United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-003
April 1995

Reregistration Eligibility Decision (RED)

Ethephon

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 ethephon. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, 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 also includes requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative, Wanda Daughtry at (703) 308-8171. Address any questions on required generic data to the Special Review and Reregistration Division representative, Judy Loranger at (703) 308-8056.

Sincerely yours,

Peter Caulkins, Acting Director
Special Review
and Reregistration Division

Enclosures

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

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--A Product Specific Data Call-In is enclosed with this RED and must be completed and submitted within 90 days of receipt of this package. The response consistes of a "Data Call-In Response" form and a "Requirements Status and Registrant's Response" form. Additional generic may also be required to confirm or support the assessment of the active ingredient. If generic data are required, Generic Data Call-Ins are being sent only to certain manufacturing use registrants. Generic Data Call-Ins are **not** being sent to end use product registrants. However, please note that instructions for completing the Data Call-Ins, which are incorporated as an Appendix to the RED, may address both generic and product specific data. If you are an end use registrant, be sure to follow the instructions for product specific data.

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

ETHEPHON

LIST A

CASE 0382

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

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ETHEPHON REREGISTRATION ELIGIBILITY DECISION TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
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
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide ethephon.

Ethephon is a plant growth regulator used to promote fruit ripening, abscission, flower induction, breaking of apical dominance and other plant responses. Ethephon is registered for use on a number of terrestrial food, feed and nonfood crops, greenhouse nonfood crops and outdoor residential plants. Ethephon formulations include formulated intermediates and soluble concentrates. Application is by broadcast to plant foliage by either ground or aerial equipment. Ethephon may also be applied by hand sprayer to select home garden vegetables.

Ethephon was discovered in 1965 and introduced commercially in 1973 by the AmChem/Union Carbide company as a plant growth regulator. The Union Carbide registrations were sold to Rhone-Poulenc Ag Company. Cedar Chemical Corporation also has registered ethephon products. The Registration Standard on ethephon (NTIS # PB89-109427) was issued in September 1988. The Registration Standard continued the registration of ethephon but required submission of environmental fate, toxicology, residue chemistry, and environmental effects data. This RED document reflects a reassessment of all data which were submitted in response to the Registration Standard.

The Agency has now completed its review of the ethephon target data base including data submitted in response to the Registration Standard and has determined that uses of ethephon as currently registered will not cause unreasonable risk to humans or the environment. All currently registered uses of ethephon are eligible for reregistration. The Agency is, however, requiring product chemistry, poultry metabolism (Guideline 171-4b), residue analytical method in plants and animals (Guideline 171-4c/d), storage stability (Guideline 171-4e), magnitude of the residue in peppers, cantaloupes, grapes, wheat forage and hay, and cotton gin byproducts (Guideline 171-4k), magnitude of the residue in processed sugarcane (Guideline 171-4l), magnitude of the residue in poultry and ruminants (Guideline 171-4j), a batch equilibrium study on the degradate 2-hydroxy ethyl phosphonic acid (Guideline 163-1), and acute and subchronic neurotoxicity (Guidelines 81-8 and 82-7). These data are required to confirm the reregistration eligibility of ethephon.

The Agency has determined that there is limited potential for risk to certain nontarget plants from use of ethephon on cotton, macadamia nuts, pineapples, tobacco, blackberries and apples in North Carolina. The registrant has proposed reducing the use rate on blackberries and on apples in North Carolina. In addition the Agency has reviewed information provided by the registrant indicating that maximum use rates of ethephon are only required when certain weather conditions exist. The Agency has determined that most uses of ethephon would be below the maximum rate and the risk quotient would, therefore, be below the Agency's level of concern. The Agency has concluded that with these risk reduction measures the risk to nontarget plants from the use of ethephon will be limited.

Ethephon was classified as a Group D chemical (indicating insufficient weight of evidence of carcinogenicity for humans) based on available data. A Reference Dose (RfD) was established as 0.018 mg/kg/day based on clinical signs of toxicity observed at 1.8 mg/kg/day in a 28-day oral human study. An uncertainty factor of 100 was used to account for intraspecies variability and the lack of a NOEL.

The Agency has conducted acute dietary exposure and risk assessments using USDA food consumption information to estimate the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The one day dietary endpoint of concern of 1.8 mg/kg/day, based on cholinergic effects was derived from a 28-day oral human toxicity study. Margins of exposure (MOE), estimates of how closely exposure comes to the dose of concern (1.8 mg/kg/day), were calculated for various population subgroups. Agency estimates indicate that acute dietary exposures to infants (less than 1 year of age) may be of concern when the 95th percentile of exposure is used. However, the Agency has employed numerous conservative assumptions in calculating the acute dietary risk relative to the exposure. The Agency assumed that all food crops on which ethephon is registered have been treated with ethephon and that maximum residue levels reported in or on unwashed, unpeeled, uncooked commodities at the farm gate are present on all foods. However usage data indicate that the treatment percentage of major infant foods on which ethephon is registered is $< 10\%$ or even "negligible". The probable residue dilution that occurs in processed infant foods was not taken into account. In addition, ethephon degrades fairly rapidly to ethylene, phosphate and chloride in neutral and alkaline environments. Therefore, by the time the food has cleared distribution channels and/or processing plants, residues at the dinner table are likely to be significantly lower than high-end levels at the farm gate. The Agency believes that the acute dietary risk values for infants listed in Section III, B, 3 of this document represent an unrealistic worst case situation and actual risks to infants are likely to be minimal.

A 48 hour restricted-entry interval (REI), as imposed by the Worker Protection Standard (WPS), will be retained based on potential eye and skin irritation concerns. The Agency has determined that this 48-hour REI must be increased to 72 hours when ethephon is applied outdoors in arid areas. In addition, since ethephon is classified as toxicity category I for eye irritation potential, protective eyewear is now required. Because there are no toxicological endpoints of concern for dermal (systemic) or inhalation toxicity, the Agency has determined that mixer/loader/applicator and postapplication/reentry data are not required to support the reregistration of ethephon.

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

I. INTRODUCTION

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

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

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

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Ethephon
- **Chemical Name:** (2-chloroethyl) phosphonic acid
- **CAS Registry Number:** 16672-87-0
- **OPP Chemical Code:** 099801
- **Empirical Formula:** $C_2H_6ClO_3P$
- **Trade and Other Names:** Bromeflor, Ethrel, Florel, Cerone, Prep, Flordimex
- **Basic Manufacturer:** Rhone-Poulenc Ag Company
  Cedar Chemical Corporation

B. Use Profile

Information on the currently registered uses of ethephon and application methods is presented below. A detailed table of the uses of ethephon is presented in Appendix A.

Type of Pesticide: Plant growth regulator

Use Groups and sites:

TERRESTRIAL FOOD CROP - Blackberry, cantaloupe, cucurbits, cherry, macadamia nuts, peanuts, pepper, walnut

TERRESTRIAL FOOD AND FEED CROP - Apple, barley, cotton, grapes, pineapple, sugarcane, tomato, wheat

TERRESTRIAL NONFOOD CROP - Grass grown for seed, ornamental and/or shade trees (including apple, crabapple, carob, olive), ornamental herbaceous plants, ornamental nonflowering plants (conifers), ornamental woody shrubs and vines, tobacco

GREENHOUSE NONFOOD CROP - Ornamental herbaceous plants

OUTDOOR RESIDENTIAL -Ornamental trees, ornamental herbaceous plants and shrubs

Target Pests: N/A, plant growth regulator

Formulation Types:

Soluble concentrate/liquid - 3.9 to 55.4%
Formulation intermediate - 71.3%

Methods of Application:

The table below summarizes the methods of application and equipment used to apply ethephon. Use rates can be found in Appendix A.

Ethephon Rates and Methods of Application		
Crop	Purpose/Timing	Equipment
APPLE	To thin Spur Red Delicious (SLN, NC only); the high rate is for use when soil moisture is substantially below normal.	ground spray
	To increase flower bud development in young trees, 2-4 weeks after full bloom	ground spray 100-400 gal/A
	To thin crop, 10-20 days after full bloom	ground spray 300-400 gal/A
	To loosen fruit for harvest, 7-14 days before normal harvest date	ground spray 50-500 gal/A
	With a preharvest drop control agent, to promote uniform ripening without loosening, 14-21 days before normal harvest, 1-14 days before expected harvest date	ground spray 200-400 gal/A
	To eliminate undesired fruit on ornamental apples, at flower bud to full bloom, before fruit set	ground spray 20 gal (area not spec.)
	To defoliate nursery stock (WA only), to allow digging before onset of unfavorable weather	ground spray
BLACKBERRY (OR,WA)	To hasten ripening and loosen berries, 3 days before expected harvest.	ground spray 50-500 gal/A

Ethephon Rates and Methods of Application		
PINEAPPLE	To induce flowering, about 6 mon. before harvest, about 12 mon. after planting	ground spray
	To concentrate maturity, when first fruit begins color change.	ground spray
COTTON	To promote early boll opening, foliar spray when desired number of bolls have matured	aerial or ground spray
	To precondition cotton for defoliation, foliar spray 4-7 days before defoliant application.	aerial or ground spray
	To defoliate prior to boll opening trtmt., foliar spray with a defoliant 4-7 days before boll opening application	aerial or ground spray
	To hasten maturing process, foliar spray about 1-3 days before harvest, to remaining leaves	ground spray, over-the-top
MACADAMIA NUT (HI)	To promote abscission for easier mechanical harvest, foliar spray 5-12 days before harvest	ground spray
TOMATO (late season, coastal or cool conditions)	To promote uniform ripening, foliar spray when 5-30 percent of fruit in field are red and pink	aerial or ground spray
(early/mid-season, or warm conditions)	To promote uniform ripening, foliar spray when 5-15 percent of fruit in field are red and pink	aerial or ground spray
home garden	To concentrate and accelerate ripening of mature green tomatoes, foliar spray 2-3 weeks before harvest (expected first frost)	hand sprayer
WALNUT (CA)	To promote abscission for easier mechanical harvest, foliar spray	ground spray
Tobacco, flue-cured only	To hasten maturing process, foliar spray about 1-3 days before harvest, to leaves to be harvested	ground spray, drop nozzle
PEPPERS	To hasten coloring and maturity, foliar spray when 10% of bell peppers, and 10-30% of chilies and pimentos, are red and chocolate, and desired tonnage of green fruit is mature (about 3 weeks before harvest)	ground spray
CHERRIES, sweet (not CA)	To hasten maturity and promote abscission for easier mechanical harvest, high volume (300 gal/A) or low volume (50 -100 gal/A) foliar spray when all fruit is at stage 3 (yellow background color, rapid size increase)	ground spray
(Pacific NW)	To increase dormant bud hardiness and delay bloom in spring, high volume fall foliar application (September)	ground spray
CHERRIES, tart (not CA)	To hasten maturity and promote abscission for easier mechanical harvest, high volume (300 gal/A) or low volume (50 -100 gal/A) foliar spray when all fruit is at stage 3 (yellow background color, rapid size increase)	ground spray
SUGARCANE	To reduce flowering and pithy tissue formation, and increase biomass and sugar yield, foliar spray just before flower initiation	aerial spray

Ethephon Rates and Methods of Application		
GRAPES, table (AZ, CA)	To achieve more rapid and uniform maturity, foliar spray when 5-30% of berries show color (2-3 + weeks before harvest)	ground spray
GRAPES, raisin (AZ, CA)	To hasten maturity, decrease acids, increase sugars, foliar spray when 5-30% of berries show color	ground spray
ORNAMENTAL CONIFERS	To remove dwarf mistletoe, apply as low volume foliar spray before mistletoe seed dispersal	ground spray
ORNAMENTAL DECIDUOUS TREES	to remove leafy mistletoe, low volume dormant spray after leaf drop through midwinter	ground spray
ORNAMENTAL FRUITING TREES (various named species)	To eliminate setting of nuisance fruits, low volume foliar spray at flower bud through full bloom before fruit set	ground spray, hand spray
BARLEY	To shorten internode length to prevent lodging, low volume foliar application, after flag leaf is visible to boot stage, but before awns emerge or sheath splits	aerial or ground spray
WHEAT, SPRING	same	same
WINTER	same	same
CUCUMBER, SQUASH hybrid seed production	To decrease male and increase female flower formation, foliar spray at 2 leaf stage; repeat at 7-10 day interval if germination is variable	ground spray
PUMPKIN hybrid seed production	To decrease male and increase female flower formation, foliar application at 2-4 leaf stage; repeat at 3-10 day intervals up to 6 applications/yr	ground spray
CUCUMBER, pickling	To induce or enhance formation of female flowers, to increase yield potential, two low pressure foliar applications, first at 2-3 leaf stage, then 5-7 days later	ground spray
ORNAMENTAL HERBACEOUS PLANTS (Bromeliads, hyacinth, daffodil)	To initiate flowering in Bromeliads (2500 ppm), reduce stem topple in blooming hyacinths (1000 ppm), and shorten stem length in potted daffodils (1000-2000 ppm), foliar application when Bromeliads are desired size, hyacinths blooms have not shown color, and daffodils are 4-5 inches tall	Hand spray
NURSERY STOCK (WA only) Roses, tallhedge buckthorn	To defoliate nursery stock so as to allow digging of stock plants before onset of adverse weather, foliar spray after buds are matured. Use low rate on roses, high rate on buckthorn.	hand spray. backpack spray
PEANUTS (Virginia Dept. of Agr, and Consumer Svcs. Seed Laboratory only)	To break dormancy in peanuts, moisten germination paper with prepared solution [This is not a commercial use]	Germination tray

Use Practice Limitations:

Do not apply through any type of irrigation system. Do not feed or graze livestock in treated areas. Do not treat within 2 to 60 days of harvest, depending on crop.

C. Estimated Usage of Pesticide

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

Estimated Annual Usage and Percentage of U.S. Crops Treated with Ethephon, 1990 - 1993

Site	Acres Grown (000)	Acres Treated at Least Once (000)		Percent Crop Treated		Pounds A.I. Applied (000)		Acre Treatments (000)	
		Low	High	Low	High	Low	High	Low	High
Cotton	11,950	1,400	2,500	12	21	1,300	2,550	1,400	2,700
Apples	470	15	40	3	9	8	30	15	40
Cherries	100	20	30	20	30	6	9	20	32
Tomatoes	460	25	100	5	22	15	60	25	100
Wheat	63,000	60	120	< 1	< 1	10	20	60	120
Barley	7,750	15	50	< 1	< 1	5	18	15	50
Peppers (bell)	67	5	15	7	23	4	12	5	15
Grapes	740	10	50	1	7	3	15	10	50
Tobacco	770	5	25	< 1	3	8	35	5	25
Walnuts	180	5	20	3	11	4	18	5	20
Almonds	395	1	5	< 1	1	2	10	1	5
Cucumbers	155	3	5	2	3	0.2	0.4	3	5
TOTAL	86,037	1,564	2,960	n.a.	n.a.	1,365	2,777	1,564	3,162

In addition to usage estimates for the crops listed above, some negligible use was also found on cantaloupes, ornamentals, oats/rye, peaches, pears, pecans, plums/prunes, potatoes, pumpkins, soybeans, squash and sweet corn. No evidence of recent usage was found on blackberries or sugarcane. No usage information was available for pineapple.

D. Data Requirements

Data requested in the September 1988 Registration Standard for ethephon include studies on product chemistry, residue chemistry, toxicology, environmental fate, ecological effects and reentry. These data were required to support the uses listed in the Registration Standard. Appendix B includes studies identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

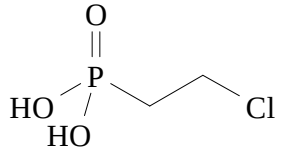
Ethephon was discovered in 1965 and introduced commercially in 1973 by the AmChem/Union Carbide company as a plant growth regulator. The Union Carbide registrations were sold to Rhone-Poulenc Ag Company. Cedar Chemical Corporation also has registered ethephon products.

The Registration Standard on ethephon (NTIS # PB89-109427) was issued in September 1988. The Registration Standard continued the registration of ethephon but required submission of environmental fate, toxicology, residue chemistry, and environmental effects data. This Registration Eligibility Decision document reflects a reassessment of all data submitted to date in response to the Registration Standard.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Ethephon [(2-chloroethyl) phosphonic acid] is a plant growth regulator that promotes fruit ripening, abscission, flower induction, and other responses by releasing ethylene gas, a natural plant hormone.



Empirical Formula:	$C_2H_6ClO_3P$
Molecular Weight:	144.5
CAS Registry No.:	16672-87-0
Shaughnessy No.:	099801

Pure ethephon is a white waxy solid with a melting point of 74-75 C. Ethephon is very soluble in water, alcohol, acetone, and propylene glycol, only slightly soluble in aromatic solvents such as benzene and toluene, and insoluble in kerosene and diesel oil.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological database on ethephon is essentially complete for reregistration purposes. The Agency has determined that acute and subchronic neurotoxicity studies are now required to support the continued registration of ethephon products. These studies are not part of the target database for ethephon and do not affect the reregistration eligibility decision.

a. Acute Toxicity

The table below summarizes the acute toxicity results for technical grade ethephon.

Acute Toxicity Testing		
Test	Result	Category
Acute Oral LD_{50} (rat)[1]	1.60 $\pm$ 0.13 g/kg	III
Acute Dermal LD_{50} (rabbit)[2]	5 $\pm$ 0.9 g/kg	III
Acute Inhalation LC_{50} (rat)[3]	4.52 mg/L	III
Eye Irritation*	not required corrosive in dermal study	I
Dermal Irritation (rabbit)[4]*	Corrosive	I
Skin Sensitization (guinea pig)[5]*	negative	N/A

[1] 81-1; MRID 00029509
[2] 81-2; MRID 00029510
[3] 81-3; MRID 41685901
[4] 81-5; MRID 00029513
[5] 81-6; MRID 41154503
*Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

b. Subchronic Toxicity

A 16-day oral human study showed plasma cholinesterase inhibition at 0.5 mg/kg/day (only dose tested). Recovery occurred within 15 days. Ten males and ten females were tested. No other signs of toxicity were observed. (MRID 00066931)

A 28-day oral human study showed no plasma or red blood cell cholinesterase inhibition at 1.8 mg/kg/day (only dose tested). Five males and five females were tested. The clinical signs/symptoms of organophosphate toxicity were reported. These include the sudden onset of diarrhea, urgency of bowel movements, stomach cramps or gas, an increased urgency and frequency of urination, and disturbances in appetite. (MRID 00036510)

In a 21-day dermal toxicity study, ten male and ten female New Zealand rabbits were dosed dermally at 0, 25, 75, and 150 mg/kg/day, five days per week for three weeks. Skin effects were observed at all doses (NOEL < 25mg/kg/day). Effects ranged from erythema and desquamation at the lowest dose to acanthosis and chronic inflammation at the highest dose. No systemic treatment related effects were observed on body weight, food consumption, organ weight or histopathology. The systemic NOEL was greater than 150 mg/kg/day. (MRID 41295901)

c. Chronic Toxicity

A combined chronic/oncogenicity study was performed in Sprague Dawley rats. Doses administered in the feed were 0, 300, 3000, 10,000 or 30,000 ppm for 95 weeks to the males and 103 weeks for the females. The doses administered relative to body weight were 0, 13, 131, 446 or 1416 mg/kg/day for males and 0, 16, 161, 543 or 1794 mg/kg/day for females. Plasma and erythrocyte cholinesterase was inhibited at all doses (NOEL < 300 ppm). Brain cholinesterase inhibition was not observed. A decrease in male body weight was observed at 10,000 ppm. At 30,000 ppm body weight decrease was observed in both sexes. Additional effects at 30,000 ppm were thyroglossal duct cysts, kidney glomerulo-sclerosis and nephritis and biliary hyperplasia cholangiofibrosis. No carcinogenic effects were observed. (MRID 41139001)

Ethephon was administered in the feed at doses of 0, 30, 300, 3000 ppm (0, 0.75, 7.5 or 75 mg/kg/day) to male and female beagle dogs. Due to toxicity/morbidity the high dose was reduced as follows:

75 mg/kg/day weeks 0-3; 50 mg/kg/day weeks 4-5; 25 mg/kg/day weeks 6-24; 37.5 mg/kg/day weeks 25-104. Plasma cholinesterase was inhibited at all doses (NOEL < 0.75 mg/kg/day). A NOEL for erythrocyte cholinesterase inhibition of 0.75 mg/kg/day with a LOEL of 7.5 mg/kg/day was observed. Histopathology showed smooth muscle atrophy in the gut at 7.5 mg/kg/day with a NOEL of 0.75 mg/kg/day. (MRID 00060359, 00147357)

Ethephon was administered in the feed at doses of 0, 100, 300, 1000, or 2000 ppm (0, 2.7, 8.2, 28.5 or 52.1 mg/kg/day) to male and female beagle dogs for 52 weeks. A systemic NOEL of 1000 ppm (28.5 mg/kg/day) was observed for decreased spleen weight, body weight, hemoglobin and hematocrit in the males. The females showed a decreased spleen/body weight ratio for the same NOEL. Cholinesterase inhibition was not determined.
(MRID 41135001)

d. Carcinogenicity

The chronic/oncogenicity study in rats summarized above showed no evidence of treatment related tumors. (MRID 41139001)

Male and female CD-1 mice were administered ethephon in the diet at 0, 100, 1000 or 10,000 ppm (0, 15.5, 156 or 1630 mg/kg/day) for 78 weeks. An additional dose level of 50,000 ppm was terminated at 12 weeks because of excessive morbidity and mortality. No evidence of treatment related tumors was observed. A NOEL of 15.5 mg/kg/day was determined for plasma cholinesterase inhibition. At 1630 mg/kg/day male body weights were increased and female body weights decreased compared with controls. (MRID 41050801)

e. Developmental Toxicity

Rats were dosed by gavage at 0, 20, 600 or 1800 mg/kg/day on days 6 through 15 of gestation. At 1800 mg/kg/day, 14 of the 24 treated female rats died. No toxic effects were observed at lower doses. The NOEL for maternal and fetal toxicity was 600 mg/kg/day. (MRID 00063745)

