-2B	**Oncogenicity - Mouse**	BC	35526, 101563, 40871801
83-3A	**Developmental Toxicity - Rat**	BC	61790
83-3B	**Developmental Toxicity - Rabbit**	BC	101558
83-4	**2-Generation Reproduction - Rat**	BC	43741501
84-2A	**Gene Mutation - Ames**	BC	42132701
84-2B	**Structural Chromosomal Aberration**	BC	40422401, 35897
84-4	**Other Genotoxic Effects**	BC	40407602
85-1	**General Metabolism**	BC	42448902
85-2	**Dermal Penetration**	BC	40407602
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	ALL	42194701
161-2	**Photodegradation - water**	ALL	42238201, 42473301
161-3	**Photodegradation - soil**	ALL	42353801

Data Supporting Guideline Requirements for the Reregistration of Hydramethylnon (118401)

REQUIREMENT		USE PATTERN	CITATION(S)
162-1	**Aerobic Soil Metabolism**	BC	42320801
162-3	**Anerobic Aquatic Metabolism**	BC	43102701
162-1	**Aerobic Soil Metabolism**	BC	42320801
165-4	**Bioaccumulation in Fish**	BC	101611
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	BD	43744501
171-4B	**Nature of Residue - Livestock**	BD	42871102
171-4C	**Residue Analytical Method - Plants**	BD	43345203, 43485201, 43632801
171-4C	**Residue Analytical Method - Animals**	BD	34024, 34025, 61804, 61805
171-4E	**Storage Stability**	BD	43636702
171-4K	**Crop Field Trials -Grass forage and hay**	BC	61797, 61798, 43485201

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

word "received."

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

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

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

BIBLIOGRAPHY

MRID	CITATION
00032641	Tegeris, A.S.; Sagartz, J.W.; Salib, M.H.; et al. (1979) AC 217, 300: 91-Day Study in the Rat: Report No. 7866; Report No. P-98178-143-1. (Unpublished study received June 11, 1980 under 241260; prepared by Pharmacopathics Research Laboratories, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 099452-A)
00034020	Tondreau, R.E. (1979) CL 217,300: Validation of GC Method M-1000 for the Determination of CL 217,300 Residues in Pasture Grass: Report No. C-1597. Includes method M-1000 dated Aug 24, 1979. (Unpublished study received June 11, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099454-A)
00034021	Tondreau, R.E.; Wang, T.; Williams, D.; et al. (1979) CL 217,300: Residues of 217,300 in Grass (GND; FL, 1979) (C-1597): Report No. C-1598. (Unpublished study received June 11, 1980 under 241-260; prepared in cooperation with U.S. Dept. of Agriculture, Science and Education Administration, submitted by American Cyanamid Co., Princeton, N.J.; CDL:099454-B)
00034025	Tondreau, R.E.; Manuel, A.J. (1980) CL 217,300: Validation of GC or HPLC Method M-1046 for the Determination of CL 217,300 Residues in Milk: Report No. C-1647. Includes method M-1046 dated Feb 4, 1980. (Unpublished study received June 11, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 099454-F)
00035525	Schroeder, R.E.; Rinehart, W.E. (1980) A Three-Generation Reproduction Study with AC 217,300 in Rats: Status Report: Project No. 79-2412. (Unpublished study received July 1, 1980 under 241260; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:099489-A)
00035526	Jessup, D.C.; Homan, S.P.; Miller, P. (1980) Eighteen-Month Feeding Study of AC 217,300 to Mice (6-Month Interim Report): IRDC 141-013. (Unpublished study received July 1, 1980 under 241-260; prepared in cooperation with International Research and Development Corp., submitted by American Cyanamid Co., Princeton, N.J.; CDL:099489-B)
00035529	Wolfe, G.W.; Marshall, P.M.; Weatherholtz, W.M.; et al. (1980) Twenty-Six Week Toxicity Study in Dogs: AC 217,300: Project No. 362-156. Final rept. (Unpublished study received July 1, 1980 under 241-260; prepared by Hazleton Laboratories America, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 099487-B)
00061790	Schroeder, R.E.; Rinehart, W.E.; Bshasso, L.; et al. (1979) Teratogenesis Study in Rats with AC 217,300: Project No. 79-2382. Final rept. (Unpublished study received July 1, 1980 under 241260; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:099770-G)
00061794	Tegeris, A.S.; Sagartz, J.W.; Myers, A.K.; et al. (1979) AC 217,300: 91-Day Study in the Dog: Report No. 7864; Report No. P-981-78-142. (Unpublished study received July 1, 1980 under 241-260; prepared