Rats were dosed by gavage at 0, 125, 250 or 500 mg/kg/day on days 6 through 15 of gestation. No toxic effects were observed at any dose. The NOEL for maternal and fetal toxicity was greater than 500 mg/kg/day. (MRID 41103001)

Rabbits (17/group) were dosed by gavage at 0, 50, 100 or 250 mg/kg/day on days 6 through 19 of gestation. The number of does with live fetuses were 10, 12, 8 and 5, respectively. Resorptions were increased at 100 mg/kg/day and statistically significantly increased at 250 mg/kg/day. At 250 mg/kg/day does were depressed, ataxic, showed an increase of clinical observations and gross pathology in the gut. A NOEL for maternal and fetal toxicity of 50 mg/kg/day was observed. (MRID 00085755)

Rabbits were dosed by gavage at 0, 62.5, 125 or 250 mg/kg/day on days 6 through 19 of gestation. Maternal morbidity, mortality and clinical signs of toxicity were observed at 250 mg/kg/day. Fetal toxicity consisting of decreased number of live fetuses per doe, increased early resorptions and post implantation loss was observed at 250 mg/kg/day. A NOEL for maternal and fetal toxicity of 125 mg/kg/day was observed. (MRID 41557201)

The data from the developmental toxicity studies show no evidence of a potential for developmental effects (malformations or variations) at doses that are not maternally toxic.

f. Reproductive Toxicity

In a two generation reproduction study, 28 Sprague Dawley rats per sex per dose were administered 0, 300, 3000 or 30,000 ppm (0, 15, 150 or 1500 mg/kg/day) of the test compound in the diet. For the offspring a NOEL of 15 mg/kg/day and a LOEL of 150 mg/kg/day was set based on decreased F_2b survival during lactation. For the adults a NOEL of 15 mg/kg/day and a LOEL of 150 mg/kg/day was set based on decreased body weight gain in the females at 150 mg/kg/day and in both sexes at 1500 mg/kg/day. No effects were observed on fertility, gestation, mating, organ weights or histopathology in any generation. (MRID 41508701)

g. Mutagenicity

Ethephon was tested in Salmonella typhimurium strains TA-1535, TAS-1535, 1537, 1538, TA-98, and TA-100 with and without S9 activation at concentrations of 1.0-50 Fg/plate. The test material was positive for mutagenicity in strain TA-1535 with and without S9 activation. (MRID 40412401)

Ethephon was tested for clastogenic effects in the CHO cell system at doses of 70 to 2000 Fg/ml with S9 activation and 200 to 2010

Fg/ml without S9 activation. The study was negative. (MRID 40555301)

Ethephon was tested for unscheduled DNA synthesis in the rat hepatocyte system at doses of 25 to 1000 Fg/ml. Cytotoxicity due to acidic pH changes has been observed at 2000 Fg/ml and higher doses. The study was negative. (MRID 40555201)

h. Metabolism

Ethephon was administered in a single intravenous dose of 50 mg/kg and single and multiple oral doses of 50 and 1000 mg/kg to male and female Crl:CD(SD)BR rats. The oral C_{max} (maximum concentration) was reached at 1.3 and 1 hours for the 50 mg/kg dose and 1.9 and 2.5 hours for the 1000 mg/kg in males and females respectively. The $t^{1/2}$ of the rapid excretion phase (A-phase) at the 50 mg/kg dose was 7 hours for both sexes and 4 and 9 hours at 1000 mg/kg for the males and females respectively. Oral and intravenous doses were rapidly excreted in the urine and accounted for 48 to 71% of the administered radioactivity. Approximately 7% was excreted in the feces. Exhaled ethylene was 10-20% and CO_2 was less than 1% of the administered dose. The highest tissue concentrations were found in the blood, bone, liver, kidney and spleen with no significant differences between single and multiple dosing. No significant differences were observed in the excretion pattern with either sex or multiple dosing. (MRID 41906101)

i. Neurotoxicity

The acute oral LD_{50} in the hen was determined to be 3800 mg/kg. Two groups of 30 hens each were dosed orally at 3850 and 3160 mg/kg and observed for 21 days. The survivors were dosed orally at 2370 mg/kg and observed for an additional 21 days. Survivors were necropsied and histopathology of the central nervous system was performed. No observational or histopathological evidence of organophosphate type delayed neurotoxicity was observed. (MRID 00144559)

Because ethephon is an organophosphate pesticide, acute and subchronic mammalian neurotoxicity studies are now required.

j. Reference Dose/Other Toxicological Considerations

The RfD for this chemical was first assessed by the Health Effects Division RfD Committee on March 8, 1988 and subsequently

verified by the Agency RfD Work Group on March 23, 1988. At that time the RfD was based on a 16-day human study (MRID 00066931) with a LOEL of 0.5 mg/kg/day (only dose tested) for plasma cholinesterase inhibition. An uncertainty factor (UF) of 100 was used to account for intraspecies variability and the lack of a NOEL. On this basis, the RfD was calculated to be 0.005 mg/kg/day. Subsequently, a new chronic feeding study in dogs and a carcinogenicity study in mice were submitted.

The OPP/HED RfD Peer Review Committee determined on February 10, 1994 that the reference dose (RfD) should be based on the 28-day study in human subjects (MRID 00036510). Clinical signs of toxicity were observed at 1.8 mg/kg/day (only dose tested) and included diarrhea, urgency of bowel movements, urinary urgency and stomach cramps. An uncertainty factor (UF) of 100 was used to account for intraspecies variability and the lack of a NOEL. On this basis the RfD was calculated to be 0.018 mg/kg/day, the chronic dietary endpoint.

The toxicological endpoints of significance for determining dietary and occupational risk assessment are as follows:

1) The acute (one day) dietary endpoint is based on clinical signs observed in the 28-day study in humans at 1.8 mg/kg/day. Although clinical signs were observed early in the study, no plasma or red blood cell cholinesterase inhibition was evident. There was some question as to the reliability of the observed clinical signs. For the purposes of risk assessment a margin of exposure (MOE) of 10 is appropriate since it is based on a human study. The Agency has determined that an additional uncertainty factor of 10 due to the lack of a NOEL is not appropriate for the acute dietary endpoint because this endpoint is near the NOEL for cholinesterase inhibition in the 16-day human study. An additional factor of 10 would overstate the acute endpoint. It should be noted that some plasma cholinesterase inhibition was observed in the 16-day human study.

2) There are no toxicological endpoints of concern associated with short term (one to seven days) or intermediate term (1 week to several months) occupational or residential exposure because there was no evidence of (systemic) toxicity by the dermal route.

3) There is no cancer concern associated with this chemical. Ethephon is classified as a Group D chemical based on the "insufficiency of the weight of evidence".

4) The RfD is 0.018 mg/kg bwt/day, for determination of chronic dietary risk, based on a human study (MRID 00036510) having a LOEL of 1.8 mg/kg/day and an uncertainty factor of 100.

Ethephon has been reviewed by the Joint Meeting of the FAO/WHO on Pesticide Residue (JMPR). An acceptable daily intake (ADI) of 0.05 mg/kg/day was established by the JMPR in 1993. The ADI was based on the 16-day oral human study at a single dose level (0.5 mg/kg/day) and a safety factor of 10.

k. Other Adverse Effects

As of August 18, 1994, the following ethephon poisoning data were available:

- The Pesticide Incident Monitoring System (PIMS) reported four cases of skin injury (irritation) in California as a result of exposure to field residues.

- California Department of Food and Agriculture reported one possible systemic case as a result of exposure to ethephon during 1982-89.

- Reports from The National Pesticide Telecommunication Network indicate that 29 calls were made between 1984-1991. Incidents that appear to be directly related to ethephon exposure include observations of eye and skin irritation from pesticide misuse. Several reported incidents involve exposure to a mixture of chemicals where it is unclear which chemical caused the adverse effects.

- The EPA Incident Data System (June, 1992 to July, 1994) contains no worker related reports for ethephon.

2. Exposure Assessment

a. Dietary Exposure

Tolerances for residues of ethephon in or on food/feed commodities are currently expressed in terms of ethephon *per se [40 CFR §180.300 (a) and (b), §185.2700 (a), (b), and (c), §186.2700 (a)]*. Adequate enforcement methods are available for the determination

of residues of ethephon *per se* in/on plant commodities and in milk and ruminant tissues.

The Ethephon Registration Standard required analysis of certain food/feed crops for residues of monochloroacetic acid (MCAA), a theoretical degradation product of an impurity in technical ethephon. Because submitted data indicated that apparent MCAA residues present in treated samples of a broad range of food/feed commodities were generally at or below the validated 0.01 ppm detection limit, the EPA/OPP/HED Metabolism Committee determined that MCAA need not be included in the tolerance expression or further considered as a component of dietary risk assessments for ethephon.

Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on tomato, cantaloupe, apple, fig, pineapple, tobacco, grape, walnut, filbert, cherry, tangerine, and lemon metabolism data. Ethephon degrades to ethylene, phosphate, and chloride. Data indicate that proximal and distal translocation of ethephon to fruits may occur following application to leaves. The residue of concern in plants is ethephon *per se*. (MRID numbers are listed in Appendix B under Guideline 171-4A).

Animal Metabolism

The qualitative nature of the residue in ruminants is adequately understood based on goat metabolism data. In ruminant tissues and milk, ethephon is incorporated into natural products (glutathione conjugates, protein, glycogen, triglycerides) and expired as CO_2 and ethylene. No residues of ethephon were detected in the goat metabolism study; however, residues of ethephon were detected in ruminant tissues and milk in a ruminant feeding study which was conducted at exaggerated dosing levels. The residue of concern in milk and ruminant tissues is ethephon *per se*. (MRID numbers are listed in Appendix B under Guideline 171-4B).

The qualitative nature of the residue in poultry is not adequately defined. A poultry metabolism study was submitted and deemed inadequate to describe the nature of the residue in poultry tissues and eggs due to inadequate characterization of organic extractable residues, inadequate storage stability information, and inadequate storage stability data to support the poultry metabolism study. Data indicate that radioactive residues are transferred to poultry muscle, fat, kidney, liver,

egg yolks and egg whites (0.023 ppm to 0.459 ppm ethephon equivalents) resulting from the consumption of [^{14}C]ethephon (five consecutive doses at a rate equivalent to 53 ppm). A new poultry metabolism study is required and is in progress. (MRID numbers are listed in Appendix B under Guideline 171-4B).

Tolerances for residues of ethephon are not currently established in poultry tissues and eggs. Until the nature of the residue is adequately delineated in poultry tissues and eggs, the total radioactive residue (TRR) levels in poultry tissues and eggs as determined from available poultry metabolism data will be used to estimate the residue levels for acute and chronic dietary risk estimates. The estimated residue levels in poultry are as follows:

poultry liver	0.015 ppm
poultry kidney	0.010 ppm
Poultry muscle	0.001 ppm
Poultry fat	0.008 ppm
Eggs	0.025 ppm

Residue Analytical Methods - Plants and Animals

Adequate methods for purposes of enforcement of ethephon tolerances in plant commodities, ruminant tissues and milk are available. The Amchem-Plant Method (PAM, VOL. II, Method I) is the recommended method for enforcement purposes for plant commodities and processed products other than wheat and barley straw. The Amchem-Cereal Method (forwarded to FDA for inclusion in the PAM, VOL. II, Method II) is the recommended method for enforcement purposes for wheat and barley straw. The Union Carbide-Animal Method (forwarded to FDA for inclusion in the PAM, VOL. II, Method III) is the recommended method for enforcement purposes for milk and animal tissues. [Note: Since the nature of the residue in poultry has not been adequately defined, the adequacy of the available analytical methods for poultry products cannot be determined.] (MRID numbers are listed in Appendix B under Guideline 171-4C/D).

The plant and animal analytical methods currently recommended for enforcement purposes employ diazomethane as a methylating agent and the Agency (in the 1991 Registration Update) required the registrant to revise the currently accepted enforcement methods to replace diazomethane with a safer methylating agent or provide documentation supporting the need for diazomethane if a suitable alternative

methylating agent is impractical. Rather than address Agency concerns about the use of diazomethane as a methylating agent, the registrant has submitted new plant and animal methods for enforcement purposes which principally involve the decomposition of ethephon to ethylene to determine the residues of ethephon in/on apples, barley grain, barley straw, blackberries, cantaloupes, cherries, cottonseed, cucumbers, grapes, macadamia nuts, peppers, pineapples, tobacco, tomatoes, sugarcane, walnuts, wheat grain, wheat straw, meat, milk and eggs. The Agency reviewed the new proposed plant and animal enforcement methods and concluded that in order for the proposed methods to be considered adequate for enforcement purposes, they must undergo a successful independent laboratory validation (ILV) as described in PR Notice 88-5 (7/15/88) followed by a successful method validation by the Agency.

The FDA Pestdata (PAM Vol. I Appendix, 8/93) indicates that ethephon is not recovered through any of the Multiresidue Protocols.

Additional confirmatory data are required to satisfy plant and animal residue analytical methods data requirements. The registrant must either revise the currently accepted enforcement methods to replace diazomethane with a safer methylating agent or provide documentation supporting the need for diazomethane in the currently accepted enforcement methods if a suitable alternative methylating agent is impractical or submit independent laboratory validation (ILV) for the proposed ethylene release methods. The registrant is required to radiovalidate the preferred animal enforcement method using samples from the new poultry metabolism study which is in progress.

Storage Stability

Adequate storage stability data are available for apples, barley grain and straw, blackberries, cherries, cottonseed, grapes, macadamia nuts, peppers, pineapples, tobacco, tomatoes, walnuts, and wheat grain and straw. Storage stability data indicate that residues of ethephon are generally stable for intervals of up to 24 months in frozen commodities. Ethephon residues are also stable in freeze-dried cherries, pineapple, apples, grapes, tomatoes, and blackberries for up to 24 months stored at room temperature. Since the registrant has committed to conduct new pepper and cantaloupe field trials, no additional storage stability data are required to support previously submitted pepper and cantaloupe magnitude of the residue data. Additional information regarding storage intervals of sugarcane test samples from previously submitted sugarcane

field trial studies remains outstanding. (MRID numbers are listed in Appendix B under Guideline 171-4E).

The registrant has committed to generate storage stability data on processed samples of cottonseed oil and apple juice to support available magnitude of the residue data for processed raw agricultural commodities. The registrant must provide an adequate description of the storage intervals and conditions of grape processed commodity samples from processing studies used to determine the potential for concentration of ethephon residues in grape juice, raisins, raisin waste, dried grape pomace, and wet grape pomace. These data are considered confirmatory.

Since the registrant has committed to conduct a new sugarcane processing study, no additional storage stability data are required to support previously submitted sugarcane processing data.

Available storage stability data adequately demonstrate that residues of ethephon are stable in meat, milk, and eggs for up to 12 months, 4 months, and 15 months, respectively, when samples are stored in polypropylene bottles at approximately -20^{o}C. Since the Agency has required new animal feeding studies, no additional storage stability data are required to support previously submitted animal feeding studies.

All future plant and animal magnitude of the residue studies must have supporting storage stability data. The Agency prefers that concurrent storage stability studies be conducted.

Magnitude of the Residue in Plants

All magnitude of the residue data requirements are satisfied for the raw agricultural commodities apples, barley grain and straw, blackberries, cherries, macadamia nuts, pineapples, sugarcane, tomatoes, walnuts, and wheat grain and straw. Field trials were performed representing the various conditions under which the pesticide can be applied. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. In addition, magnitude of the residue and pyrolysis studies have been submitted for tobacco. (MRID numbers are listed in Appendix B under Guideline 171-4K).

Assuming that the registrant adequately amends the 0.33 lb/gal SC/L label (EPA Reg. No. 264-263) to prohibit the harvesting of any

treated pumpkins for human or animal consumption and specify that treatments are to be made to pumpkins for seed production only, no additional cucumber, squash, or pumpkin residue data are required since the Agency considers these non-food uses. Currently established tolerances for cucumbers and pumpkins should be revoked.

Assuming that all pertinent product labels are amended to reflect a maximum allowable use rate of 2 lb/A/season for application of ethephon to cotton and the registrant amends the established tolerance for residues of ethephon in/on cottonseed from 2 ppm to 4 ppm, no additional cottonseed residue data are required.

New residue field trials are required by the Agency for cantaloupes, grapes, and peppers and are in progress. To supplement available grape field trial data, the registrant has agreed to conduct additional trials in California. The registrant has also committed to conduct repeat cantaloupe and pepper field trials that are required due to stability problems encountered in earlier studies. These data are considered confirmatory.

The Agency currently recognizes cotton gin byproducts and aspirated wheat grain fractions as raw agricultural commodities and has determined that label restrictions for barley forage, barley hay, wheat forage, and wheat hay are not appropriate (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II (June 1994)). Data depicting residues of ethephon in/on cotton gin byproducts, wheat forage, and wheat hay resulting from maximum registered use rates are hereby required. A minimum of six (6) field trials for cotton gin byproducts and twenty (20) field trials for wheat forage and hay are required. For additional guidance on sampling and geographical locations for field trials the registrant should consult "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances" issued 6/2/94. Data on wheat forage and hay will be translated to barley forage and hay, respectively. Wheat grain dust data were previously submitted which indicated that residues of ethephon do not concentrate in aspirated wheat grain fractions. In accordance with guidance (issued June 2, 1994) on aspirated grain fractions (grain dust), additional aspirated wheat grain fractions data are not required and no tolerance is needed for residues of ethephon in/on aspirated wheat grain fractions.

Ethephon residue data requirements for cotton gin byproducts and wheat forage and hay which result from changes in the Livestock Feeds Table (Pesticide Assessment Guidelines, Subdivision O, Residue

Chemistry, TABLE II (June 1994)) will be imposed at the issuance of this document but should not impinge on the reregistration eligibility decision for ethephon. The need for additional tolerances and revisions to exposure/risk assessments will be made upon receipt of required data.

Magnitude of the Residue in Processed Food/Feed

Processing studies have been conducted on apples, barley, cottonseeds, grapes, pineapples, tomatoes, and wheat and, pending the receipt of adequate storage stability data, are deemed adequate to determine the extent to which residues of ethephon concentrate in food/feed items upon processing of the raw agricultural commodity. (MRID numbers are listed in Appendix B under Guideline 171-4L).

Data indicate that ethephon residues concentrate in apple juice, dried apple pomace, barley hulls, cottonseed meal, grape juice, raisins, raisin waste, dried grape pomace, pineapple bran and pulp, dried tomato pomace, wheat bran, wheat shorts and germ and red dog.

The registrant has committed to generate new sugarcane processing data. These data are considered confirmatory.

The Agency no longer considers dried apple pomace a feed item (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II (June 1994)). Available apple processing data indicate that residues of ethephon do not concentrate in wet apple pomace. Therefore, a feed additive tolerance on apple pomace is not required. Pending the receipt of adequate storage stability data, no additional apple processing data are required.

The Agency currently considers tomato paste a processed food (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II (June 1994)). Available tomato processing data indicate that residues of ethephon do not concentrate in tomato paste and, therefore, no tolerance is needed. Pending the receipt of adequate storage stability data, no additional tomato paste residue data are required.

The Agency no longer considers pineapple bran a processed commodity of pineapples, but now considers pineapple juice and the wet waste byproduct from fresh-cut product line, referred to as pineapple process residue, as the processed commodities of pineapples (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II (June 1994)). Pineapple processing data indicate that residues of ethephon concentrate in dried pineapple bran (5.3x) and wet pulp (1.2x)

but do not concentrate in juice, syrup, and slices. Based on these data which demonstrate that there is no significant concentration of residues of ethephon in pineapple wet pulp (1.2x), the Agency concludes that no feed additive tolerance for residues of ethephon in pineapple process residue is required. Pending the receipt of adequate storage stability data, no additional pineapple processing data are required.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Tolerances exist for milk and fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep. Tolerances for residues of ethephon in poultry tissues or eggs have not been established. The 1988 Ethephon Guidance Document deferred evaluation of the available ruminant and poultry feeding studies. These previously submitted feeding studies have been evaluated and are deemed inadequate. New ruminant and poultry feeding studies must be conducted at 1x, 3x, and 10x the maximum theoretical dietary burden in order to refine current dietary exposure estimates, adequately reassess the currently established ruminant tissue and milk tolerances, and determine the appropriate tolerances for poultry tissues and eggs. These data are considered confirmatory. (MRID numbers are listed in Appendix B under Guideline 171-4J).

Until these data are generated, the existing ruminant feeding study and poultry metabolism data will be used in exposure/risk assessments.

Confined Rotational Crops

A confined rotational crop study (MRID 43143601) is currently in review.

Field Rotational Crops

The requirement for field rotational crop studies will be determined after the confined rotational crop study has been evaluated.

b. Occupational and Residential

Handler (Mixers, Loaders, Applicators, etc.) Exposure

The Agency has determined that there is an exposure potential for mixers, loaders, applicators, and or other handlers during the usual use-patterns associated with ethephon. The mixing, loading, and

application methods include open pouring, broadcast (aerial and ground) application and application with hand-held equipment.

Exposure data requirements are triggered based on the potential for exposure and the toxicological significance of the active ingredient. Since there is no indication that ethephon is absorbed by the dermal route based on the lack of systemic effects noted, ethephon meets the exposure criteria, but not the toxicity criteria. Therefore, exposure data for occupational and residential activity patterns (M/L/A) associated with the use of ethephon are not required for reregistration eligibility. Similarly, an exposure assessment is not required.

Post-Application Exposure

The Agency has determined that there is an exposure potential for persons entering treated sites after the application is completed. These potential exposures exist for persons after applications to crops such as tobacco, grapes, apples, peppers, blackberries, cantaloupes, and ornamentals. Because there are no toxicological endpoints of concern for dermal (systemic) toxicity, neither exposure data nor an exposure analysis are required for reregistration eligibility.

The Agency has determined that based on concerns regarding potential eye and skin irritation, a 48 hour restricted-entry interval (REI) as imposed by the Worker Protection Standard (WPS) will be retained. Further, the Agency has determined that this 48-hour REI must be increased to 72 hours when ethephon is applied outdoors in arid areas. (Refer to Section IV, B, 4 for discussions of labeling rationale and uses within scope of the WPS. Refer to Section V for labeling requirements).

3. Risk Assessment

In order to adequately determine the risk associated with a chemical the toxicological end-points of concern must be identified in relation to the potential route(s), duration and/or frequency of the exposure(s). The toxicological endpoints of significance for dietary and occupational exposure are as follows:

1) The acute (one day) dietary endpoint is based on cholinergic signs in humans at 1.8 mg/kg/day and a margin of exposure (MOE) of less than 10 will generally indicate a risk concern.

2) There are no toxicological endpoints of concern associated with short term (one to seven days) or intermediate term (1 week

to several months) occupational or residential exposure because there was no evidence of (systemic) toxicity by the dermal route.

3) There is no cancer concern associated with this chemical. Ethephon is classified as a Group D chemical based on the "insufficiency of the weight of evidence".

4) The reference dose (RfD) is 0.018 mg/kg bwt/day, for determination of the chronic dietary risk, based on a human study (MRID 00036510) having a LOEL of 1.8 mg/kg/day and an uncertainty factor of 100.

a. Dietary

Food uses evaluated in this analysis were the published food uses listed in 40 CFR 180.300, food additive tolerances listed in 185.2700, an increase in tolerance for cottonseed from 2 ppm to 4 ppm recommended in the Tolerance Reassessment Summary, a proposed food additive tolerance of 10 ppm for residues of ethephon in apple juice, and estimated residues in poultry and eggs (see dietary exposure above). The following uses were recommended for revocation in the Tolerance Reassessment Summary:

blueberries
coffee beans
cranberries
cucumbers
figs
filberts
guavas
lemons
pumpkins
tangerines and tangerine hybrids

Dietary risk was calculated both with and without these uses, based on the assumption that until tolerances are revoked, import use of a pesticide could still occur on these sites.

Residue data required to ascertain the adequacy of the established tolerances for cantaloupes, grapes, peppers, milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep were deemed unacceptable for reassessment purposes. In the absence of reassessed tolerances for these crops existing tolerances were used in the analysis. This could result in overestimation or underestimation of risk if

acceptable studies suggest adjustment of the existing tolerances to be appropriate.

Though a reassessed tolerance for grapes was not possible at this time, available processing data which indicate that ethephon does concentrate in "grape juice" was considered. The existing tolerance of 2 ppm on grapes was multiplied by the supplied concentration factor of 4X to get a derived high end residue of 8 ppm for grape juice which was also applied to the food item "wine and sherry" in the analysis.

Percent of crop treated (PCT) values used in the chronic exposure analysis can be found in Section IIC, of this document. The percent crop treated information was provided as ranges of values for the commodities. The high end of the range was used for the analysis. Though percent of crop treated values were not specifically given for blackberries or sugarcane, it was noted that no recent usage of ethephon on these crops was found. Rather than assume the default that 100 percent of these crops are treated, 1% was used in the analysis. Percent of crop treated information was not supplied for many of the crops recommended for revocation. The default value of 100 percent crop treated was assumed for these crops, with the result being probable overestimation of exposure and risk in the chronic analysis that included tolerances recommended for revocation.

Though no tolerances have been established for poultry meat and eggs, estimates of residue levels were used in analyses until additional required poultry metabolism and feeding studies are received and the need for tolerances is determined. These estimated residues are based on the current maximum poultry dietary exposure estimate in relation to the total radioactive residue (TRR) levels demonstrated in available poultry metabolism data. The estimated residues were used in both the acute and chronic analyses. Tolerance level residues were assumed in the acute exposure analysis.

The *chronic dietary exposure analysis* used tolerance level residues and 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Anticipated residues and refined percent of crop treated data were used to calculate the Anticipated Residue Contribution (ARC) for those same population groups. The ARC is considered the more accurate estimate of dietary exposure. These exposure estimates were then compared to the RfD for ethephon to derive estimates of chronic dietary risk. Two analyses were performed: the first assessing exposure and risk from all uses for which

tolerances either exist, have been recommended in the Tolerance Reassessment Summary in this document, or have been proposed; and the second excluding those uses for which revocation was recommended in the Tolerance Reassessment Summary.

When all published tolerances are considered, the ARC for the overall U.S. population is 0.001572 mg/kg bwt/day, which represents 8.7% of the RfD. When residues in poultry and eggs, the recommended increase in the tolerance on cottonseed, and the proposed tolerance for "apple juice" are considered, the ARC is raised to 0.001624 mg/kg bwt/day, or 9.0% of the RfD. The ARC for the subgroup most highly exposed, non-nursing infants less than one year old, is 0.008227 mg/kg bwt/day (46% of the RfD) from published tolerances and 0.008781 mg/kg bwt/day (49% of the RfD) from published, proposed and recommended uses.

When tolerances recommended for revocation are excluded from the analysis, the ARC for the U.S. population from all uses recommended through reregistration (including poultry and eggs, the increased tolerance on cottonseed and the proposed tolerance for "apple juice") is 0.001553 mg/kg bwt/day, or 8.6% of the RfD. Non-nursing infants less than one year have an ARC of 0.008427 mg/kg bwt/day, or 47% of the RfD.

Given the estimates arrived at in these analyses, it appears that chronic dietary risk from food uses of ethephon recommended through reregistration is not of concern. The proposed tolerance of 10 ppm for apple juice does not appear to present a chronic risk of concern.

A detailed acute dietary exposure analysis was performed in which all food uses and food uses recommended for revocation in the Tolerance Reassessment summary were included at tolerance levels. The analysis evaluated individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and estimated the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis assumed uniform high-end (at tolerance) residues of ethephon in the commodity supply. Because cholinesterase inhibition (neurotoxicity) is the endpoint of concern, exposure and risk were calculated for all standard population subgroups.

The Margin of Exposure (MOE) is a measure of how closely estimated exposure comes to the dose of concern (usually a NOEL), in this case a LOEL of 1.8 mg/kg/day. In the analysis the MOE was

calculated as the ratio of the LOEL to the exposure (LOEL/exposure = MOE).

MOEs were calculated using an estimate of the 95th percentile of exposure for five of the population subgroups (U.S. population- 48 states, Infants < 1 year, Children ages 1 through 6 years, Females (13+ years), and Males (13+ years). "Infants < 1 year" are the only population subgroup that appears to be a concern, with 5% of the population estimated to have MOEs of less than 7. However, the Agency believes this risk estimate represents an unrealistic worst case situation because the following conservative assumptions were employed in calculating exposure:

1. The Agency assumed that all food crops on which ethephon is registered have been treated with ethephon and that maximum residue levels reported in or on unwashed, unpeeled, uncooked commodities at the farm gate are present on all foods. However usage data indicate that the treatment percentage of major infant foods on which ethephon is registered is < 10% or even "negligible".

2. The probable residue dilution that occurs in processed infant foods was not taken into account.

3. Ethephon degrades fairly rapidly to ethylene, phosphate and chloride in neutral and alkaline environments. Therefore, by the time the food has cleared distribution channels and/or processing plants, residues at the dinner table are likely to be significantly lower than high-end levels at the farm gate.

For the reasons stated above the Agency believes it is unlikely that infants will be exposed to ethephon treated commodities at levels that will result in acute dietary risk.

b. Occupational and Residential

There is a potential for mixer/loader/applicator (handlers) exposure and post-application exposure via the inhalation and dermal route; however, there are no toxicological endpoints of concern regarding dermal (systemic) toxicity, inhalation toxicity or other adverse effects. There is a potential for eye and skin irritation from surface or spray contact for post-application workers; therefore, a 48-hour restricted entry interval is required following applications of ethephon to reduce the risk of irritation. Based on the lack of toxicological

concerns, the risk posed by this chemical is considered minimal for occupational/residential workers/users. Labeling and personal protective equipment requirements are discussed in Sections IV and V.

C. Environmental Assessment

1. Environmental Fate

The environmental fate database for ethephon is adequate for reregistration purposes. Although the aged leaching data requirement was waived by the Agency in April 1990, recent information has documented an additional degradate, which was not known at the time the waiver was granted. A batch equilibrium study with 2-hydroxy ethyl phosphonic acid is needed in order to determine the mobility of this major, persistent degradate. Although it appears from the photodegradation on soil, aerobic soil metabolism, and anaerobic aquatic metabolism studies, that this degradate may be bound to soil, Freundlich adsorption and desorption values (K_{ads} and K_{des}) are needed to confirm the reregistration eligibility of ethephon. This information is not expected to change the overall environmental fate and transport assessment of ethephon.

Because ethephon may induce modifications in plant growth, the Spray Drift data requirements were imposed in order to assess the extent of exposure of nearby non-target plants to ethephon. These studies are being held in reserve pending the work currently being conducted by industry's Spray Drift Task Force.

a. Environmental Chemistry, Fate and Transport

Detailed information regarding the fate of ethephon in the environment is provided below. Environmental fate studies used to support the reregistration of ethephon are given in Appendix B.

Hydrolysis

Ethephon is stable to hydrolysis in acidic sterilized water, but does rapidly hydrolyze in neutral and alkaline environments. Ethephon was stable towards hydrolytic degradation in a sterile pH 5 buffered solution incubated in the dark at 25 ± 1EC for 30 days, and has a calculated half-life of approximately 73 days. However, under neutral and basic conditions, rapid degradation was observed, with approximate half-lives of 2.4 days and 1.0 day for pH 7 and pH 9, respectively. Ethylene gas was the only labeled degradate

detected under all three pH conditions. In addition to ethylene, phosphoric acid was also found (MRID 41545701).

Photodegradation in water

Ethephon is stable to photolysis in water. Ethephon was stable towards photodegradation in a sterile pH 5 aqueous buffered solution exposed to continuous artificial sunlight for 15 days at 25 ± 1EC. Ethylene gas was the only radiolabeled degradate, however, phosphoric acid was also identified in solution. These two degradates were also identified in the dark controls and are attributed to hydrolysis. There were no distinctive photolytic products formed. The half-life under irradiated conditions was calculated to be 61 days. Under the non-irradiated control conditions, the half-life was 111 days. If it is assumed that hydrolysis occurs concurrently to the same degree under irradiated conditions, then a "photodegradation-only" half-life can be determined to be 139 days. (MRID 41545601).

Photodegradation on soil

Photodegradation on soil does not appear to be a significant route of dissipation of ethephon. Ethephon degraded with a half-life of 5.1 days on sandy loam soil that was irradiated with an artificial light source on a 12-hour photoperiod for 30 days. Ethephon degraded with a half-life of 8.0 days in the dark controls. Based on the calculated rate constants, photodegradation accounted for approximately 36% of the total degradation observed over a given 24-hour period. Other degradative processes accounted for the additional 64%. The major degradates were ethylene gas and soil-bound 2-hydroxy ethyl phosphonic acid. 2-Hydroxy ethyl phosphonic acid appeared to be persistent; its concentration increasing throughout the study period. Both degradates were found in the irradiated and dark control systems. (MRID 41681401).

Aerobic soil metabolism

Ethephon degrades fairly rapidly to ethylene gas and 2-hydroxy ethyl phosphonic acid in soil under aerobic conditions. Ethephon degraded with a half-life of 7.5 days in aerobic sandy loam soil that was incubated in the dark at 25EC. The major degradates were ethylene gas and soil-bound 2-hydroxy ethyl phosphonic acid. 2-Hydroxy ethyl phosphonic acid appeared to be persistent; its concentration increasing throughout the study period. ^{14}C Ethephon comprised an average of 4.7% of the applied radioactivity after 30 days. Two radiolabeled degradates were isolated. Ethylene gas was a maximum average of 15.0% of the applied at 21 days and was 8.5% at 30 days posttreatment. The nonvolatile degradate, 2-hydroxy ethyl phosphonic acid, increased throughout

the study period to a maximum average of 63.5% of the applied at 30 days posttreatment.(MRID 41757701).

Anaerobic aquatic metabolism

Ethephon degrades fairly rapidly to ethylene gas and 2-hydroxy ethyl phosphonic acid in flooded sediment under anaerobic conditions. Ethephon degraded with a half-life of 5.3 days in flooded silt loam sediment that was incubated in the dark under a nitrogen atmosphere at 25EC. The major degradates were ethylene gas and soil-bound 2-hydroxy ethyl phosphonic acid. 2-Hydroxy ethyl phosphonic acid appeared to be persistent; its concentration increasing throughout the study period. In the sediment/pond water system, approximately 1.8% of ^{14}C ethephon was detected at 30 days postapplication. It was found that the radioactivity in the water layer was almost entirely due to parent ethephon. Two radiolabeled degradates were isolated in the sediment/pond water system. Ethylene gas averaged 27.2% of the applied at 1 day posttreatment, 41.6% at 3 days, and 50.6-52.1% at days 14 through 30. The nonvolatile degradate, 2-hydroxy ethyl phosphonic acid, increased throughout the study period to a maximum average of 42.6% of the applied at 30 days. (MRID 41757702).

Leaching and adsorption/desorption

Ethephon can be characterized as having moderate to low mobility in soil. Based on batch equilibrium experiments, ^{14}C-ethephon in solution at 0.4, 1.3, 5.1, and 10.1 ppm can be characterized as having moderate to low mobility in loamy sand and silt loam soil, and as being immobile in sandy loam and clay soil and in sandy loam pond sediments that were equilibrated in the dark for 24 hours at 25EC. Freundlich adsorption values (K_{ads}) were 2.4 for the silt loam soil, 7.2 for the loamy sand soil, 29.8 for sandy loam soil, 53.1 for the clay soil, and 57.3 for the sandy loam pond sediment. Respective K_{oc} values were 608, 3117, 4078, 3220, and 1676. Freundlich desorption values (K_{des}) were 3.9 for the silt loam soil, 17.5 for the loamy sand soil, 62.4 for sandy loam soil, 69.0 for the clay soil, and 87.9 for the sandy loam pond sediment; respective K_{oc} values were 992, 7600, 8547, 4181, and 2570 (MRID 42126001).

Terrestrial field dissipation

Ethephon dissipates fairly rapidly and shows moderate to low mobility under actual field conditions. At field sites in southern **California**, **North Carolina**, and **Washington**, ethephon (2-6 lb/gallon soluble concentrate (SC)/l), at 1.6-2 lb ai/A, dissipated with half-lives of approximately 7-25 days. Although ethephon was detected at depths of 45 and 60 cm in the loam soil in California and the loamy sand soil in Washington, respectively, these detections were likely the result of sample contamination through the use of the bucket auger sampling apparatus, given that these detects were first encountered within 1 week after application. In North Carolina sand soil, ethephon did not move below the 15-cm depth .

In **California**, ethephon dissipated with a calculated half-life of 11.7 days in the 0-to-45 cm depth of loam soil after spraying with ethephon (Ethrel, 2 lb/gallon SC/L) at a nominal concentration of 1.6 lb ai/A (maximum label rate). At the time of application (May 1990), the field plot contained tomato plants that were 10-30 cm in height. In the 0-to-15 cm soil depth, ethephon concentrations ranged from 0.62-0.87 ppm immediately posttreatment, 0.31-0.39 ppm at 4 days, 0.13-0.19 ppm at 15 days, 0.06-0.08 ppm at 29 days, and 0.02 ppm at 98 days. In the 15-to-30 cm soil depth, ethephon averaged 0.026 ppm at 4 and 9 days posttreatment and #0.01 ppm at 15 through 98 days. Ethephon was detected in the 30-to-45 cm depth only at 4 and 9 days posttreatment, at 0.010-0.020 ppm. Ethephon was not detected below a depth of 45 cm.

In **North Carolina**, ethephon dissipated with a calculated half-life of 6.8 days in the 0-to-15 cm depth of sand soil that was sprayed with ethephon (Prep, 6 lb/gallon SC/L) at a nominal concentration of 2 lb ai/A (maximum label rate). At the time of application (August 1990), the field plot contained cotton plants that had been trimmed to 0.2 m in height. In the 0-to-15 cm soil depth, ethephon was detected at 0.72-1.29 ppm immediately posttreatment, 0.35-0.41 ppm at 4 days, 0.06-0.11 ppm at 16 days, and 0.03-0.05 ppm at 31 days. Ethephon was not detected below a depth of 15 cm.

In **Washington State**, ethephon dissipated with a calculated half-life of 25.0 days in the 0-to-60 cm depth of loamy sand soil that was sprayed with ethephon (Cerone, 4 lb/gallon SC/L) at a nominal concentration of 1.66 lb ai/A (> 3x maximum label rate). At the time of application (April 1990), the field plot contained wheat plants that were 0.5-0.7 cm in height. In the 0-to-15 cm soil depth, ethephon was detected at 1.18-1.34 ppm immediately posttreatment, 0.14-0.31 ppm at 7 days, 0.10-0.21 ppm at 30 days, and 0.01-0.04 ppm at 58 through 128 days. In the 15-to-30 cm soil depth, ethephon averaged 0.30 ppm at 7 days posttreatment and steadily decreased to 0.01 ppm at

128 days. Ethephon averaged a maximum 0.205 ppm in the 30-to-45 cm depth and 0.06 ppm in the 45-to-60 cm depths; both maximum concentrations were measured at 7 days posttreatment. (MRID 42011501)

b. Environmental Fate Assessment

Ethephon is not persistent in the environment. The major routes of dissipation appear to be chemical hydrolysis under neutral and alkaline conditions and microbial degradation. Although ethephon does degrade fairly rapidly in somewhat acidic soils (pH 6.1) under aerobic and anaerobic conditions, it does not hydrolyze in sterile, acidic water (pH 5). The major degradates of ethephon are ethylene gas and 2-hydroxy ethyl phosphonic acid, the latter formed by microbially mediated hydrolytic dehalogenation. Ethephon can be characterized as having moderate to low mobility in soil. The mobility of the soil degradate 2-hydroxy ethyl phosphonic acid is not conclusively known, however, it is believed that it binds to soil.

Ethephon is reported to have a very low octanol/water partition coefficient ($K_{ow} < 0.00626$), therefore, it is not expected to accumulate in fish.

In the field, ethephon exhibited the same characteristics (rapid degradation and moderate to low mobility) as those seen in the laboratory. At field sites in southern California, North Carolina, and Washington, ethephon dissipated with half-lives of approximately 7 to 25 days. Although ethephon was detected at depths of 45 and 60 cm in the loam soil in California and the loamy sand soil in Washington, respectively, these detections were likely the result of sample contamination through the use of the bucket auger sampling apparatus, given that these detects were first encountered within 1 week after application. In North Carolina sand soil, ethephon did not move below the 15 cm depth.

2. Ecological Effects

All data requirements for assessing the ecological risk of ethephon have been satisfied.

a. Ecological Effects Data

(1) Terrestrial Data

Avian Acute Toxicity

Avian Acute Oral Toxicity Findings			
Species	**% Test Material**	**LD_{50}** mg ai /kg	**Conclusions**
Bobwhite Quail	TGAI	1072 mg/kg	slightly toxic
Bobwhite Quail	75%	596 mg/kg	slightly toxic
Mallard Duck	TGAI	1998 mg/kg	slightly toxic to practically nontoxic

Acute oral toxicity studies show that ethephon is slightly toxic to bobwhite quail and slightly toxic to practically nontoxic to mallard duck. (MRIDs 00026041, 00027493, 00026040).

Avian Subacute Dietary Toxicity

Avian Subacute Dietary Toxicity Findings			
Species	**% Test Material**	**LC_{50}** ppm	**Conclusions**
Bobwhite Quail	21.3%	> 10,000 ppm	practically nontoxic
Mallard Duck	TGAI	> 10,000 ppm	practically nontoxic
Mallard Duck	75%	> 5000 ppm	practically nontoxic

On a subacute dietary basis, ethephon has been characterized as practically nontoxic to mallard duck and bobwhite quail (MRIDs 00085446, 00122414, 00056480).

Toxicity to Nontarget Mammals

Acute oral toxicity studies in rats show that ethephon is slightly toxic to mammals with an LD_{50} of 1600 mg/kg. (MRID 00029509).

(2) Aquatic Data

Acute Fish Toxicity

Acute Fish Toxicity Findings			
Species	**% Test Material**	**LC_{50}** mg ai/l	**Conclusions**
Bluegill sunfish, warm water	71.3%	221.7 mg/l	practically nontoxic
Fathead minnow, warm water	75%	88 mg/l	slightly toxic
Rainbow trout, cold water	71.3%	254.5 mg/l	practically nontoxic

Ethephon was found to be practically nontoxic to coldwater fish and practically nontoxic to slightly toxic to warmwater fish. (MRIDs 00122412 and 00027496).

Acute Invertebrate Toxicity

Acute Invertebrate Toxicity Findings			
Species	**% Test Material**	**EC_{50}** ppm	**Conclusions**
Daphnia magna	75%	54 ppm	slightly toxic
Daphnia magna	TGAI	31.7 ppm	slightly toxic
Chironomus teatans (midge)	TGAI	165 ppm	practically nontoxic
Gammarus fasciatus (amphipod)	TGAI	92.5 ppm	slightly toxic

Ethephon has been found to be practically nontoxic to slightly toxic to freshwater invertebrates. (MRIDs 00027496 and 00054013).