BIBLIOGRAPHY

MRID **CITATION**

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by Pharmacopathics Research Laboratories, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 099772-A)

00101558 Schardein, J.; Lang, P.; Laughlin, K.; et al. (1982) Teratology Study with AC 217,300 in Rabbits: 141-024. (Unpublished study received May 14, 1982 under 2F2627; prepared by International Research and Development Corp., submitted by American Cyanamid Co., Princeton, NJ; CDL:070849-C)

00101559 Thompson, G.; Rao, G.; MacWilliams, P.; et al. (1982) Subchronic 21-day Dermal Toxicity Study of AC 217,300 in Rabbits: Raltech Study No. 80033. Final rept. (Unpublished study received May 14, 1982 under 2F2627; prepared by Hazleton Raltech, Inc., submitted by American Cyanamid Co., Princeton, NJ; CDL:070849-D)

00101560 Siglin, J.; Becci, P. (1982) Dermal Sensitization Study in Guinea Pigs with AC 217,300 Technical (92%) and AC 217,300 3.2% Concentrate: FDRL Study No. 7180. Final rept. (Unpublished study received May 14, 1982 under 2F2627; prepared by Food and Drug Research Laboratories, Inc., submitted by American Cyanamid Co., Princeton, NJ; CDL:070849-E)

00101563 Brewer, L. (1982) Eighteen-month Feeding Study of AC 217,300 to Mice: 141-013. (Unpublished study received May 14, 1982 under 2F2627; prepared by International Research and Development Corp., submitted by American Cyanamid Co., Princeton, NJ; CDL: 070850-A; 070851; 070852; 070853; 070854)

00101565 Blair, M.; Brewer, L.; Kopplin, J. (1982) 24-month Feeding Study of AC 217,300 to Rats: 141-014. (Unpublished study received May 18, 1982 under 241-260; prepared by International Research and Development Corp., submitted by American Cyanamid Co., Princeton, NJ; CDL:070865-B; 070866; 070867; 070868; 070869)

00106033 Kim, D. (1982) Amdro Fire Ant Insecticide (Cl 217,300): Determination of the Vapor Pressure of Cl 217,300 by the Gas-saturation Technique: Report No. PD-A 18-1: 1-10. (Unpublished study received June 23, 1982 under 241-267; submitted by American Cyanamid Co., Princeton, NJ; CDL:247831-A)

00101611 Barringer, D.; Stanley-Millner, P. (1982) Amdro Fire Ant Insecticide (CL 217,300): Identification and Characterization of CL 217,300 and Its Metabolite in Bluegill Sunfish Exposed to 1.8 ppb of CL 217,300 in Water: Report No. PD-M 19-6:1-185. (Unpublished study received May 14, 1982 under 241-260; submitted by American Cyanamid Co., Princeton, NJ; CDL:247502-D)

00164248 Morrissey, A. (1979) The Acute Toxicity of AC 217,300 to the Water Flea: Daphnia magna Straus: UCES Project No. 11506-20-21. Unpublished study prepared by Union Carbide Environmental Services, Union Carbide Corp. 10 p.