Chronic Invertebrate Toxicity

Based on data from an aquatic invertebrate life-cycle study with *Daphnia magna*, the Maximum Allowable Tolerated Concentration (MATC) was determined to be between 17 and 38 mg ai/l. (MRID 42294501)

Estuarine/marine Toxicity

Estuarine/marine Toxicity Findings			
Species	**% Test Material**	**Value** mg ai/l	**Conclusions**
Oyster	72.2%	EC_{50} = 60 mg ai/l NOEL < 17 mg ai/l	slightly toxic
Grass shrimp	88.3%	LC_{50} > 370 mg ai/l	practically nontoxic

There is sufficient information to characterize ethephon as slightly toxic to estuarine/marine mollusks and practically nontoxic to shrimp. The requirement for testing acute toxicity with an estuarine/marine fish has been waived. Of the species tested, the eastern oyster is the most sensitive with effects on shell deposition being observed at concentrations as low as 17 ppm. (MRIDs 41296202, 00054013 and 00027496).

(3) Non-Target Insects Data

There is sufficient information to characterize ethephon as relatively nontoxic to honey bees. The LD_{50} of technical ethephon is 7.0 Fg/bee. (MRID 00009181)

(4) Non-Target Plants Data

The following table provides the results for the non-target plant testing.

Toxicity to Non-Target Plants		
Study Type, Species	**% Test Material**	**Results**
Seed Germination/Seedling Emergence (Tiers 1 and 2)	71.9%	Seed Germination: NOEL = 6.5 mg ai/l (ryegrass) Seedling Emergence: NOEL = 5.5 mg ai/l (all crops). Shoot Length: NOEL = 0.33 mg ai/l (oat), EC_{25} < 5.4 mg ai/l (cabbage, lettuce, oat, soybean, and tomato)
Seedling Emergence (Tier 2)	71.9%	NOEL = 0.23 lb ai/A EC_{25} = 0.24 lb ai/A EC_{50} = 1.50 lb ai/A (ryegrass)
Vegetative Vigor (Tier 1 and 2)	71.9%	NOEL = 0.29 lb ai/A (corn) EC_{25} < 2.3 lb ai/A (cabbage, corn, cucumber, lettuce, and tomato)
Vegetative Vigor (Tier 2)	71.9%	NOEL = 0.49 lb ai/A EC_{25} = 0.79 lb ai/A EC_{50} = 1.80 lb ai/A (carrot)
Aquatic Plant Growth and Reproduction, Selenastrum capricornutum	71.9%	NOEL = 1.4 mg ai/l
Aquatic Plant Growth and Reproduction, Anabaena flosaquae	71.9%	NOEL = 1.8 mg ai/l
Aquatic Plant Growth and Reproduction, Navicula pelliculosa	71.9%	NOEL = 1.5 mg ai/l
Aquatic Plant Growth and Reproduction, Skeletonema costatum	71.9%	NOEL = 1.8 mg ai/l
Aquatic Plant Growth and Reproduction, Duckweed	71.9%	NOEL < 0.10 mg ai/l EC_{50} = 2.5 mg ai/l

The most significant effect of ethephon on terrestrial plants was a reduction of plant growth resulting in reduced shoot lengths and weights. For emerging seedlings, ryegrass was the most sensitive species tested, with a 25% reduction in shoot length occurring at an application rate of 0.24 lbs ai/acre. For mature plants, carrot was the most sensitive species tested, with a 25% reduction in shoot weight occurring at an application rate of 0.49 lb ai/acre. Duckweed was the most sensitive aquatic plant species. A 50% reduction in

growth of duckweed occurs at a concentration of 2.5 mg ai/L. (MRIDs 41403301,41403302,41403303, 41403304,41403305, 41509001,41659401).

b. Ecological Effects Risk Assessment

This section consists of numerous risk assessments each covering a different combination of endpoint and exposure scenarios. Each risk assessment includes a risk quotient which combines the toxicity and exposure information. For each risk quotient there is an established value above which the risk is considered to be at a high level of concern (LOC). The generic risk quotients and their respective LOC's for each risk assessment are provided in the following table. Note that the same risk quotients are used for non-endangered and endangered species, but the acute LOC is lower for endangered species.

Established Levels of Concern (LOC's)

Endpoint/Scenario	Risk Quotient	LOC Non-Endangered	LOC Endangered
Mammalian acute	EEC/LC_{50}	0.5	0.1
Mammalian chronic	EEC/LEL	1.0	1.0
Avian acute	EEC/LC_{50}	0.5	0.1
Avian chronic	EEC/LEL	1.0	1.0
Aquatic acute	EEC/LC_{50}	0.5	0.05
Aquatic chronic	EEC/LEL	1.0	1.0
Nontarget insects and plants	Not quantified	N/A	N/A

Non-Endangered Species

Terrestrial Organisms

Ethephon is expected to have minimal effects on birds. Minimal effects are also expected for mammals.

The maximum residues that would be expected in animal forage are given in the following table. Since 3 lb/A is the maximum use rate for any use site, 720 ppm is the maximum possible expected environmental concentration (EEC). This is over ten times smaller than the LC_{50} for mallards (LC_{50} > 10,000 ppm) or 3 times smaller than the LC_{50} for bobwhites (LC_{50} > 2130 ppm).

Maximum Residues of Ethephon on Vegetation Immediately Following Application (Hoerger and Kenaga, 1972)

Maximum Residues (ppm)			
Vegetation Type	3 lb/A	2 lb/A	1 lb/A
Short grass	720	480	240
Long grass	330	220	110
Leaves and leafy crops	375	250	125
Forage Crops (legumes)	174	116	58
Pods with seeds (legumes)	36	24	12
Grain	30	20	10
Fruit	21	14	7

Aquatic Organisms

Freshwater Fish

Ground Application

Minimal impact on fish is expected from ground application of ethephon.

The following scenario is applicable to ground application on all crops except peanuts, for which seed treatments are used. Since ethephon is highly soluble in water (1.2×10^3 ppm), 5% of the amount applied is expected to enter the aquatic environment in surface runoff. The maximum application rate is 3 lb/A for foliar spraying on apples (local use in North Carolina). Assuming that ten acres of crop land drain into a 1 acre water body, the maximum rate of loading from runoff would be:

$$10 \text{ A} \times 3.0 \text{ lb/A} \times 0.05 = 1.5 \text{ lb/A}.$$

Given that residues for direct application of pesticide to a 1 acre water body 6 in. deep are 734 ppb/lb ai, this loading would be expected to yield a concentration of 1.1 ppm in a water body that is 6 in. deep (1.5 lb/A x 734 ppb/lb). It would be expected to yield a concentration of 0.092 ppm in a water body 6 ft. deep (1.5 lb/A x 61 ppb/lb ai).

The most sensitive fish species tested was the fathead minnow, which has a LC_{50} of 88 ppm ai. This makes the maximum risk quotients 0.0125 and 0.0010 for bodies of water 6 inches and 6 feet deep, respectively. Minimal impact on fish is therefore expected from spraying of ethephon with ground equipment at any use site.

Aerial Application

Minimal impact on fish is expected from aerial spray of ethephon.

Among the crops for which aerial spray is allowed, the maximum use rate is 2 lb ai/A for use on cotton and pineapples. It is assumed that ten acres of treated crop land will drain into a 1 acre water body. Sixty percent of the amount sprayed is expected to reach the treatment area, and 5% of that is expected to enter aquatic habitat via surface runoff. The maximum loading into the water body from runoff therefore would be:

$$10 \text{ A} \times 2.0 \text{ lb/A} \times 0.6 \times 0.05 = 0.60 \text{ lb}$$

An additional 5% of the amount sprayed on an adjacent acre of land is expected to enter the water body via spray drift. At the maximum use rate, then, the loading into the water body from drift would be:

$$1 \text{ A} \times 2.0 \text{ lb/A} \times 0.05 = 0.10 \text{ lb}$$

Thus, the total loading into the aquatic habitat would be:

$$0.60 \text{ lb} + 0.10 \text{ lb} = .70 \text{ lb}$$

Given that residues for direct application of a pesticide to a 1 acre water body 6 in. deep are 734 ppb/lb ai, this loading would be expected to yield a concentration of 0.51 ppm in a water body that is 6 in deep (0.70 x 734 ppb/lb ai). It would be expected to yield a concentration of 0.043 ppm in a water body 6 ft. deep (0.70 x 61 ppb/lb ai).

The LC_{50} (130 ppm) for the most sensitive species (the fathead minnow) is at least 255 times greater than the maximum EEC in either a 6-in or 6-ft pond, making all risk quotients less than 0.004. Minimal impact on fish is, therefore, expected from aerial spray of ethephon at any use site.

Freshwater Invertebrates

Minimal acute and chronic effects are expected for freshwater invertebrates.

The EEC's for aquatic invertebrates are identical to those calculated above for fish. The maximum EEC is 1.1 ppm in a 6-in water body when ethephon is applied with ground equipment at a rate of 2 lb ai/A. The most sensitive species is Daphnia magna which has an EC_{50} of 31.7 ppm. Therefore, the maximum risk quotient for freshwater invertebrates is $1.1/31.7 = 0.035$ and the level of concern is not exceeded.

For chronic effects of ethephon in Daphnia magna, the maximum EEC is less than the maximum acceptable toxicant concentration (MATC). Thus, minimal chronic effects are expected for freshwater invertebrates.

Marine and Estuarine Organisms

Minimal effects to marine and estuarine organisms are expected from use of ethephon.

Exposure of marine and estuarine habitats is expected from certain uses of ethephon. The maximum use rates for these sites are 2.19 lb ai/A when using ground equipment (blackberries) and 2.0 lb ai/A when using aerial application (cotton). These are identical to the maximum rates used in the risk assessment for fish. Thus, the EEC's for marine and deep estuarine habitats are the same as those calculated before for a 6-ft water body (0.092 ppm for ground applications and 0.043 ppm for aerial applications). For shallow estuaries, the EEC's are the same as those calculated before for a 6-in water body (0.8 ppm for ground applications and 0.51 ppm for aerial applications).

The most sensitive marine/estuarine species tested is the eastern oyster which has an EC_{50} of 60 mg ai/l. The greatest EEC is 0.8 ppm for shallow estuaries with ground application. Therefore, the maximum risk quotient is 0.013 (0.8/60). Since the risk quotient is far less than 0.5 for the worst case scenario, minimal effects to marine and estuarine organisms are expected from any use of ethephon at any use site.

Non-Target Plants

Aquatic Plants

No more than minimal effects are expected on aquatic plants for all use site. For aquatic plants, the EEC's are identical to those calculated above for fish. The maximum EEC among all scenarios is 1.1 ppm for a 6 inch water body when ethephon is applied using ground equipment at a rate of 2 lb ai/A. The most sensitive aquatic plant is duckweed, which has an EC_{50} of 2.5 ppm. Since this is greater than the maximum EEC, no more than minimal effects are expected on aquatic plants for all use site.

Terrestrial Plants (dry land)

Minimal effects to terrestrial plants that inhabit dry land are expected from ground and aerial applications of ethephon.

Ground Application

For terrestrial plants that inhabit dry land, one acre of treated land is assumed to expose plants on one acre of adjacent land as the result of surface runoff. The maximum application rate for ground application of ethephon is 3 lb ai/A for apples in North Carolina and pineapples in Hawaii. Assuming that 5% of what is applied will migrate via runoff, the expected loading in the soil of an adjacent acre of land is:

$$1 \text{ A} \times 3 \text{ lb/A} \times 0.05 = 0.15 \text{ lb}$$

The EC_{25} for ryegrass, the most sensitive plant species, is 0.24 lb/A. Since the maximum loading for plants on dry land (0.15 lb/A) is less than the EC_{25}, minimal effects are expected for these species from all ground applications of ethephon.

Aerial Application

When aerially applied, the soil may be contaminated from spray drift as well as surface runoff. For the maximum use rate of 2 lb/A, the total loading is:

$$\underbrace{(1 \text{ A} \times 2 \text{ lb/A} \times 0.6 \times 0.05)}_{\text{(Runoff)}} + \underbrace{(1 \text{ A} \times 2 \text{ lb/A} \times 0.05)}_{\text{(Drift)}} = 0.16 \text{ lb/A}$$

This EEC is less than the EC_{25} for ryegrass (0.24 lb/A). Therefore, minimal detrimental effects to terrestrial plants that inhabit dry land are expected from aerial applications of ethephon.

Terrestrial Plants (wet land) and Semi-Aquatic Plants

Risk to semi-aquatic plants is possible from ethephon use on apples (local use in NC), cotton, tobacco, macadamia nuts, blackberries and pineapples. However, the magnitude of the risk quotients, from 1.0 to 1.5, is not particularly high.

The following scenario is used for EEC estimates for terrestrial or semi-aquatic plants that inhabit low, wet areas. It is assumed that 10 acres of treated land drains into each acre of habitat. The runoff collects in the wet area and is assumed to eventually drain into the soil. Any pesticide contained within this runoff would be loaded into the soil. This predicted amount of loading is compared to the loading that phytotoxicity tests have shown to cause a 25% inhibition of emergence and growth of plants, the EC_{25}.

The preliminary EEC (PEEC) calculation for this scenario resulted in an EEC greater than the EC_{25} for inhibition of emergence and growth in plants. Therefore, high risk to semi-aquatic plants at some use sites was predicted. As a result, a refinement of the PEEC was completed.

The refined model estimated the environmental concentrations in a 2-m water body based on the aerobic soil metabolism half-life, the K_{oc} for desorption, the solubility, and the average interval between storms. The maximum possible runoff and average storm interval were assumed to be 10% and 7 days, respectively. The values used for the K_{oc}, aerobic soil half-life, and solubility were 922 L/kg, 7.5 d, and 124,000 mg/L. With aerial applications, the model predicts the following EEC's:

Application Rate (lb/A)	EEC (ppb)
0.5	3.4
1.0	6.8
1.5	10.2
2.0	13.6
3.0	20.4

However, for a plant scenario, instead of calculating the concentration of the chemical in water, the rate of loading onto the soil (lb/A) must be calculated. The above EEC values were, therefore, converted to lb/A by dividing by 56 (an EEC of 56 ppb corresponds to loading of 1 lb of chemical into a 1-ha water body with a depth of 2 m). These environmental loading rates onto the soil are:

Application Rate (lb/A)	Environmental Loading (lb/A)
0.5	0.06
1.0	0.12
1.5	0.18
2.0	0.24
3.0	0.36

The EC_{25} for ryegrass, the species most sensitive to ethephon, is 0.24 lb/A. Therefore, applications at rates of less than 2.0 lb/A will not exceed the EC_{25}. Since the maximum use rate for cotton, macadamia nuts, pineapple (other than in Hawaii), and tobacco is 2.0 lb/A, the environmental loading just equals the EC_{25}. The maximum use rate for blackberries is 2.1875 lb/A. The environmental loading rate predicted for this use rate is 0.26 lb/A, which exceeds the EC_{25} with a risk quotient of 1.08. The Special Local Use for treatment of apples in North Carolina (NC82000700) and pineapples in Hawaii also results in EEC's that exceed the EC_{25}. For both cases, the maximum use rate is 3.0 lb/A, and the predicted environmental loading is 0.36 lb/A. Therefore, the risk quotient is 1.5.

In summary, risk to semi-aquatic plants is possible from the use of ethephon on apples (local use in NC), cotton, tobacco, macadamia nuts, blackberries and pineapple.

However, ethephon is a growth regulator, and as such is not intended to be toxic to plants. Compared to herbicides, the magnitude of the risk quotients, 1.0 to 1.5, is not particularly high.

While the potential for risk to semi-aquatic plants exists, it should not be extensive. The risk quotient for cotton, macadamia nuts, pineapple (other than in HI), and tobacco equals but does not exceed 1.0. Since this risk quotient is based on a high exposure scenario, the conditions necessary to pose risk to semi-aquatic plants are expected to occur infrequently. For use sites that have risk quotients exceeding 1.0, the environmental impact would be geographically limited. Blackberries is a minor crop, and the local state use registrations involve relatively few acres. According to the 1987 Agriculture Census, about 18,000 acres of apples are grown in North Carolina and about 22,000 acres of pineapples are grown in Hawaii.

Endangered Species

No detrimental effects are expected for any endangered animal. However, some uses of ethephon may harm certain endangered plants that live in wet areas.

The above risk assessments indicated that freshwater invertebrates would be the animals most likely to be at risk from the use of ethephon. However, the maximum risk quotient for freshwater invertebrates was determined to be 0.035. This ratio is less than 1/20 of the EC_{50}, therefore, no detrimental effects are expected for endangered freshwater invertebrates, or for any other endangered animal.

Risk to endangered semi-aquatic plants is possible from the use of ethephon on apples (local use in NC), cotton, tobacco, macadamia nuts, blackberries, and pineapple.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

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

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient ethephon, the Agency has sufficient information on the health effects of ethephon and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing ethephon for all uses are eligible for reregistration.

The Agency has determined that ethephon products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

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

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.300(a)

The tolerances listed in 40 CFR §180.300(a) are for residues of ethephon *per se*.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.300(a) for the following commodities: apples, barley grain and straw, blackberries, cherries, cottonseed, Macadamia nuts, pineapples, tomatoes, walnuts, and wheat grain and straw. Sufficient data are available to assess residue levels of ethephon in tobacco.

The established tolerance of 2 ppm for residues of ethephon in/on cottonseed should be increased to 4 ppm. The registrant has proposed an amendment to increase the currently established tolerance level for residues of ethephon in/on cottonseed from 2 ppm to 4 ppm.

Pending the further amendment of the 0.33 lb/gal SC/L product label (EPA Reg. No. 264-263 dated 8/11/94) to prohibit the harvesting of any treated pumpkins for human or animal consumption and specify that treatments are to be made to pumpkins for seed production only, the Agency has hereby concluded that the currently registered use of ethephon on cucumbers, squash, and pumpkins for hybrid seed production is a non-food use and the 0.1 ppm tolerances for cucumbers and pumpkins should be revoked. [Note: No tolerance is established for residues of ethephon in/on squash.]

Blueberries, coffee, cranberries, figs, filberts, guavas, lemons, and tangerines, and tangerine hybrids have been deleted from ethephon product labels. Tolerances for residues in/on these commodities should be revoked.

The Agency no longer considers pineapple forage and pineapple fodder raw agricultural commodities. Tolerances for residues of ethephon in/on these commodities should be revoked.

Additional data are required to ascertain the adequacy of the established tolerances for cantaloupes, grapes, peppers, milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep. The required cantaloupe, grape, and pepper field trials are in progress.

No tolerances for residues of ethephon in poultry tissues or eggs have been established. The need for tolerances will be assessed upon

submission and evaluation of the new poultry metabolism and feeding studies. The poultry metabolism study is currently in progress.

A summary of the ethephon tolerance reassessment and modifications in commodity definitions are presented in the table at the end of this section.

Tolerances Listed Under 40 CFR §180.300(b)

The tolerance listed in 40 CFR §180.300(b) is with a regional registration as defined in 180.1(n) for residues of ethephon *per se* in/on sugarcane. Pending the submission of sugarcane test sample storage information, data are available to ascertain the adequacy of this established tolerance.

Tolerances Listed Under 40 CFR §185.2700 (a)

The food additive tolerances listed in 40 CFR §185.2700 [a] are for residues of ethephon *per se*.

Pending the receipt of adequate processed commodity storage stability data, sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §185.2700 [a] for barley, milling fractions, except flour and wheat, milling fractions, except flour.

The established tolerance of 12 ppm for raisins was erroneously excluded from 40 CFR §185.2700(a). Pending the receipt of adequate sample storage information and processed commodity storage stability data and after an appropriate tolerance is determined for residues of ethephon in/on grapes, the adequacy of the established food additive tolerance for residues of ethephon in raisins will be assessed. Available residue data indicate that a concentration factor of 4.7x is appropriate.

Data are required from a new sugarcane processing study. This study is currently in progress.

Tolerances Listed Under 40 CFR §185.2700(b)

The existing food additive tolerance of 7 ppm listed in 40 CFR §185.2700 [b] on sugarcane, molasses resulting from application of ethephon in accordance with an experimental use program should be revoked.

Tolerances Listed Under 40 CFR §186.2700

The feed additive tolerances listed in 40 CFR §186.2700 are for residues of ethephon *per se*.

Pending the receipt of adequate processed commodity storage stability data, sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §186.2700 for the following commodities: barley, milling fractions, except flour and wheat milling fractions, except flour.

Pending the receipt of adequate sample storage information and processed commodity storage stability data and after an appropriate tolerance is determined for residues of ethephon in/on grapes, the adequacy of the established feed additive tolerance for residues of ethephon in raisin waste will be assessed. Available residue data indicate that a concentration factor of 120x is appropriate.

A new sugarcane processing study is in progress.

New Tolerances

Tolerances have been proposed for the following commodities: cottonseed meal (5 ppm); apple pomace (10 ppm), apple juice (10 ppm), tomato pomace (4 ppm), and pineapple bran (12 ppm).

Pending the receipt of adequate processed commodity storage stability data, sufficient data are available to support the establishment of the following proposed food/feed additive tolerances: apple, juice, 10 ppm; cotton, meal, 5 ppm; and tomato, pomace (dried), 4 ppm.

The Agency no longer considers dried apple pomace a feed item (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II, June 1994) and available apple processing data indicate that residues of ethephon do not concentrate in wet apple pomace. Therefore, the proposed feed additive tolerance of 10 ppm for apple pomace is not required.

The Agency no longer considers pineapple bran a processed commodity of pineapple (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II, June 1994). Therefore, the proposed feed additive tolerance of 12 ppm for pineapple bran is not required.

Pending the receipt of adequate sample storage information and processed commodity storage stability data and after an appropriate tolerance is determined for residues of ethephon in/on grapes, a food additive tolerance for residues of ethephon in grape juice and a feed additive tolerance for grape pomace (dried) must be established using a concentration factor of 4x.

The Agency currently recognizes cotton gin byproducts and aspirated wheat grain fractions as raw agricultural commodities and has determined that livestock feeding restrictions for barley forage, barley hay, wheat forage, and wheat hay are not appropriate (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II, June 1994). Data depicting residues of ethephon in/on cotton gin byproducts, wheat forage, and wheat hay resulting from maximum registered use rates are hereby required. Data on wheat forage and hay will be translated to barley forage and hay, respectively. Wheat grain dust data were previously submitted which indicated that residues of ethephon do not concentrate in aspirated wheat grain fractions. In accordance with guidance (issued June 2, 1994) on aspirated grain fractions (grain dust), additional aspirated wheat grain fraction data are not required and no tolerance is needed for residues of ethephon in/on aspirated wheat grain fractions. Additional ethephon residue data requirements for cotton gin byproducts and wheat forage and hay which result from changes in the Livestock Feeds Table (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II, June 1994) will be imposed with this document. On receipt of the required cotton gin byproducts and wheat forage and hay data, the need for tolerances for residues of ethephon in/on cotton gin byproducts, barley forage, barley hay, wheat forage, and wheat hay will be determined.

As a result of changes in the Livestock Feeds Table (Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, TABLE II, June 1994), the Agency currently recognizes tomato paste as a processed commodity of tomatoes and pineapple process residue as a processed commodity of pineapples. Available tomato processing data indicate that residues of ethephon do not concentrate in tomato paste, therefore, the Agency hereby concludes that, pending receipt of adequate processed commodity storage stability data, no tolerance is needed for residues of ethephon in tomato paste. Available pineapple processing data indicate that residues of ethephon do not significantly concentrate in wet pulp (1.2x) and the Agency hereby concludes that, pending the receipt of adequate processed commodity storage stability data, no tolerance is needed for residues of ethephon in pineapple process residue.

Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.300 (a)			
Apples	5	5	
Barley, grain	2	2	
Barley, straw	10	10	
Blackberries	30	30	
Blueberries	20	Revoke	No registered uses exist.
Cantaloupes	2	Cannot be reassessed	Additional residue data are required.
Cattle, fat	0.1	Cannot be reassessed	Additional feeding studies are required.
Cattle, mbyp	0.1	Cannot be reassessed	Additional feeding studies are required.
Cattle, meat	0.1	Cannot be reassessed	Additional feeding studies are required.
Cherries	10	10	
Coffee beans	0.1	Revoke	No registered uses exist.
Cottonseed	2	4	Increase in tolerance required/*Cotton, seed*, PP0F2312 has been proposed
Cranberries	5	Revoke	No registered uses exist.
Cucumbers	0.1	Revoke	Registrant limiting use to cucumbers grown solely for seed.
Figs	5	Revoke	No registered uses exist.
Filberts	0.5	Revoke	No registered uses exist.
Goats, fat	0.1	Cannot be reassessed	Additional feeding studies are required.
Goats, mbyp	0.1	Cannot be reassessed	Additional feeding studies are required.
Goats, meat	0.1	Cannot be reassessed	Additional feeding studies are required.
Grapes	2.0	Cannot be reassessed	Additional residue data are required.
Guavas	0.1[1]	Revoke	No registered uses exist.
Hogs, fat	0.1	Cannot be reassessed	Additional feeding studies are required.
Hogs, mbyp	0.1	Cannot be reassessed	Additional feeding studies are required.
Hogs, meat	0.1	Cannot be reassessed	Additional feeding studies are required.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Horses, fat	0.1	Cannot be reassessed	Additional feeding studies are required.
Horses, mbyp	0.1	Cannot be reassessed	Additional feeding studies are required.
Horses, meat	0.1	Cannot be reassessed	Additional feeding studies are required.
Lemons	2	Revoke	No registered uses exist.
Macadamia nuts	0.5	0.5	
Milk	0.1	Cannot be reassessed	Additional feeding studies are required.
Peppers	30	Cannot be reassessed	Additional residue data are required.
Pineapples	2	2	
Pineapple fodder	3	Revoke	Pineapple fodder and pineapple forage are no longer considered as RACs.
Pineapple forage	3	Revoke	same
Pumpkins	0.1	Revoke	Use limited to pumpkins grown solely for seed.
Sheep, fat	0.1	Cannot be reassessed	Additional feeding studies are required.
Sheep, mbyp	0.1	Cannot be reassessed	Additional feeding studies are required.
Sheep, meat	0.1	Cannot be reassessed	Additional feeding studies are required.
Tangerines	0.5	Revoke	No registered uses exist.
Tangerine hybrids	0.5	Revoke	No registered uses exist.
Tomatoes	2	2	
Walnuts	0.5	0.5	
Wheat, grain	2	2	
Wheat, straw	10	10	
Proposed Tolerances to be listed under 40 CFR §180.300(a)			
Tolerances listed under 40 CFR §180.300(b)			
Sugarcane	0.1	0.1	Pending receipt of sample storage information the tolerance may be reassessed. Regional registration (HI only).
Tolerances listed under 40 CFR §185.2700 (a)			
Barley, milling fractions, except flour	5.0	5	*Barley, milled fractions (except flour)*.
Sugarcane, molasses	1.5	Cannot be reassessed	Additional data are required.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Wheat, milling fractions, except flour	5.0	5	*Wheat, milled fractions (except flour)*.
Tolerances listed under 40 CFR §185.2700 (b)			
Sugarcane, molasses	7.0	Revoke	Experimental use program was scheduled to expire 7/88.
Proposed Food Additive Tolerances to be listed under 40 CFR §185.2700			
Apple juice	N/A	10 ppm	Tolerance proposed for *apples, juice*. (Pending the receipt of adequate storage stability for processed commodities, an appropriate tolerance will be determined).
Grape juice	None	Cannot be reassessed	Concentration factor of 4x to be used for tolerance on grape juice once an appropriate tolerance for grapes is determined/*Grapes, juice*. (Pending the receipt of adequate sample storage information and storage stability for processed commodities, an appropriate tolerance will be determined).
Raisins	12[1]	Cannot be reassessed	Concentration factor of 4.7x to be used for tolerance on raisins once an appropriate tolerance for grapes is determined/*Grapes, raisins*. (Pending the receipt of adequate sample storage information and storage stability for processed commodities, an appropriate tolerance will be determined).
Tolerances listed under §186.2700			
Barley, milling fractions, except flour	5.0	5	*Barley, milled fractions (except flour)*.
Raisin waste	65.0	Cannot be reassessed	Concentration factor of 120x to be used to determine tolerance for raisin waste once an appropriate tolerance is determined for grapes/*Grapes, raisin, waste*. (Pending the receipt of adequate sample storage information and storage stability for processed commodities, an appropriate tolerance will be determined).
Sugarcane, molasses	1.5	Cannot be reassessed	Sugarcane processing study in progress.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Wheat, milling fractions, except flour	5.0	5	*Wheat, milled fractions (except flour)*.
Proposed Feed Additive Tolerances to be listed under §186.2700			
Cottonseed meal	None	5 ppm	Tolerance proposed for cottonseed meal. (Pending the receipt of adequate storage stability for processed commodities, an appropriate tolerance will be determined).
Grape pomace (dried)	None	Cannot be reassessed	Concentration factor of 4x to be used for tolerance on raisins once an appropriate tolerance for grapes is determined/*Grapes, pomace, dried*. (Pending the receipt of adequate storage stability for processed commodities, an appropriate tolerance will be determined).
Tomato pomace, dried	None	4 ppm	Tolerance proposed for dried tomato pomace. (Pending the receipt of adequate storage stability for processed commodities, an appropriate tolerance will be determined).

[1] The established tolerance of 0.1 ppm for guavas and 12 ppm for raisins were erroneously excluded from 40 CFR §180.300(a) and §185.2700(a), respectively.

CODEX HARMONIZATION

Several maximum residue limits (MRLs) for ethephon have been established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. Both Codex and the U.S. regulate ethephon *per se*. The Codex MRLs, applicable U.S. tolerances, and recommendations for harmonizing U.S. tolerances with Codex MRLs are presented below.

Codex MRLs and applicable U.S. tolerances.

Commodity	MRL (mg/kg) [1]	U.S. Tolerance (ppm)	Recommendation
Apple	5	5	Compatibility exists.
Blackberries	30	30	Compatibility exists.
Blueberries	20	20	U.S. tolerance to be revoked; no registered uses.
Cherries	10	10	Compatibility exists.
Coffee beans	0.1	0.1	U.S. tolerance to be revoked; no registered uses.
Cranberry	5	5	U.S. tolerance to be revoked; no registered uses.
Currant, Black	5	None	
Fig	5	5	U.S. tolerance to be revoked; no registered uses.
Grapes	10	2	Field residue data remain outstanding.
Hazelnuts	0.5	None	
Lemons and Limes	2	2	U.S. tolerance to be revoked; no registered uses.
Mandarins	0.5	None	
Melons, except watermelon	2	2 (cantaloupes)	Field residue data on cantaloupes remain outstanding.
Onion, bulb	0.5	None	
Peach	0.5	None	
Peppers	30	30	Field residue data remain outstanding.
Pineapple	2	2	Compatibility exists.
Tomato	3	2	Increase U.S. tolerance, toxicological considerations permitting.
Walnuts	0.5	0.5	Compatibility exists.

[1] All ethephon MRLs are Step 4.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

- Compatibility between the U.S. tolerances and Codex MRLS exists for apples, blackberries, cherries, pineapples, and walnuts.

- The Codex MRLs proposed for ethephon residues in/on tomatoes (3 ppm) is higher than the established U.S. tolerance (2 ppm). Should the Codex Committee adopt this recommendation, compatibility could be achieved by increasing the U.S. tolerance to 3 ppm.

2. Risk Mitigation

A. Acute Dietary Risks

The Agency estimates indicate that acute dietary exposures to infants (less than 1 year of age) may be of concern when the estimated 95th percentile of exposure is used. The Agency however, has concluded that these risk values represent an unrealistic worst case situation because the following conservative assumptions were employed in calculating the acute dietary risks:

1. The Agency assumed that all food crops on which ethephon is registered have been treated with ethephon and that maximum residue levels reported in or on unwashed, unpeeled, uncooked commodities at the farm gate are present on all foods. However usage data indicate that the percentage of treated crops to be processed into major infant foods on which ethephon is registered is < 10% or even "negligible".

2. The probable residue dilution that occurs in processed infant foods was not taken into account.

3. Ethephon degrades fairly rapidly to ethylene, phosphate and chloride in neutral and alkaline environments. Therefore, by the time the food has cleared distribution channels and/or processing plants, residues at the dinner table are likely to be significantly lower than high-end levels at the farm gate.

For the reasons stated above the Agency believes it is unlikely that infants and children will be exposed to ethephon treated commodities at levels that will result in acute dietary risk.

B. Risks to Plants

The Agency concludes that while the potential for risk to plants exists, the risk should not be extensive. As stated in Section III, C, 2, b the risk quotients for effects on semi-aquatic plants equal but do not exceed 1.0 for cotton, macadamia nuts, pineapples (outside Hawaii), and tobacco. The risk quotient for dry land plants also equals 1.0 for use on pineapples in Hawaii. Use sites for which the risk quotients for semi-aquatic plants exceed 1.0 are blackberries, apples in North Carolina and pineapples in Hawaii. All of these sites are limited geographically.

Rhone-Poulenc has responded to Agency concerns by proposing the following risk mitigation measures:

1. reduce the maximum use rate for blackberries and apples in North Carolina to 2.0 lbs per acre, and

2. provide information indicating that ethephon is only occasionally used at maximum rates when certain weather conditions exist, such as cool temperatures.

The Agency concludes that with these risk mitigation measures the risk to nontarget plants from the use of ethephon will be limited.

3. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered plant species to ethephon as discussed above in the science assessment chapter.

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

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in 1995 and to have enforceable county-specific bulletins available approximately one year after. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any

requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

4. Labeling Rationale

A. Worker Protection Standard

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

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

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

Uses within the scope of the Worker Protection Standard

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

Some of the registered uses of ethephon are within the scope of the WPS and some uses are outside the scope of the WPS. Those that are outside the scope of the WPS include use:

- on flowering fruit and ornamental trees growing in ornamental gardens, parks, golf courses, and public or private lawns and grounds that are intended only for decorative or environmental benefit;

- on home garden tomatoes, geraniums, azaleas, bromeliads, and potted hyacinths and daffodils.

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

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

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

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

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

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

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

There are no special toxicological concerns about ethephon that warrant the establishment of active-ingredient-based minimum PPE requirements.

Entry Restrictions

Entry Restrictions for Occupational-Use Products (WPS Uses)

Restricted Entry Interval -- Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas based on potential dermal and eye irritation. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data and (2) interim REI's that are longer than those that would be established under the WPS.

The interim WPS REI in effect until now was 48 hours. A 24-hour reentry interval was established for these uses by the 1988 Guidance for the Reregistration of Ethephon. That reentry interval was converted into a 48-hour **restricted-entry interval** through modifications specified in PR Notice 93-7, which implemented the labeling requirements of the 1992 Worker Protection standard for Agricultural Pesticides.

For occupational end-use products containing ethephon as an active ingredient, the Agency is now establishing 48 hour REI pertaining to each use of the product that is within the scope of the Worker Protection Standard. This 48-hour REI is to be increased to 72 hours when applied outdoors in arid areas. The WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. These existing WPS protections are sufficient to mitigate post-application exposures of workers who contact surfaces treated with ethephon.

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

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

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

Based on the acute toxicity of the active ingredient ethephon (toxicity category I for primary skin irritation), the PPE required for early entry is coveralls over long-sleeved shirt and long pants, chemical-resistant gloves such as any waterproof gloves, chemical-resistant footwear plus socks, and chemical-resistant headgear for overhead exposures. In addition, since ethephon is classified as toxicity category I for eye irritation potential, protective eyewear is also required.

Double Notification When an active ingredient within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) is classified as toxicity category I for acute dermal toxicity or for primary skin irritation, the WPS requires that agricultural workers must be orally warned of application AND that WPS warning signs must be posted at entrances to treated areas. Since ethephon is classified as toxicity category I for primary skin irritation, EPA is specifying that a statement requiring such "double" notification be placed on the labeling of all ethephon end-use products which contain uses within the scope of the WPS.

Refer to Section V for other required worker protection label requirements.

B. Environmental Hazard

The Agency is requiring labeling to address risk to wetland areas. (Refer to Section V).

C. Spray Drift Advisory

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

the Agency evaluation is completed, there may be further refinements in spray drift management practices.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

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

Product chemistry
Animal metabolism (poultry)
Residue analytical method in plants and animals
Storage stability
Magnitude of the residue in plants:
peppers, cantaloupes, grapes, wheat forage and hay and cotton gin byproducts
Magnitude of the residue in processed sugarcane
Magnitude of the residue in poultry and ruminant
Batch equilibrium on the degradate of 2-hydroxy ethyl phosphonic acid
Acute and subchronic neurotoxicity

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling Requirements for End-Use Products

A. Worker Protection

Personal Protective Equipment for Handlers

The personal protective equipment (PPE) for handlers is to be based on the toxicity of the end-use product. See PR Notice 93-7 or more recent Agency guidance for instructions on establishing PPE for occupational handlers. If PPE is necessary for homeowner uses of ethephon, such PPE will be established by EPA during end use product reregistration.

Entry Restrictions for Occupational-Use Products (WPS Uses)

The Agency is establishing a 48-hour restricted entry interval (REI). The REI increases to 72 hours in outdoor areas where average rainfall is less than 25 inches a year. Personal protective equipment required for WPS-permitted early entry into treated areas is coveralls over long-sleeved shirt and long pants, chemical-resistant gloves such as any waterproof gloves, chemical-resistant footwear plus socks. Chemical-resistant headgear is only required if potential exists for overhead exposures. In addition, since ethephon is classified as toxicity category I for eye irritation potential, protective eyewear is also required.

Entry Restrictions for Occupational-Use Products (Non WPS Uses)

Some registered uses of ethephon are outside the scope of the Worker Protection Standard (WPS). For nonWPS uses the Agency is requiring the following.

> "Do not allow people or pets to touch treated plants until the sprays have dried."

Entry Restrictions for Homeowner-Use Products

Some products containing ethephon have directions for use by homeowners. The Agency is concerned about post-application exposures to homeowners following application of ethephon. Therefore, the Agency is requiring that home-use products contain the following requirement:

> "Do not allow people or pets to touch treated plants until the sprays have dried."

Other Labeling Requirements

Reduce PPE when Engineering Controls Used

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

User Safety Requirements

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

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

User Safety Statements

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

"Users should remove clothing immediately if pesticide gets inside."

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

Application Restrictions

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

Notification

"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."

B. Environmental Hazard

The following precautionary statement is required to address risks to wetlands:

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark."

For residential use sites (i.e. ornamental trees, shrubs, vines, and herbaceous plants), the statement "do not apply directly to water" may be used in lieu of the above statement.

C. Spray Drift

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

"AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR."

"The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions."

"The following drift management requirements must be followed to avoid off-target 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 below.

AERIAL DRIFT REDUCTION ADVISORY

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

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

INFORMATION ON DROPLET SIZE

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

CONTROLLING DROPLET SIZE

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

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

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

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

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

BOOM LENGTH

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

APPLICATION HEIGHT

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

SWATH ADJUSTMENT

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

WIND

Drift potential is lowest between winds speeds of 2 - 10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

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

TEMPERATURE INVERSIONS

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

SENSITIVE AREAS

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

D. Residue Chemistry Label Requirements

The following label revisions must be added to pertinent end-use products:

-Product labels must be amended to reflect a maximum allowable use rate of 2 lb ai/A/season for application of ethephon to cotton.

-Label directions for apples, cranberries, carob, and olives that are for ornamental use only must be clearly designated as such.

-The 0.33 lb/gal SC/L label (264-263) must be amended to prohibit the harvesting of any treated pumpkins for human or animal consumption and must specify that treatments are to be made to pumpkins for seed production only.

-Labels must be amended to reduce the maximum use rate for blackberries and for apples in NC (24C) to 2.0 lb per acre. (Refer to Section IV, B, 2 for a discussion of the risk mitigation measures proposed by Rhone-Poulenc).

The Agency has completed the review of available residue data to support the reregistration of Rhone-Poulenc end-use products. The following table identifies the currently accepted food/feed use patterns for the Rhone-Poulenc products only. Data will be required for all new product registrations or new uses where the label use rates exceed the rates listed below. The Agency is requiring that all end-use product labels be amended such that they are consistent with the basic producer labels.

Food/Feed Use Patterns Subject to Reregistration for Ethephon (Case 0382).

Site Application Type Application Timing Application Equipment [1]	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Use Limitations
Crop Uses					
Apples					
Foliar Fruit loosening Fruit coloration 1 to 2 weeks before harvest Ground equipment	2 lb/gal SC/L	1.25 0.25	1.25	7	Grazing or feeding of cover crops to livestock is prohibited. The SLN No. NC820007 permits one broadcast foliar ground application to Red Delicious apple trees in NC at a maximum of 0.5 lb ai/100 gal at up to 600 gal/A (3 lb ai/A).
Apples and crabapples (fruit elimination) [2,3]					
Foliar Fruit removal At flower bud to full bloom stage, prior to fruit set Ground equipment	2 lb/gal SC/L (264-267) 0.33 lb/gal SC/L (264-263)	0.15 oz ai/gal 0.13 oz ai/gal		NA	For elimination of nuisance fruit.
Barley					
Foliar, broadcast Early to late boot stage prior to awn emergence Ground and aerial equipment	2 lb/gal SC/L (264-376) 4 lb/gal SC/L (264-377)	0.5	0.5	40	Apply ground and aerial applications in a minimum of 7 and 3 gal/A, respectively. Grazing or foraging by livestock or cutting for hay or silage are prohibited.[4] Mature straw at normal harvest may be consumed by animals. A 30-day plant-back interval is specified.
Blackberries					
Foliar Ground equipment	2 lb/gal SC/L (264-267)	2.2	2.2	3	Use permitted in OR and WA only.

Site Application Type Application Timing Application Equipment [1]	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Use Limitations
Crop Uses					
Cantaloupes					
Foliar Aerial or ground equipment	2 lb/gal SC/L (264-267)	0.75	0.75	2	Ground and aerial applications can be made in a minimum of 40 and 10 gal/A, respectively. Only ground equipment may be used for application in CA and AZ. Aerial or ground applications are allowed in TX. A 30-day plant-back interval is specified.
Carob (fruit elimination) [2,3]					
Foliar At flower bud to full bloom stage, prior to fruit set Ground equipment	2 lb/gal SC/L (264-267) 0.33 lb/gal SC/L (264-263)	0.08 oz ai/gal 0.07 oz ai/gal		NA	For the elimination of nuisance fruit.
Cherries (sweet and tart)					
Foliar Fruit loosening Apply at stage 3 fruit development Ground equipment	2 lb/gal SC/L (264-267)	1 (sweet) 0.25 (tart)	1	7	This use is not permitted in CA. Apply in a minimum of 50 gal/A.
Cotton					
Foliar, Broadcast Boll opening Preconditioning for defoliation Defoliation Ground and aerial equipment	6 lb/gal EC (264-418)	 2 1 0.25	2	7	Apply in a minimum of 2 gal/A by air and 15 gal/A by ground. In AZ and CA, aerial spray volume must be at least 5 gal/A. A 30-day plant-back interval is specified.