BIBLIOGRAPHY

MRID	CITATION
40098001	Mayer, F., Ellersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base 410 Chemicals and 66 Species of Freshwater Animals. US Fish and Wildlife Service; Resource Publication (160): 579 p.
41607801	Thompson, M.; Hoxter, K.; Smith, G. (1990) AC 217,300: An Acute Contact Toxicity Study with the Honey Bee: Lab Project Number: 130-151B. Unpublished study prepared by Wildlife International Ltd. 26 p.
41612501	Long, D.; Cardaciotto, S.; Conley, J. (1990) Product Identity, Description of Manufacturing Process and Discussion of Impurities for Technical AMDRO. Unpublished study prepared by American Cyanamid Co. 151 p.
41612502	Long, D.; Teeter, J.; Mangels, G. (1990) EPA Pesticide Assessment Guidelines, Subdivision D-Product Chemistry, Physical and Chemical Characteristics of the Technical/ Manufacturing Use Product: Technical AMDRO: Lab Project Number: CHDVVOLUME30/REPORT. Unpublished study prepared by American Cyanamid Co. 180 p.
41612503	Fischer, J. (1990) Oral LD50 Study in Albino Rats with AC 217,300 [Amdro Technical Insecticide]: Lab Project Number: A90-117. Unpublished study prepared by American Cyanamid Co. 14 p.
41612504	Fischer, J. (1990) Dermal LD50 Study in Albino Rabbits with AC 217, 300 [Amdro Technical Insecticide]: Lab Project Number: A90-114. Unpublished study prepared by American Cyanamid Co. 11 p.
41612505	Lowe, C. (1990) Eye Irritation Study in Albino Rabbits with AC 217, 300 [AMDRO Technical Insecticide]: Lab Project Number: A90-140. Unpublished study prepared by American Cyanamid Co. 12 p.
41612506	Fischer, J. (1990) Skin Irritation Study in Albino Rabbits with AC 217, 300 [Amdro Technical Insecticide]: Lab Project Number: A9095. Unpublished study prepared by American Cyanamid Co. 12 p.
41888302	Mangels, G. (1990) Hydramethylnon (AC217,300): Adsorption/Desorption: Lab Project Number: E-90-21. Unpublished study prepared by American Cyanamid Co. 35 p.
42194701	Beckman, K.; Cranor, W. (1992) Hydrolysis of Hydramethylnon as a Function of pH at 25 C: Lab Project Number: 38960. Unpublished study prepared by ABC Labs., Inc. 67 p.
42238201	Cranor, W.; Beckman, K. (1992) Determination of the Aqueous Photolysis Rate of Hydramethylnon (Interim Report): Lab Project Number: 38961. Unpublished study prepared by ABC Labs, Inc. 51 p.

BIBLIOGRAPHY

MRID	CITATION
42320801	Gorman, M. (1992) Aerobic Soil Metabolism of Hydramethylnon: Lab Project Number: 38977. Unpublished study prepared by ABC Laboratories, Inc. 86 p.
42353801	Melcer, M. (1992) Hydramethylnon (AC 217,300): Photodegradation on Soil: Lab Project Number: E-91-9. Unpublished study prepared by American Cyanamid Comp. 192 p
42473301	Cranor, W. (1992) Determination of the Aqueous Photolysis Rate of Hydramethylnon: [Final Report]: Lab Project Number: 38961. Unpublished study prepared by ABC Labs, Inc. 79 p.
42871101	Hoffman, G. (1993) Acute Inhalation Toxicity Study with AC217,300 in Rats: Hydramethylnon: Lab Project Number: 92-8399. Unpublished study prepared by Bio/dynamics, Inc. 197 p.
42871102	Hoffman, S.; Robinson, R. (1993) Hydramethylnon (CL217,300): Metabolism Fate of Carbon 14 Labeled CL217,300 in Milk and Edible Tissues of the Lactating Goat: Lab Project Number: XBL91049: M91A300NJ1: M 91A300NJ1. Unpublished study prepared by Hazleton Wisconsin, Inc. and Xeno Biotic Labs, Inc. 423 p.
43093901	Sharp, D. (1993) Dermal Absorption of AC 217,300 Gel in Male Rats: Lab Project Number: HWI 6123-180. Unpublished study prepared by Hazleton Wisconsin, Inc. 88 p.
43293101	York, C. (1994) CL 217,300 (hydramethylnon/G): Rate of Dissipation of CL 217,300 Residues in Soil after Treatment with AMDRO Fire Ant Insecticide (FL; 1992): Lab Project Number: RES/94/051. Unpublished study prepared by American Cyanamid Co., Huntingdon Analytical Services. 120 p.
43293102	York, C. (1994) CL 217,300 (hydramethylnon/G): Rate of Dissipation of CL 217,300 Residues in Soil after Treatment with AMDRO Fire Ant Insecticide (TX; 1992): Lab Project Number: RES/94/065. Unpublished study prepared by American Cyanamid Co., Huntingdon Analytical Services. 119 p.
43485201	Schaefer, T. (1994) CL 217,300 (Hydramethylnon): Residues of CL 217,300 in Pasture/Rangeland Grass after Ground Applications of AMDRO Granular Insecticide: Lab Project Number: CY78: RES 94-032: RES 94-102. Unpublished study prepared by American Cyanamid Co. and Huntingdon Analytical Services. 418 p.
43636702	Khunachak, A. (1995) CL 217,300: Freezer Stability of Residues of CL 217,300 in Pasture Grass: Lab Project Number: RES 95-017: AM92PT02: A011.098. Unpublished study prepared by American Cyanamid Co. and Huntingdon Analytical Services. 39 p.
43741501	Schoeder, R. (1995) A Two-Generation Reproduction Study with AC 217,300 in Rats: Final Report: Lab Project Number: 92-4046: 971-92-115. Unpublished study prepared by Pharmaco LSR, Inc. 1658 p.