Site Application Type Application Timing Application Equipment [1]	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Use Limitations
Crop Uses					
Foliar Boll opening Preconditioning for defoliation Aerial or ground equipment	4 lb/gal EC (264-380) [5]	2 1		7	Apply in a minimum of 2 gal/A by air and 15 gal/A by ground. In AZ and CA, aerial spray volume must be at least 5 gal/A. Do not mix with defoliants or desiccants in CA and AZ. A 30-day plant-back interval is specified.
Cucumbers (hybrid seed production) [2,6]					
Foliar Apply at 2-leaf stage Ground equipment	0.33 lb/gal SC/L (264-263)	0.08	0.16	NA	For hybrid seed production. Do not use on cucumbers to be harvested for fresh or processed markets. Do not harvest any treated cucumbers or squash for human or animal consumption. Treatments are to be made for seed production only. Spray plants at the two leaf stage.
		0.25 (CA only)	1.5 (CA only)	60	In CA only, six applications are allowed beginning at the first true leaf stage and at 3- to 10-day intervals thereafter.
Foliar Apply when 5-30% of berries show color Ground or aerial equipment	2 lb/gal SC/L (264-267)	0.5	0.5	14	Use permitted in CA and AZ only. Aerial application is allowed only for 'Tokay' grapes. SLN No. CA8300034 permits one application at 0.5 lb ai/A at time of berry color initiation.
Macadamia Nuts					
Foliar Prior to harvest Ground equipment	4 lb/gal SC/L (264-257)	1	1	5	SLN No. HI840004 permits one application to leaves and nuts in HI only. Grazing and foraging of cover crops is not permitted.

Site Application Type Application Timing Application Equipment [1]	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Use Limitations
Crop Uses					
Olives (fruit elimination) [2,3]					
Foliar At flower bud to full bloom stage, prior to fruit set Ground equipment	2 lb/gal SC/L (264-267) 0.33 lb/gal SC/L (264-263)	0.15 oz ai/gal 0.13 oz ai/gal		NA	For the elimination of nuisance fruit, not intended for use as a thinning agent in commercial fruit production.
Peppers					
Foliar Apply at fruit maturity Ground and aerial equipment	2 lb/gal SC/L (264-267)	1	1	5	SLN Nos. AZ870021 and CA760194 permit a single aerial or ground application to chili, bell, and pimento peppers only in AZ and CA. Apply aerial and ground applications in a minimum of 15 and 40 gal/A, respectively. Crop is to be harvested at optimum maturity generally 14 or more days following treatment. A 30-day plant-back interval is specified.
Pineapples					
Foliar broadcast Floral induction Fruit maturation Ground equipment	4 lb/gal SC/L (264-257)	 2 1	3	2	Apply in a minimum of 100 gal/A. Grazing of pineapple forage is not permitted.
Pumpkins (hybrid seed production) [2]					
Foliar Ground equipment	0.33 lb/gal SC/L (264-263)	0.25	1.5	42	For hybrid seed production in IL only. Six applications permitted at 7- to 10-day intervals beginning at the 2-4 leaf stage. Apply in a minimum of 40 gal/A.

Site Application Type Application Timing Application Equipment [1]	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Use Limitations
Crop Uses					
				60	For hybrid seed production in CA only. Six applications permitted at 3- to 10-day intervals beginning at the first true leaf stage. Apply in a minimum of 40 gal/A.
Squash (hybrid seed production) [2]					
Foliar Apply at 2- to 4-leaf stage Ground equipment	0.33 lb/gal SC/L (264-263)	0.08	0.16	NA	For hybrid seed production. Do not harvest any treated cucumbers or squash for human or animal consumption. Treatments are to be made for seed production only. Spray plants at the two leaf stage.
		0.25	1.5	60	In CA only. Six applications permitted at 3- to 10-day intervals beginning at the first true leaf stage. Apply in a minimum of 40 gal/A. Do not use on squash to be harvested for fresh or processed markets.
Sugarcane					
Foliar, broadcast Prior to floral initiation Aerial equipment	4 lb/gal SC/L (264-257)	0.5	0.5	2 months	Application permitted in HI only. Grazing of sugarcane forage is not permitted.
Tobacco (Flue-cured only) [2]					
Foliar, directed Foliar, broadcast At leaf maturity Ground equipment	2 lb/gal SC/L (264-267) (264-292)	1 2		24	A 30-day plant-back interval is specified and the 264-292 label prohibits the use of surfactants or wetting agents.
Foliar, directed Foliar, broadcast At leaf maturity Ground equipment	6 lb/gal EC (264-418)	1 2		24	A 30-day plant-back interval is specified.

Site Application Type Application Timing Application Equipment [1]	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Use Limitations
Crop Uses					
Tomatoes (fresh market)					
Foliar, broadcast At fruit maturity Aerial and ground equipment	2 lb/gal SC/L (264-267)	1.25	1.25	3	This use is permitted only in CA. Do not use on greenhouse grown tomatoes. Apply in a minimum of 40 (ground) and 10 (air) gal/A. A 30-day plant-back interval is specified.
Foliar At fruit maturity Ground equipment	0.33 lb/gal SC/L (264-263)	0.3 oz ai/gal	0.3 oz ai/gal		For Home garden tomato production: the PHI for fresh market tomatoes in CA is 3 days.
Tomatoes (for processing)					
Foliar, broadcast At fruit maturity Aerial and ground equipment	2 lb/gal SC/L (264-267)	1.6	1.6	3	Apply in a minimum of 20 (ground) and 10 (air) gal/A. A 30-day plant-back interval is specified. Do not use on greenhouse grown tomatoes.
Foliar At fruit maturity Ground equipment	0.33 lb/gal SC/L (264-263)	0.3 oz ai/gal	0.3 oz ai/gal		For Home garden tomato production: the PHI for tomatoes for processing is 14 days.
Walnuts					
Foliar Ground Equipment	2 lb/gal SC/L (264-267)	1.25	1.25	5	Apply in a minimum of 100 gal/A

Site Application Type Application Timing Application Equipment [1]	Formulation (EPA Reg No.)	Maximum Single Application Rate (lb ai/A)	Maximum Seasonal Rate (lb ai/A)	PHI (days)	Use Limitations
Crop Uses					
Wheat					
Foliar, broadcast Early to late boot stage prior to awn emergence Ground and aerial equipment	2 lb/gal SC/L (264-376) 4 lb/gal SC/L (264-377)	0.5	0.5	40	Apply ground and aerial applications in a minimum of 7 and 3 gal/A, respectively. Grazing or foraging by livestock or cutting for hay or silage are prohibited.[4] Mature straw at normal harvest may be consumed by animals. A 30-day plant-back interval is specified.

1 All labels except EPA Reg. No. 264-380 state that application through an irrigation system is prohibited.

2 Non-food use.

3 Label directions for apples, crabapples, carob, and olives that are for ornamental use only must be clearly designated as such on all pertinent labels.

4 These label restrictions are no longer appropriate since the Agency has determined that barley and wheat forage and hay are not under grower/farmer control (TABLE II (June 1994)).

5 Label 264-380 must be amended to state a maximum 2 lb ai/A/season on cotton.

6 The registrant has deleted the use of ethephon on cucumbers for fresh or processed markets from the 0.33 lb/gal SC/L product label (EPA Reg. No. 264-263 dated 8/11/94). The Agency, has hereby, rescinded the previous label amendment requirement to limit use to states representing cucumber seed production regions but has imposed a new label amendment requirement to prohibit the harvesting of any treated pumpkins for human or animal consumption and specify that treatments are to be made to pumpkins for seed production only.

C. Existing Stocks

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

The Agency has determined that registrants may distribute and sell products bearing old labels/labeling, i.e., labels absent the modifications specified in this RED document, except as noted below, 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. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES												
APPLE			Use Group: TERRESTRIAL FOOD+FEED CROP									
Defoliation. Use Pesticide Type code "42"., Nurserystock., Sprayer.	SC/L	NA	UC	*	NS NS	.165 lb	NS	3	2	WA		C46, C92
High volume spray (dilute)., Bloom through foliar., High volume ground.	SC/L	NA	1 lb A	*	NS NS	NS	NS	NS	2			C46, C92, G20, H01(7)
High volume spray (dilute)., Bloom., High volume ground.	SC/L	NA	3 lb A	*	NS 1/1 yr	NS	NS	NS	NS	NC		
	SC/L	NA	.375 lb A	*	NS NS	NS	NS	NS	2			C46, C92, G20, H01(7)
High volume spray (dilute)., Foliar., High volume ground.	SC/L	NA	.25 lb A	*	NS NS	NS	NS	NS	2			C46, C92, G20, H01(7)
High volume spray (dilute)., Nonbearing., High volume ground.	SC/L	NA	.5 lb A	*	NS NS	NS	NS	NS	2			C46, C92, G20, H01(7)
Spray., Bloom., Sprayer.	SC/L	NA	UC	*	NS NS	NS	NS	NS	2			C46, C92
	SC/L	NA	UC	*	NS NS	NS	NS	NS	2			C46, C92, G20, H01(7)
Spray., Foliar., Ground.	SC/L	NA	1.25 lb A	*	NS NS	NS	NS	NS	2			C46, C92, G20, H01(7)
BARLEY			Use Group: TERRESTRIAL FOOD+FEED CROP									
Low volume spray (concentrate)., Boot., Controlled droplet applicator.	SC/L	NA	.5 lb A	*	1 NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
Low volume spray (concentrate)., Postemergence., Controlled droplet applicator.	SC/L	NA	.25 lb A	*	1 NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
Spray., Boot., Aircraft.	SC/L	NA	.5 lb A	*	1 NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
	SC/L	NA	.5 lb A	*	NS NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
Spray., Boot., Controlled droplet applicator.	SC/L	NA	.5 lb A	*	NS NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
Spray., Boot., Ground.	SC/L	NA	.5 lb A	*	1 NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
	SC/L	NA	.5 lb A	*	NS NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /crop cycle /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
BARLEY (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)								
Spray., Postemergence., Aircraft.	SC/L	NA	.5 lb A	*	1 NS	.5 lb NS	NS	2			C46, GA6, H01(40)
	SC/L	NA	.5 lb A	*	NS NS	NS .5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
Spray., Postemergence., Controlled droplet applicator.	SC/L	NA	.5 lb A	*	NS NS	NS .5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
Spray., Postemergence., Ground.	SC/L	NA	.5 lb A	*	1 NS	.5 lb NS	NS	2			C46, GA6, H01(40)
	SC/L	NA	.5 lb A	*	NS NS	NS .5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
BLACKBERRY			Use Group: TERRESTRIAL FOOD CROP								
Spray., Foliar., Ground.	SC/L	NA	2.188 lb A	*	NS NS	NS NS	NS	2	OR, WA		C46, C92, H01(3)
CAROB			Use Group: TERRESTRIAL FEED CROP								
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS NS	NS NS	NS	2			C46, C92
			Use Group: TERRESTRIAL FOOD CROP								
Spray., Bloom., Ground.	SC/L	NA	UC	*	NS NS	NS NS	NS	2			C46, C92
CHERRY			Use Group: TERRESTRIAL FOOD CROP								
High volume spray (dilute)., Fall., High volume ground.	SC/L	NA	.75 lb A	*	NS NS	NS NS	NS	2	018	CA	C46, C92, H01(7)
High volume spray (dilute)., Foliar., High volume ground.	SC/L	NA	.333 lb A	*	NS NS	NS NS	NS	2		CA	C46, C92, H01(7)
Low volume spray (concentrate)., Foliar., Low volume ground.	SC/L	NA	.75 lb A	*	NS NS	NS NS	NS	2		CA	C46, C92, H01(7)
COFFEE			Use Group: TERRESTRIAL FOOD CROP								
Spray., Foliar., Ground.	SC/L	NA	.125 gal A	*	NS NS	NS NS	NS	NS	PR		
COTTON (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP								
Defoliation. Use Pesticide Type code "42"., Foliar., Aircraft.	EC	NA	.248 lb A	*	NS NS	NS 1.995 lb	NS	2			C46, C92, H01(7)
	SC/L	NA	1.999 lb A	*	NS NS	UC NS	NS	2			C46, C92

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
COTTON (UNSPECIFIED) (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Defoliation. Use Pesticide Type code "42"., Foliar., Ground.	EC	NA	.248 lb A	*	NS	NS	NS	1.995 lb	NS	2			C46, C92, H01(7)
	SC/L	NA	1.999 lb A	*	NS	NS	UC	NS	NS	2			C46, C92
Spray., Foliar., Aircraft.	EC	NA	1.995 lb A	*	NS	NS	NS	1.995 lb	NS	2			C46, C92, H01(7)
	SC/L	NA	UC	*	NS	1/1 yr	NS	UC	NS	2			C92, H01(7)
Spray., Foliar., Ground.	EC	NA	1.995 lb A	*	NS	NS	NS	1.995 lb	NS	2			C46, C92, H01(7)
	SC/L	NA	UC	*	NS	1/1 yr	NS	UC	NS	2			C92, H01(7)
CRABAPPLE			Use Group: TERRESTRIAL FOOD CROP										
Spray., Bloom., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
CUCUMBER			Use Group: TERRESTRIAL FOOD CROP										
Spray., Foliar., Low pressure ground sprayer.	SC/L	NA	.1031 lb A	*	2	NS	NS	NS	5	2			C46, C92, H01(17)
Spray., Seed crop., Ground.	SC/L	NA	.248 lb A	*	NS	6/1 yr	NS	NS	3	1	CA		C46
	SC/L	NA	.248 lb A	*	NS	6/1 yr	NS	NS	3	2	CA		C46, C92, H01(60)
Spray., Seed crop., Sprayer.	SC/L	NA	.083 lb A	*	NS	NS	NS	NS	7	2			C46, C92
GRAPES			Use Group: TERRESTRIAL FOOD+FEED CROP										
Spray., Foliar., Ground.	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	AZ, CA		C46, C92, H01(14)
Spray., Preharvest., Aircraft.	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	AZ, CA		C46, C92, H01(14)
Spray., Preharvest., Ground.	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	AZ, CA		C46, C92, H01(14)
	SC/L	NA	.5 lb A	*	NS	NS	NS	NS	NS	NS	CA		
GRASS FORAGE/FODDER/HAY			Use Group: TERRESTRIAL FEED CROP										
Spray., Postemergence., Not on label.	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2		CA	C14, C46, CAA, G96, GF3
Spray., Seed crop., Aircraft.	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2		CA	C14, C46, CAA, G96, GF3

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
GRASS FORAGE/FODDER/HAY (con't)			Use Group: TERRESTRIAL FEED CROP (con't)										
Spray., Seed crop., Ground.	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2		CA	C14, C46, CAA, G96, GF3
MACADAMIA NUT (BUSHNUT)			Use Group: TERRESTRIAL FOOD CROP										
Spray., Preharvest., Ground.	SC/L	NA	2 lb A	*	1	NS	NS	NS	NS	NS	HI		G06, H01(5)
MELONS, CANTALOUPE			Use Group: TERRESTRIAL FOOD CROP										
Spray., Fruiting., Aircraft.	SC/L	NA	.75 lb A	*	NS	NS	NS	NS	NS	2	CA, AZ, TX		C46, C92, H01(2)
Spray., Fruiting., Ground.	SC/L	NA	.75 lb A	*	NS	NS	NS	NS	NS	2	CA, AZ, TX		C46, C92, H01(2)
Spray., Preharvest., Aircraft.	SC/L	NA	.75 lb A	*	NS	NS	NS	NS	NS	2	CA, AZ, TX		C46, C92, H01(2)
Spray., Preharvest., Ground.	SC/L	NA	.75 lb A	*	NS	NS	NS	NS	NS	2	CA, AZ, TX		C46, C92, H01(2)
OLIVE			Use Group: TERRESTRIAL FOOD CROP										
Spray., Bloom., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
PEANUTS			Use Group: TERRESTRIAL FOOD CROP										
Seed treatment., Germination., Not on label.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS	VA		
PEPPER			Use Group: TERRESTRIAL FOOD CROP										
Spray., Foliar., Aircraft.	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	AZ		
	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	CA		
Spray., Foliar., Ground.	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	AZ		
	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	CA		
	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2			C46, C92, H01(5)
PEPPER (CHILI TYPE)			Use Group: TERRESTRIAL FOOD CROP										
Spray., Foliar., Aircraft.	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	AZ		
	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	CA		
Spray., Foliar., Ground.	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	AZ		
	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	CA		

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
PEPPER (CHILI TYPE) (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)									
	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2			C46, C92, H01(5)
PIMENTO				Use Group: TERRESTRIAL FOOD CROP									
Spray., Foliar., Aircraft.	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	AZ		
	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	CA		
Spray., Foliar., Ground.	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	AZ		
	SC/L	NA	1 lb A	*	1	NS	NS	NS	NS	NS	CA		
	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2			C46, C92, H01(5)
PINEAPPLE				Use Group: TERRESTRIAL FOOD+FEED CROP									
Spray., Prebloom., Aircraft.	SC/L	NA	2 lb A	*	NS	NS	NS	NS	NS	2			C46, C92, GC1, H01(2)
Spray., Prebloom., Ground.	SC/L	NA	2 lb A	*	NS	NS	NS	NS	NS	2			C46, C92, GC1, H01(2)
Spray., Preharvest., Aircraft.	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2			C46, C92, GC1, H01(2)
Spray., Preharvest., Ground.	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2			C46, C92, GC1, H01(2)
PUMPKIN				Use Group: TERRESTRIAL FOOD CROP									
Spray., Foliar., Ground.	SC/L	NA	.248 lb A	*	NS	6/1 yr	NS	NS	NS	2	IL		C14, C46, C92, H01(42)
Spray., Seed crop., Ground.	SC/L	NA	.248 lb A	*	NS	6/1 yr	NS	NS	3	1	CA		C46
	SC/L	NA	.248 lb A	*	NS	6/1 yr	NS	NS	7	2	IL		C14, C46, C92, H01(42)
SQUASH (ALL OR UNSPECIFIED)				Use Group: TERRESTRIAL FOOD CROP									
Spray., Seed crop., Ground.	SC/L	NA	.248 lb A	*	NS	6/1 yr	NS	NS	3	1	CA		C46
	SC/L	NA	.248 lb A	*	NS	6/1 yr	NS	NS	7	2			C14, C46, C92, H01(60)

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SUGARCANE			Use Group: TERRESTRIAL FOOD+FEED CROP										
Spray., Prebloom., Fixed-wing aircraft.	SC/L	NA	.5 lb A	*	NS	NS	NS	NS	NS	2	HI		C46, C92, GC1, H01(60)
Spray., Prebloom., Helicopter.	SC/L	NA	.5 lb A	*	NS	NS	NS	NS	NS	2	HI		C46, C92, GC1, H01(60)
TOMATO			Use Group: TERRESTRIAL FOOD+FEED CROP										
Spray., Foliar., Aircraft.	SC/L	NA	1.625 lb A	*	NS	NS	NS	NS	NS	2			, C46, C92, H01(3)
Spray., Foliar., Ground.	SC/L	NA	1.625 lb A	*	NS	NS	NS	NS	NS	2			, C46, C92, H01(3)
Spray., Foliar., Hand held sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92, H01(14)
	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			C46, CAE, H01(14)
WALNUT (ENGLISH/BLACK)			Use Group: TERRESTRIAL FOOD CROP										
Spray., Foliar., Ground.	SC/L	NA	1.25 lb A	*	NS	NS	NS	NS	NS	2	CA		C46, C92, H01(5)
WHEAT			Use Group: TERRESTRIAL FOOD+FEED CROP										
Low volume spray (concentrate)., Boot., Controlled droplet applicator.	SC/L	NA	.5 lb A	*	1	NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
Low volume spray (concentrate)., Postemergence., Controlled droplet applicator.	SC/L	NA	.25 lb A	*	1	NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
Spray., Boot., Aircraft.	SC/L	NA	.5 lb A	*	1	NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
Spray., Boot., Controlled droplet applicator.	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
Spray., Boot., Ground.	SC/L	NA	.5 lb A	*	1	NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
Spray., Postemergence., Aircraft.	SC/L	NA	.5 lb A	*	1	NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
WHEAT (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
Spray., Postemergence., Controlled droplet applicator.	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
Spray., Postemergence., Ground.	SC/L	NA	.5 lb A	*	1	NS	.5 lb	NS	NS	2			C46, GA6, H01(40)
	SC/L	NA	.5 lb A	*	NS	NS	NS	.5 lb	NS	2	012	011	C46, CAA, G96, H01(40)
NON-FOOD/NON-FEED													
ORNAMENTAL AND/OR SHADE TREES				Use Group: TERRESTRIAL NON-FOOD CROP									
Spray., Bloom., Hand held sprayer.	SC/L	NA	.019 lb tree	*	NS	NS	NS	NS	NS	NS	CA		C46
Spray., Bloom., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	NS			C46, CAE
Spray., Foliar., Ground.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
Spray., Prebloom through foliar., Ground.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
Spray., Prebloom through foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
ORNAMENTAL HERBACEOUS PLANTS				Use Group: GREENHOUSE NON-FOOD CROP									
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
Spray., Potted., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
Spray., Potted., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
ORNAMENTAL NONFLOWERING PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP									
Spray., Foliar., Ground.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL WOODY SHRUBS AND VINES			Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL										
Defoliation. Use Pesticide Type code "42"., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
Spray., Foliar., Sprayer.	SC/L	NA	UC	*	NS	NS	NS	NS	NS	2			C46, C92
			Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP										
Spray., Foliar., Sprayer.	SC/L	NA	.825 lb A	*	NS	NS	NS	NS	NS	2			C46, C92
TOBACCO			Use Group: TERRESTRIAL NON-FOOD CROP										
Directed spray., Preharvest., Ground.	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	2			C46, C92
	SC/L	NA	1 lb A	*	NS	NS	NS	NS	NS	NS			C46
Directed spray., Preharvest., Tractor-mounted sprayer.	EC	NA	.998 lb A	*	NS	NS	NS	NS	NS	2			C46, C92
Spray., Preharvest., Aircraft.	EC	NA	1.995 lb A	*	NS	NS	NS	NS	NS	2			C46, C92
Spray., Preharvest., Ground.	SC/L	NA	2 lb A	*	NS	NS	NS	NS	NS	2			C46, C92
	SC/L	NA	2 lb A	*	NS	NS	NS	NS	NS	NS			C46

LEGEND
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HEADER ABBREVIATIONS
Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)

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

FORMULATION CODES
EC : EMULSIFIABLE CONCENTRATE
SC/L : SOLUBLE CONCENTRATE/LIQUID

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

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

USE LIMITATIONS CODES
C14 : Grown for seed only.
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAA : Do not apply to any body of water.
CAE : Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
G06 : Do not feed or graze livestock on cover crops in treated areas.
G20 : Do not feed or graze animals on cover crops in treated areas.
G96 : Do not graze livestock in treated areas or cut treated crops for feed.
GA6 : Do not graze treated areas or harvest for forage or hay.
GC1 : Do not graze treated areas.
GF3 : Do not feed treated grasses, seed or seed screenings to livestock.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
011 : West of the Mississippi River
012 : East of the Mississippi River
018 : Pacific Northwest
AZ : Arizona
CA : California
HI : Hawaii
IL : Illinois
NC : North Carolina
OR : Oregon
PR : Puerto Rico
TX : Texas
VA : Virginia
WA : Washington

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

GUIDE TO APPENDIX B

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

The data table is organized in the following format:

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

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

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

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

APPENDIX B

Generic Data Supporting Guideline Requirements for the Reregistration of Technical Ethephon

REQUIREMENT		USE PATTERN	CITATIONS
PRODUCT CHEMISTRY			
	Registrant: Rhone-Poulenc Ag Company Product: EPA Reg. No. 264-511		
61-1	**Chemical Identity**	**All**	**DATA GAP**
61-2A	**Start. Mat. & Mnfg. Process**	**ALL**	**41154505**
61-2B	**Formation of Impurities**	**ALL**	**41154505**
62-1	**Preliminary Analysis**	**ALL**	**41154506, DATA GAP**
62-2	**Certification of limits**	**ALL**	**DATA GAP**
62-3	**Analytical Method**	**ALL**	**41154506, DATA GAP**
63-2	**Color**	**ALL**	**41267001**
63-3	**Physical State**	**ALL**	**41267001**
63-4	**Odor**	**ALL**	**41267001**
63-5	**Melting Point**	**ALL**	**41267001**
63-7	**Density**	**ALL**	**41267001**
63-8	**Solubility**	**ALL**	**41267001**
63-9	**Vapor Pressure**	**ALL**	**41267001**
63-10	**Dissociation Constant**	**ALL**	**41267001**
63-11	**Octanol/Water Partition**	**ALL**	**41267001**
63-12	**pH**	**ALL**	**41267001**

Generic Data Supporting Guideline Requirements for the Reregistration of Technical Ethephon

REQUIREMENT		USE PATTERN	CITATIONS
63-13	**Stability**	**ALL**	**DATA GAP**
63-14	**Oxidizing/Reducing Action**	**ALL**	**41267001**
63-15	**Flammability**	**ALL**	**41267001**
63-16	**Explodability**	**ALL**	**41267001**
63-17	**Storage stability**	**ALL**	**42430501**
63-18	**Viscosity**	**ALL**	**41267001**
63-19	**Miscibility**	**ALL**	**41267001**
63-20	**Corrosion Characteristics**	**ALL**	**41267001**
	Registrant: Cedar Chemical Corporation Product: 56077-50		
61-1	**Chemical Identity**	**ALL**	**42926301, 43115301**
61-2A	**Start. Mat. & Mnfg. Process**	**ALL**	**42926301, 43115301**
61-2B	**Formation of Impurities**	**ALL**	**42926301, 43115301**
62-1	**Preliminary Analysis**	**ALL**	**42926301, 43115301**
62-2	**Certification of Limits**	**ALL**	**42926301, 43115301**
62-3	**Analytical Method**	**ALL**	**42926301, 43115301**
63-2	**Color**	**ALL**	**42926301, 43115301**
63-3	**Physical State**	**ALL**	**42926301, 43115301**
63-4	**Odor**	**ALL**	**42926301, 43115301**
63-6	**Boiling Point**	**ALL**	**42926301, 43115301**

REQUIREMENT		USE PATTERN	CITATIONS
63-7	**Density**	**ALL**	**42926301, 43115301**
63-8	**Solubility**	**ALL**	**42926301, 43115301**
63-9	**Vapor Pressure**	**ALL**	**42926301, 43115301**
63-10	**Dissociation Constant**	**ALL**	**42926301, 43115301**
63-11	**Octanol/Water Partition**	**ALL**	**42926301, 43115301**
63-12	**pH**	**ALL**	**42926301, 43115301**
63-13	**Stability**	**ALL**	**42926301, 43115301**
63-14	**Oxidizing/Reducing Action**	**ALL**	**N/A**
63-15	**Flammability**	**ALL**	**N/A**
63-16	**Explodability**	**ALL**	**N/A**
63-20	**Corrosion Characteristics**	**ALL**	**42926301, 43115301**
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	**A,B,C,K**	**00026041, 00026040**
71-1B	**Acute Avian Oral - Quail/Duck TEP**	**A,B,C,K**	**00027493**
71-2A	**Avian Dietary - Quail**	**A,B,C,K**	**00085446**
71-2B	**Avian Dietary - Duck**	**A,B,C,K**	**00056480, 00122414, 00107428**
72-1A	**Fish Toxicity Bluegill**	**A,B,C,K**	**00027495, 00027496, 00122412**
72-1C	**Fish Toxicity Rainbow Trout**	**A,B,C,K**	**00027495, 00122412**
72-2A	**Invertebrate Toxicity**	**A,B,C,K**	**00054013**

Generic Data Supporting Guideline Requirements for the Reregistration of Technical Ethephon

REQUIREMENT		USE PATTERN	CITATIONS
72-2B	**Invertebrate Toxicity - TEP**	**A,B,C,K**	**00122448, 00027496**
72-3B	**Estuarine/Marine Toxicity - Mollusk**	**A,B,C,K**	**41296202**
72-3C	**Estuarine/Marine Toxicity - Shrimp**	**A,B,C,K**	**00027496, 00054013**
72-4B	**Life Cycle Invertebrate**	**A,B,C,K**	**42294501**
122-1A	**Seed Germination/Seedling Emergence**	**A,B,C,K**	**41403305**
122-1B	**Vegetative Vigor**	**A,B,C,K**	**41403305**
122-2	**Aquatic Plant Growth**	**A,B,C,K**	**41403301- 41403304**
123-1A	**Seed Germination/Seedling Emergence**	**A,B,C,K**	**41403305, 41659401**
123-1B	**Vegetative Vigor**	**A,B,C,K**	**41403305, 41659401**
123-2	**Aquatic Plant Growth**	**A,B,C,K**	**41509001**
141-1	**Honey Bee Acute Contact**	**A,B,C,K**	**00009181**
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	**A,B,C,K**	**00029509**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	**A,B,C,K**	**00029510**
81-3	**Acute Inhalation Toxicity - Rat**	**A,B,C,K**	**41685901**
81-4	**Primary Eye Irritation - Rabbit**		**NOT REQUIRED**
81-5	**Primary Dermal Irritation - Rabbit**	**A,B,C,K**	**00029513**
81-6	**Dermal Sensitization - Guinea Pig**	**A,B,C,K**	**41154503**

Generic Data Supporting Guideline Requirements for the Reregistration of Technical Ethephon

REQUIREMENT		USE PATTERN	CITATIONS
81-7	**Acute Neurotoxicity - hen**	**A,B,C,K**	**00144559**
81-8-SS	**Acute Neurotoxicity - rat**	**A,B,C,K**	**DATA GAP**
82-1A	**90-Day Feeding - Rodent**		**NOT REQUIRED**
82-1B	**90-Day Feeding - Non-rodent**		**NOT REQUIRED**
82-2	**21-Day Dermal - Rabbit/Rat**	**A,B,C,K**	**41295901**
82-7-SS	**90-Day Neurotoxicity - Mammal**	**A,B,C,K**	**DATA GAP**
83-1A	**Chronic Feeding Toxicity - Rodent**	**A,B**	**41139001**
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	**A,B**	**00060359, 41135001**
83-2A	**Oncogenicity - Rat**	**A,B**	**41139001**
83-2B	**Oncogenicity - Mouse**	**A,B**	**41050801**
83-3A	**Developmental Toxicity - Rat**	**A,B**	**00063745, 41103001**
83-3B	**Developmental Toxicity - Rabbit**	**A,B**	**00085755, 41557201**
83-4	**2-Generation Reproduction - Rat**	**A,B**	**41508701**
84-2A	**Gene Mutation (Ames Test)**	**A,B,C,K**	**40412401**
84-2B	**Structural Chromosomal Aberration**	**A,B,C,K**	**40555301**
84-4	**Other Genotoxic Effects**	**A,B,C,K**	**40555201**
85-1	**General Metabolism**	**A,B**	**41906101**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	**A,B,C,I,K**	**41545701**
161-2	**Photodegradation - Water**	**A,B,C**	**41545601**

Generic Data Supporting Guideline Requirements for the Reregistration of Technical Ethephon

REQUIREMENT		USE PATTERN	CITATIONS
161-3	**Photodegradation - Soil**	**A,B,C**	**41681401**
162-1	**Aerobic Soil Metabolism**	**A,B,C,I,K**	**41757701**
162-2	**Anaerobic Soil Metabolism**	**A,B,C**	**41757702**
162-3	**Anaerobic Aquatic Metabolism**	**A,B,C**	**41757702**
163-1	**Leaching/Adsorption /Desorption**	**A,B,C,I,K**	**42126001, DATA GAP**
164-1	**Terrestrial Field Dissipation**	**A,B,C,K**	**42011501**
201-1	**Droplet Size Spectrum**	**A,B,C**	**RESERVED**
202-1	**Drift Field Evaluation**	**A,B,C**	**RESERVED**
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	**A,B**	**00038793, 00038796, 00053153, 00054018, 00054021, 00067489, 00081783, 00088983, 00097422, 00108993, 00116123, 00117893, 00121613, 00122410, Makhijan (1971), Wright and Rains (1984) Zee (1984)**
171-4B	**Nature of Residue - Livestock**	A,B	**00118508, 00141506, 00165339, 42236701, DATA GAP**

Generic Data Supporting Guideline Requirements for the Reregistration of Technical Ethephon

REQUIREMENT		USE PATTERN	CITATIONS
171-4C/D	**Residue Analytical Method - Plants and Animals**	A,B	**00030190, 00036500, 00038795, 00038797, 00038880, 00038881, 00042977, 00041465, 00047911, 00047913, 00053149, 00103287, 00108992, 00116123, 00117893, 00121613, 00122410, 00122421, 00122433, 00122435, 00123237, 00128726, 00142265, 00145613, 41296201, 41668205, 41668207, 41704501, 42268901 -42268903, 42298201, 42300801 -42300807, 42410401 -42410403, 42718101, 42957301, 42957302, DATA GAP**
171-4E	**Storage Stability**	A,B	**00151127, 41668201, 41668202, 41668203, 41668204, 41668206, 41668208, 41668209, 41668210, 41668211, 41668212, 41668213, 41668215, 42010401, 42410401, 42410402, 42410403, 42464401, 42268904 -42268909, 42300801, 42300802 -42300808, 42718101, 42957301, DATA GAP**
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	**00083773, 00100517, 00121613, DATA GAP**
171-4k	**Crop Field Trials**		
	Fruiting Vegetables Group		
	-Peppers		**00061719, 00121613, DATA GAP**
	-Tomatoes		**00121613, 42016701, 42268903**
	Cucurbit Vegetables Group		
	-Cantaloupes		**00117893, 41668207, 42718101, DATA GAP**

REQUIREMENT	USE PATTERN	CITATIONS
-Cucumbers (seed treatment only)		**PP#9E2225, 00122429**
-Pumpkins (seed treatment only)		**00122717**
Pome Fruits Group		
-Apples		**00061717, 00108992, 00123222, 41872502, 42379101**
Stone Fruits Group		
-Cherries		**00081782, 00136287**
Small Fruits and Berries Group		
-Blackberries		**00121613, 41668205**
-Grapes		**00053150, 00051353, 00080482, 00121613, 41872501, 42116501, 42410301, DATA GAP**
Tree Nuts Group		
-Macadamia		**00128726**
-Walnuts		**00038795, 00117752, 42464401**
Cereal Grains Group		
-Barley		**00103287**
-Wheat		**00103287, 42268902**
Forage, Fodder, and Straw of Cereal Grains		
-Barley straw		**00103287**
-Barley forage		**DATA GAP**

REQUIREMENT		USE PATTERN	CITATIONS
	-Barley hay		**DATA GAP**
	-Wheat straw		**00103287, 42268902**
	-Wheat forage		**DATA GAP**
	-Wheat hay		**DATA GAP**
	-Wheat aspirated grain fractions		**42268901**
	Miscellaneous Commodities		
	-Cotton, seed		**00030190, 00122423, 41704501**
	-Cotton, gin byproducts		**DATA GAP**
	-Pineapples		**00040268, 00040269, 00054022, 00116123, 00122452, 00123222, 42298201**
	-Sugarcane		**00032573, 00145613, 40954401**
	-Tobacco		**00122410, 41746501**
171-4L	**Processed Food**		
	Processed Food		
	-Apples, juice		**41872502, 42379101**
	-Barley, milled fractions, except flour		**00103287, 42268901**
	-Grapes, raisins		**00080482, 00121613**
	-Grapes, juice		**00053150**
	-Sugarcane, molasses		**40954401, 42381701, DATA GAP**
	-Tomatoes, paste		**42016701**

REQUIREMENT		USE PATTERN	CITATIONS
	-Wheat, milling fractions, except flour		**42268901**
	Processed Feed		
	-Barley, milling fractions, except flour		**00103287, 42268901**
	-Cottonseed, meal		**00030190, 00122423**
	-Pineapples, bran		**42298201**
	-Grapes, raisin waste		**00080482, 41872501, 42116501, 42410301**
	-Grapes, pomace, dried		**00053150**
	-Sugarcane, molasses		**40954401, 42381701**
	-Tomatoes, pomace, dried		**42016701**
	-Wheat, milling fractions, except flour		**42268901**
165-1	**Confined Rotational Crop**		**43143601, RESERVED, DATA IN REVIEW**
165-2	**Field Rotational Crop**		**RESERVED PENDING REVIEW OF GUIDELINE 165-1**

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

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
00009181	Atkins, E.L., Jr; Anderson, L.D.; Greywood, E.A. (1969) Effect of Pesticides on Apiculture: Project No. 1499. (Unpublished study received Jul 29, 1976 under 352-342; prepared by Univ. of California-Riverside, Dept. of Entomology, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL: 224800-C)
00026040	Beavers, J.B.; Fink, R.; Brown, R. (1979) Final Report: Acute Oral LD50--Mallard Duck: Project No. 113-146. (Unpublished study received Dec 19, 1979 under 264-267; prepared by Wildlife International, Ltd. in cooperation with Washington College, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL: 099158-A)
00026041	Beavers, J.B.; Fink, R.; Brown, R. (1979) Final Report: Acute Oral LD50--Bobwhite Quail: Project No. 113-145. (Unpublished study received Dec 19, 1979 under 264-267; prepared by Wildlife International, Ltd. in cooperation with Washington College, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL: 099158-B)
00027493	Beavers, J.B.; Fink, R.; Brown, R. (1978) Final Report: Acute Oral LD50--Bobwhite Quail: Project No. 164-104. (Unpublished study received Apr 3, 1980 under 1529-EX-2; prepared by Wildlife International, Ltd. in cooperation with Washington College, submitted by GAF Corp., Chemical Div., New York, N.Y.; CDL: 099355-A)
00027495	Bentley, R.E. (1974) Acute Toxicity of CPGR Formulation and CPGR 100% to Bluegill (Lepomis macrochirus) and Rainbow Trout (Salmo gairdneri). (Unpublished study received Apr 3, 1980 under 1529-EX-2; prepared by Bionomics, EG&G Environmental Consultants, submitted by GAF Corp., Chemical Div., New York, N.Y.; CDL:099355-D)
00027496	Foote, K.C. (1978) Toxicity Test of GAF's Corporation: Teceth 75 8065-20: Contract No. L1362-05. (Unpublished study received Apr 3, 1980 under 1529-EX-2; prepared by Syracuse Research Corp., submitted by GAF Corp., Chemical Div., New York, N.Y.; CDL:099355-E)

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MRID	CITATION
00029509	Griffiths, J.T.; Parent, R.A. (1979) The Approximate Acute Oral Toxicity (LD50) of GAF CPD 71921/L9 in Male Sprague-Dawley Rats: Laboratory No. 2-6153. (Unpublished study received Apr 3, 1980 under 1529-EX-2; prepared by Food and Drug Research Laboratories, Inc., submitted by GAF Corp., Chemical Div., New York, N.Y.; CDL:099356-A)
00029510	Deprospo, J.R. (1975) Acute Dermal LD50 Test in Rabbits: Contract No. 120-2544-35. (Unpublished study received Apr 3, 1980 under 1529-EX-2; prepared by Affiliated Medical Research, Inc., submitted by GAF Corp., Chemical Div., New York, N.Y.; CDL: 099356-B)
00029513	Stevens, K.R. (1979) Primary Skin Irritation Study with Rabbits: Laboratory No. 6153. (Unpublished study received Apr 3, 1980 under 1529-EX-2; prepared by Food and Drug Research Laboratories, Inc., submitted by GAF Corp., Chemical Div., New York, N.Y.; CDL:099356-E)
00030190	Hegidio, J.; Dyson, D.; Thomas, N.B.; et al. (1979) Residues. Includes method dated Oct 1979. (Unpublished study received Dec 19, 1979 under 264-267; prepared in cooperation with Salyer Land Co. and others, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:099158-C)
00032573	Harrison, S.L.; Nygren, R.E.; Gross, S.M.; et al. (1980) Residues: Ethrel(R) Sugarcane: Project No. 10223. (Unpublished study received May 15, 1980 under 264-EX-59; prepared in cooperation with Hawaiian Sugar Planters' Association, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:099427-A)
00036500	Obenauf, G.L. (1973) Residues: Ethephon. (Unpublished study received Mar 19, 1974 under 4F1490; prepared in cooperation with Greenwood Laboratories, Inc., submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093944-B)
00036510	Reese, W.H., Jr. (1972) Final Report--Phase II: Evaluation of Ethrel in Human Volunteers: BRL Project No. 7223. (Unpublished study received on unknown date under 4F1490; prepared by Litton Industries, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093946-D)
00038793	Union Carbide Agricultural Products Company (1972) Metabolism: The Nature and Quantities of Residues and Metabolic Degredation Products Resulting from

BIBLIOGRAPHY

MRID	CITATION

the Treatment of Walnuts with Ethephon. (Unpublished study received Dec 20, 1972 under 3F1344; CDL: 093599-C)

00038795 Sibbett, S.; Hendricks, L.; Schraeder, W. (1972) Residues: Ethephon. (Unpublished study received Dec 20, 1972 under 3F1344; prepared in cooperation with Morse Laboratories, Inc., submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:093599-E)

00038796 Union Carbide Agricultural Products Company (1970) Metabolism: The Nature and Quantities of Residues and Metabolic Degredation Products Resulting from the Treatment of Filberts with Ethephon. (Unpublished study received Dec 20, 1972 under 3F1344; CDL: 093599-F)

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41757701	Das, Y. (1991) Metabolism of Ethyl(U)-carbon 14Ethephon Under Aerobic Soil Conditions: Lab Project Number: EC-90-111: 90031. Unpublished study prepared by Innovative Scientific Services, Inc. 82 p.
41757702	Das, Y. (1991) Metabolism of Ethyl(U)-carbon 14Ethephon Under Anaerobic Aquatic Soil Conditions: Lab Project No: EC-90-112. Unpublished study prepared by Innovative Scientific Services, Inc. 92 p.
41872501	Nygren, R. (1990) Ethrel/Grape/Residue: Lab Project Nos: USA89E25; 40869. Unpublished study prepared by Rhone-Poulenc Ag Co., in cooperation with Mckenzie Laboratories, Inc. 141 p.
41872502	Nygren, R. (1990) Ethrel Apple 1989 Residue Program: Lab Project Nos: USA89E32; 40891. Unpublished study prepared by RhonePoulenc Ag Co., in cooperation with Mckenzie Laboratories, Inc. 150 p.
41906101	Savage, E.; (1990) Carbon 14-Ethephon: Absorption, Distribution, Metabolism, and Excretion in the Rat: Lab Project No: RP P89/ 366. Unpublished study prepared by Hazleton, UK. 626 p.

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42010401 Nygren, R. (1991) Storage Stability of Ethephon in/on Walnut Nutmeats: Lab Project Number: 89-REN-WA-S: 41007. Unpublished study prepared by Rhone-Poulenc Ag Co. 34 p.

42011501 Norris, F. (1991) A Terrestrial Field Soil Dissipation Study with Ethephon: Lab Project Number: EC-89-070: R092-079: R094-052. Unpublished study prepared by Rhone-Poulenc Ag Co., A & L Eastern Agriculteral Labs and A & L Western Agriculteral Labs. 250 p.