BIBLIOGRAPHY

MRID	CITATION

43744501 Lansinger, J. (1995) CL 217,300: Metabolism of Carbon-14 Labeled CL 217,300 in Rangeland Grass: Lab Project Number: MET 95-013: M93P300CA1. Unpublished study prepared by American Cyanamid Co. and Pan-Agricultural Labs, Inc. 378 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

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

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

This Notice is divided into six sections and 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 - Generic Data Call-In and Product Specific Data Call-In Response Forms(Insert A) with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms (Insert B) with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Insert B) 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 (Telephone number: 703-605-6000).

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

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

a. Voluntary Cancellation -

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

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

b. Use Deletion -

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

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

c. Generic Data Exemption -

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

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

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

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

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

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

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

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

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

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

Option 1. Developing Data

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

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for

studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

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

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may

request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you did not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed Certification with Respect to Citations of Data (in PR Notice 98-5) (EPA Form 8570-34) . In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B) committing to develop and submit the data required by this Notice.

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

Option 4. Submitting an Existing Study

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

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

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

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

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submission of 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 documents available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

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

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

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

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 entitled "Standard Format for Data Submitted under FIFRA."

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

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

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

Option 6. Citing Existing Studies

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

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form No. 8570-34, Certification with Respect to Citations of Data.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form(Insert A) that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form(Insert B) 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(Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

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

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

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

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

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

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

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

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

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

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

and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

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

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

   a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant’s Response Form(Insert B).

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

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

Hydramethylnon DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Cynthia Williams at (703) 308-8195.

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

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

RE: **2585**

Hydramethylnon DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Dean Monos at (703) 308-8074.

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

Dean Monos, Chemical Review Manager
Reregistration Branch 3
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: 2585

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

INTRODUCTION

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

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

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

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

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FOR BOTH MUP and EUP products

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

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2137, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" (Insert B)

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific

requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my

own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

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

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

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

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

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

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

submission of data as specified by the original Data Call-In notice will not change.

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

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

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

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

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

EPA'S BATCHING OF AMDRO PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers

to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Twenty-eight active products were found which contain Amdro as the active ingredient. These products have been placed in three batches and a "no batch" group based on the active and inert ingredients and formulation type. Furthermore, the following bridging/citing strategies may also be employed:

- Products in batch 1 may cite category III/IV acute data performed with technical Amdro.

- With the exception of primary eye irritation, products in batch 2 may cite category III/IV acute data performed with technical Amdro.

- With the exception of primary eye irritation, products in batch 3 may cite category III/IV acute data performed with technical Amdro.

The technical Amdro acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	% Active Ingredient	Formulation Type
	241-260	0.88	Solid
	241-261	0.88	Solid
	241-322	0.73	Solid
	241-357	0.73	Solid
	241-358	0.88	Solid
	241-371	0.31	Solid
	64240-1	1.0	Solid
	64240-2	2.0	Solid
	64240-25	1.0	Solid
	64240-27	0.5	Solid
	64240-28	0.65	Solid
	64248-5	2.15	Gel

Batch 1	EPA Reg. No.	% Active Ingredient	Formulation Type
	64248-6	1.0	Solid
	64248-7	0.65	Solid

Batch 2	EPA Reg. No.	% Active Ingredient	Formulation Type
	241-293	1.65	Solid
	241-304	1.0	Solid
	241-320	0.9	Solid
	64240-3	0.9	Solid
	64240-4	1.0	Solid
	64240-5	0.9	Solid
	64248-1	2.0	Solid
	64248-2	1.0	Solid
	64248-3	1.0	Solid

Batch 3	EPA Reg. No.	% Active Ingredient	Formulation Type
	241-313	2.0	Solid
	64240-10	2.0	Solid
	64240-35	2.15	Solid
	64248-4	2.0	Solid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	241-270	95.0	Solid

This page has been inserted as a place marker and is replaced by an electronically generated PDCI List of Registrants page number 1 in the actual Printed version of the Red document

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   c. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   d. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   e. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   f. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.
3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

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

Electronic
File Format: Portable Document Format (.PDF) requires Adobe® Acrobat or compatible reader. Electronic copies are available on our website at www.epa.gov/REDs, or contact Dean Monos at (703) 308-8074.

1. PR Notice 86-5.
2. PR Notice 91-2
3. A full copy of this RED document
4. A copy of the fact sheet for Hydramethylnon

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

1. Health and Environmental Effects Science Chapters.

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