42016701 Nygren, R. (1991) Ethrel Tomato Residues: Lab Project Number: USA89E30: 40941. Unpublished study prepared by Rhone-Poulenc Ag Co. and McKenzie Labs, Inc. 246 p.

42116501 Nygren, R. (1991) Ethrel: Magnitude of the Residue/Crop Field Trials on Grapes: Amended Report: Lab Project Number: USA89E25: 41024. Unpublished study prepared by Rhone Poulenc Ag Co. in coop with McKenzie Labs, Inc., Cal State Univ., Viticulture and Enology Research Ctr. and others. 182 p.

42126001 Das, Y. (1991) Soil Adsorption and Desorption of carbon 14 Ethephon: Lab Project Number: ISSI 91020: EC-91-166. Unpublished study prepared by Innovative Scientific Services, Inc. 182 p .

42236701 Byrd, J. (1992) A Metabolism Study with carbon 14 Ethephon in Laying Hens (Gallus gallus): Lab Project Number: 9015C. Unpublished study prepared by Southwest Bio-Labs, Inc. 284 p.

42268901 Conn, R. (1992) Magnitude of the Residue of Ethephon in the Processed Fractions of Wheat: Lab Project Number: SARS-89-2A-24P: SARS-90-TX-24P: MKL-001-90-02. Unpublished study prepared by Stewart Agricultural Research Services, Inc., The Texas A&M Univ. System, and McKenzie Laboratories, Inc. 164 p.

42268902 Conn, R. (1992) Magnitude of the Residue of Ethephon and Monochloroacetic Acid (MCAA) in or on Wheat: SARS-89-24: MKL-001-90-02: SPRA-90-100. Unpublished study prepared by Stewart Agricultural Research Services, Inc., Rhone-Poulenc Ag Co., and McKenzie Laboratories, Inc. 330 p.

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42268904	Upalawanna, S. (1992) Storage Stability of Monochloroacetic Acid (MCAA) on Cottonseed: Lab Project Number: EC-90-133. Unpublished study prepared by Rhone-Poulenc Ag Co. 45 p.
42268905	Upalawanna, S. (1992) Storage Stability of Monochloroacetic Acid (MCAA) on Grapes and Raisin Waste: Lab Project Number: EC-90-136. Unpublished study prepared by Rhone-Poulenc Ag Co. 56 p.
42268906	Upalawanna, S. (1992) Storage Stability of Monochloroacetic Acid (MCAA) on Wheat Straw: Lab Project Number: EC-90-135. Unpublished study prepared by Rhone-Poulenc Ag Co. 49 p.
42268907	Upalawanna, S. (1992) Storage Stability of Monochloroacetic Acid (MCAA) on Tomatoes: Lab Project Number: EC-90-134. Unpublished study prepared by Rhone-Poulenc Ag Co. 41 p.
42268908	Upalawanna, S. (1992) Storage Stability of Monochloroacetic Acid (MCAA) on Cantaloupes: Lab Project Number: EC-90-138. Unpublished study prepared by Rhone-Poulenc Ag Co. 41 p.
42268909	Upalawanna, S. (1992) Storage Stability of Monochloroacetic Acid (MCAA) on Blackberries: Lab Project: EC-90-137. Unpublished study prepared by Rhone-Poulenc Ag Co. 42 p.
42294501	Putt, A. (1992) Ethephon Technical--The Chronic Toxicity to Daphnia magna Under Flow-through Conditions: Final Report: Lab Project Number: 92-1-4074: 10566.0891.6210.130. Unpublished study prepared by Springborn Labs., Inc. 98 p.
42298201	Nygren, R. (1992) Ethrel/Pineapple/Residue Magnitude of the Residue Crop Trials and Processing Fractions: Lab Project Number: USA89E27. Unpublished study prepared by Rhone-Poulenc Ag Co., Maui Pineapple Co. Ltd., and Hawaiian Sugar Planters Assoc. 291 p.

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42300801	Nygren, R. (1992) Storage Stability Study of Ethephon in/on Whole Fresh Peppers: Lab Project Number: 89-REN-P-S. Unpublished study prepared by Rhone-Poulenc Ag Co. 45 p.
42300802	Nygren, R. (1992) Storage Stability Study of Ethephon in/on Whole Fresh Cherries: Lab Project Number: 89-REN-CH-S. Unpublished study prepared by Rhone-Poulenc Ag Co. 42 p.
42300803	Eckert, J. (1992) Determination of the Storage Stability of Ethephon in Pineapple Fruit: Lab Project Number: RP-01-89E. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 57 p.
42300804	Eckert, J. (1992) Determination of the Storage Stability of Ethephon in Apple Fruit: Lab Project Number: RP-01-89C. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 57 p.
42300805	Eckert, J. (1992) Determination of the Storage Stability of Ethephon in Grape Berries: Lab Project Number: RP-01-89D. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 57 p.
42300806	Eckert, J. (1992) Determination of the Storage Stability of Ethephon in Tomato Fruit: Lab Project Number: RP-01-89A. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 57 p.
42300807	Eckert, J. (1992) Determination of the Storage Stability of Ethephon in Blackberry Fruit: Lab Project Number: RP-01-89B. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 57 p.
42300808	Upalawanna, S. (1992) Storage Stability on Monochloroacetic Acid (MCAA) on Pineapples: Lab Project Number: EC-90-139. Unpublished study prepared by Rhone-Poulenc Ag Co. 41 p.
42379101	Nygren, R. (1992) Chromatograms and Answers Raised in EPA Reviews for Ethephon use on Apples: Addendum to MRID No. 41872502: Lab Project Number: USA89E32: 40891. Unpublished study prepared by McKenzie Laboratories, Inc. 194 p.
42381701	Nygren, R. (1992) Chromatograms and Answers Raised in EPA Reviews for Ethephon Use on Sugarcane: Addendum to MRID 40954401: Lab Project

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Number: 40289: R87-023-R01. Unpublished study prepared by Rhone-Poulenc Ag. Co. 62 p.

42410301 Nygren, R. (1992) Chromatograms and Answers Raised in EPA Reviews for Ethephon Use on Grapes: An Addendum: Lab Project Number: USA89E25: 40869. Unpublished study prepared by McKenzie Laboratories, Inc. 265 p.

42410401 Eckert, J. (1992) Determination of the Storage Stability of Ethephon in Wheat Straw: Lab Project Number: RP-01-89H. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 51 p.

42410402 Eckert, J. (1992) Determination of the Storage Stability of Ethephon in Cottonseed: Lab Project Number: RP-01-89J. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 52 p.

42410403 Eckert, J. (1992) Determination of the Storage Stability of Ethephon in Wheat Grain: Lab Project Number: RP-01-891. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 52 p.

42430501 Helfant, L. (1992) Ethephon Base 250 Storage Stability Study: Lab Project Number: AC-91-008: 41247. Unpublished study prepared by Rhone Poulenc Ag Co. 50 p.

42464401 Nygren, R. (1992) Ethrel Brand Plant Regulator: Walnut/Magnitude of the Residue: Lab Project Number: USA91E29. Unpublished study prepared by Rhone-Poulenc Ag Co. 99 p.

42718101 Eckert, J. (1993) Determination of the Storage Stability of Ethephon in Cantaloupe Fruit: Lab Project Number: RP-01-89G: 90070: EBT-241.00. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 59 p.

42926301 Bernard, M. (1993) Product Chemistry: Manufacturing and Analytical Data for Ethephon Technical Concentrate. Unpublished study compiled by Cedar Chemical Corp. 31 p.

42957301 Leonard, M. (1993) Storage Stability of Ethephon in/on Frozen Bovine Meat, Bovine Milk and Chicken Eggs Spiked with Ethephon: Lab Project Number: EC-92-198: 44198. Unpublished study prepared by Rhone-Poulenc Ag Co. 66 p.

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MRID	CITATION
42957302	Nygren, R. (1993) Ethephon--Validation of Ethylene Release Method of Analysis for Residues of Ethephon in Crop Materials: Lab Project Number: EC-92-228: 44155. Unpublished study prepared by Rhone-Poulenc Ag Co. 233 p.
43115301	Bernard, M. (1994) Product Chemistry: Manufacturing and Analytical Data for Ethephon. Unpublished study prepared by Cedar Chemical Corp. 31 p.
43143601	Miller, N. (1994) A Confined Rotational Crop Study with (carbon 14) Ethephon Using Radishes (Raphanus sativus), Collards (Brassica oleracea), and Wheat (Triticum aestivum): Lab Project Number: EC/91/158. Unpublished study prepared by Rhone-Poulenc Ag Co., A&L Great Lakes Lab., Inc. 326 p.

APPENDIX D. List of Available Related Documents

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

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Ethephon RED Fact Sheet

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

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

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

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A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,…. of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the com-plete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, …250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in mul-tiple volumes is permissible so long as the entire study is pag-inated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10,

151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with pet-itions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d) (1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for

microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous corres-pondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a tran-smittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____
Signature Name

Company Name _____

Company Contact: _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

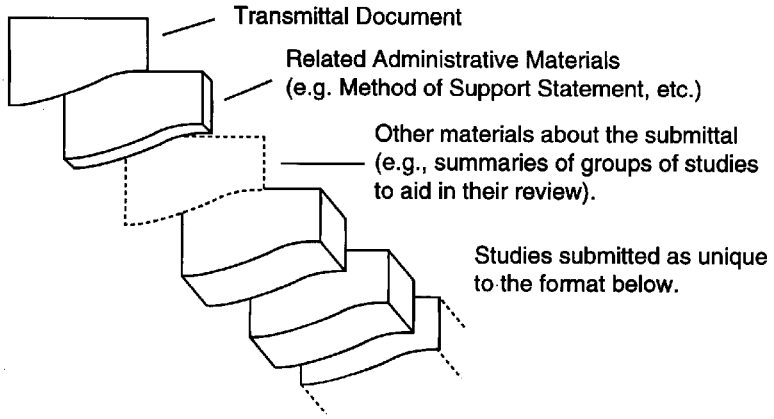
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

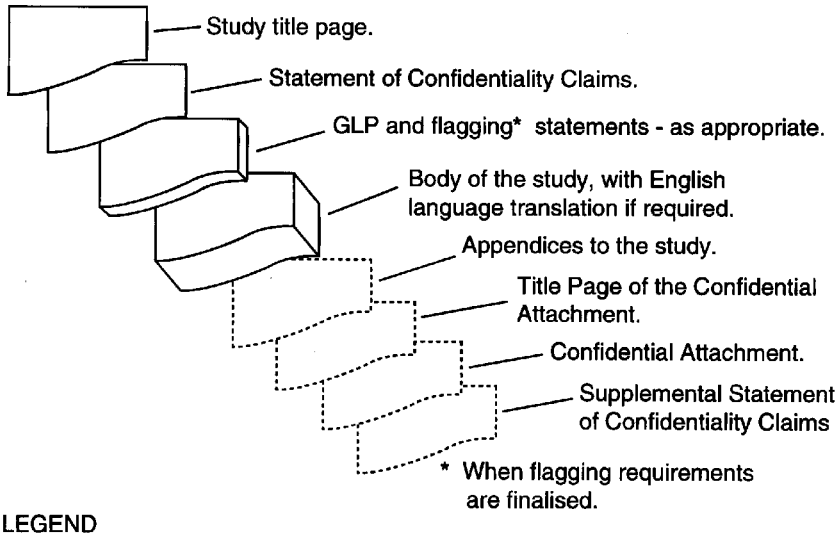
Submitter_____

ATTACHMENT 7.

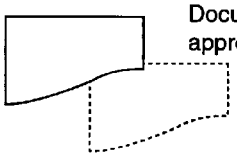
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients
Statement

I. PURPOSE:

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

II. BACKGROUND

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

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

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

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

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the

certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

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

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

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

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

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

a. Voluntary Cancellation -

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

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

b. Use Deletion -

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

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

c. Generic Data Exemption -

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

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

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

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

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

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

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

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

Option 1. Developing Data

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

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

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

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

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

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

Option 4. Submitting an Existing Study

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the

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

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

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

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

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

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

Option 5. Upgrading a Study

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

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

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

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

Option 6. Citing Existing Studies

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

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

2. Product Specific Data

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

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

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

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

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.1., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

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

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

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

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

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

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

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

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

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

parameters in item 3 above), and costs of data development pertaining to the active ingredient.

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

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You

should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of

voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Peter Caulkins, Acting Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

Attachment 1. Chemical Status Sheets

ETHEPHON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Ethephon. 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 Ethephon Generic Data CallIn (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Ethephon are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Ethephon are needed. These data are needed to fully complete the reregistration of all eligible Ethephon 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 Judy Loranger at (703) 308-8056.

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

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

ETHEPHON DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Ethephon, please contact Judy Loranger at (703) 308-8056.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Wanda Daughtry at (703) 308-8171.

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

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

RE: **Ethephon**

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

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

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form**. **BOTH** "Data Call-In Response" forms must be completed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FOR BOTH MUP and EUP products

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

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

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

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

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

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

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

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

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

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

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

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A Terrestrial food
B Terrestrial feed
C Terrestrial non-food

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

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

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

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

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

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the

date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA'S BATCHING OF ETHEPHON 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 ethephon 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. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the 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 products were found which contain ethephon as the active ingredient. The products have been placed into 5 batches in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each batch.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	264-263	3.9	Liq
	264-543	3.9	Liq
	CA90002800	3.9	Liq
2	264-267	21.7	Liq
	264-292	21.7	Liq
	264-376	21.7	Liq
	AZ87002100	21.7	Liq
	CA76019400	21.7	Liq
	CA83003400	21.7	Liq
	VA83001700	21.7	Liq
3	264-257	39.9	Liq
	264-377	39.9	Liq
	264-380	39.9	Liq
	HI84000400	39.9	Liq
	HI94000400	39.9	Liq
	PR89000200	39.9	Liq
4	264-418	55.4	Liq
	56077-49	55.4	Liq
5	264-511	71.3	Liq
	56077-50	71.3	Liq

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

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

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

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

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

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

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

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

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

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C (±2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

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

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

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Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-004 April 1995

R.E.D. FACTS

Ethephon

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0382, Ethephon.

Use Profile

Ethephon is a plant growth regulator used to promote fruit ripening, abscission, flower induction, and other responses. Ethephon is registered for use on a number of food, feed and nonfood crops, greenhouse nursery stock, and outdoor residential ornamental plants, but is used primarily on cotton. Formulations include formulation intermediates and soluble concentrates/liquids. Ethephon is applied to plant foliage by either ground or aerial equipment. It also may be applied by hand sprayer to certain home garden vegetables and ornamentals.

Use practice limitations include prohibitions against applying ethephon through any type of irrigation system; feeding or grazing livestock in treated areas; and treating within 2 to 60 days of harvest, depending on the crop.

Regulatory History

Ethephon was discovered in 1965, and was first registered as a pesticide in the U.S. in 1973. EPA issued a Registration Standard for ethephon in September 1988 (PB89-109427), requiring toxicology, residue chemistry, and environmental fate and effects data.

Human Health Assessment

Toxicity

Ethephon is corrosive in acute dermal irritation studies using rabbits, has the potential to cause eye irritation, and has been placed in Toxicity Category I (the highest of four categories) for these effects. It is moderately acutely toxic by the oral, dermal and inhalation routes (Toxicity Category III), and does not cause skin sensitization.

An organophosphate pesticide, ethephon caused plasma cholinesterase inhibition in a 16-day oral human study and clinical signs of toxicity in a second study. In a dermal toxicity study using rabbits, skin effects were observed at all doses.

In a combined chronic/oncogenicity study using rats, plasma and erythrocyte cholinesterase were inhibited at all doses. At the highest dose levels, ethephon caused body weight decrease and kidney effects, but no carcinogenic effects were observed. In a cancer study using mice, no evidence of treatment related tumors was observed. Ethephon has been classified as a Group D carcinogen based on "the insufficiency of the weight of evidence" regarding its cancer-causing potential.

One chronic toxicity study using beagle dogs caused plasma cholinesterase inhibition at all doses, and smooth muscle atrophy in the gut. In a second beagle dog study, treatment related effects included decreased spleen and body weight plus decreased hemoglobin and hematocrit in the males.

Developmental toxicity studies using rats and rabbits show no evidence of a potential for developmental effects at doses that are not toxic to the mother. In a reproductive toxicity study using rats, administration of the test compound caused decreased survival in the offspring and decreased body weight gain in adult females, but no effects on fertility, gestation, mating, organ weights, or histopathology in any generation.

Ethephon was positive in one mutagenicity study and negative in two others. It does not appear to cause delayed neurotoxicity based on a study using hens, however studies using mammals are now required as confirmatory data.

Human poisoning incidents involving ethephon include four cases of skin injury (irritation) in California as a result of exposure to field residues, one possible systemic poisoning case, and 29 telephone calls to the National Pesticides Telecommunications Network reporting eye and skin irritation from misuse of ethephon, sometimes in combination with other pesticides.

Dietary Exposure

People may be exposed to residues of ethephon through the diet. Tolerances or maximum residue limits have been established for ethephon in many raw agricultural commodities, processed foods, and feed. Please see 40 CFR 180.300(a) and (b), 185.2700(a), (b) and (c), and 186.2700(a).

Several additional tolerances, including food and feed additive tolerances, have been proposed.

Sufficient data are available to assess the adequacy of most established ethephon tolerances, although some require additional residue chemistry or animal feeding studies. Some changes are needed; certain tolerances must be revoked because registrations for these crop uses no longer exist, and a tolerance for cottonseed must be increased. Several new tolerances may need to be established.

EPA has assessed the chronic dietary risk posed by ethephon, evaluating exposure and risk, first, from all uses for which tolerances exist, have been recommended or have been proposed and, second, excluding uses for which revocation is recommended. For the overall U.S. population and 22 subgroups, the Anticipated Residue Contribution (ARC) from all current and proposed ethephon tolerances represents 9% of the Reference Dose (RfD), an amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The ARC of the most highly exposed subgroup, non-nursing infants less than one year old, represents 49% of the RfD. Excluding the tolerances recommended for revocation, the ARC for the overall U.S. population represents 8.6% of the RfD, while the ARC for non-nursing infants represents 47% of the RfD. Therefore, it appears that chronic dietary risk is not of concern.

Because ethephon causes neurotoxic effects (cholinesterase inhibition), an acute dietary exposure analysis also was conducted. Margins of Exposure (MOEs), which show how closely estimated exposure comes to a dose of concern, were calculated for several population subgroups. Infants less than one year old are the only subgroup whose exposure may be of concern, with 5% of the population estimated to have MOEs of less than 7 (an MOE of 10 or greater is desirable). However, these risk values represent an unrealistic worst case situation. Many conservative assumptions were included in calculating these risks, such as: all registered food crops are treated; maximum residue levels are present on all foods; and no dilution or degradation of residues has occurred during preparation or processing of food. EPA believes it is unlikely that infants and children will be exposed to ethephon-treated commodities at levels that will result in acute dietary risk.

Several international Codex Maximum Residue Limits (MRLs) have been established for ethephon. Compatibility between U.S. tolerances and Codex MRLs exists for apples, blackberries, cherries, pineapples and walnuts, and may be achieved for tomatoes by raising the U.S. tolerance. For other crops, the U.S. tolerances are being revoked or additional field residue data are needed.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to ethephon in agricultural and other settings, during and after applications using open pouring methods and broadcast (aerial and ground) treatment or hand-held spray equipment. Ethephon does not pose risks of systemic dermal or inhalation toxicity. However, since it does pose risks of severe skin and eye irritation (Toxicity Category I), certain Worker Protection Standard (WPS) provisions apply.

To protect post-application workers, a 48-hour restricted entry interval (REI) imposed by the WPS is being retained. This interval must be increased to 72 hours when ethephon is applied outdoors in arid areas. Certain personal protective equipment (PPE), including protective eyewear, is required for early entry into treated areas. In addition, since ethephon is in Toxicity Category I for primary skin irritation, "double notification" is required: agricultural workers must be warned orally of its application, **and** WPS warning signs must be posted at entrances to treated areas.

Human Risk Assessment

Ethephon has the potential to cause severe skin and eye irritation (Toxicity Category I), but otherwise is moderately acutely toxic. An organophosphate pesticide, it has the potential to cause cholinesterase inhibition. Ethephon is classified as a "Group D" carcinogen because there is insufficient weight of evidence regarding its cancer-causing potential.

Ethephon is used on many food and feed crops. Its tolerances have been reassessed, and while they generally are acceptable, some changes are required. EPA's dietary risk assessments indicate that infants less than one year old encounter the greatest exposure and risk as a result of ethephon crop use. However, since the Agency used many conservative assumptions in calculating these risks, actual dietary exposure and risk to infants as well as the overall U.S. population are believed to be minimal.

Pesticide handlers may be exposed to ethephon during application, and post-application workers may be exposed to residues on treated crops. To reduce workers' skin and eye irritation risks, a 48-hour REI is being retained and is increased to 72 hours in arid areas, use of certain PPE including protective eyewear is required for early entry, and double notification of workers is required.

Environmental Assessment

Environmental Fate

Ethephon is not persistent in the environment. The major routes of dissipation appear to be chemical hydrolysis and microbial degradation. Although ethephon degrades in somewhat acidic soils (pH 6.1), it does not hydrolyze in sterile, acidic water (pH 5). The major degradates are ethylene gas and 2-hydroxy ethyl phosphonic acid. Ethephon has moderate to low mobility in soil. It has a very low octanol/water partition coefficient and, therefore, is not expected to accumulate in fish.

In the field, ethephon exhibits the same characteristics of rapid degradation and moderate to low mobility as seen in the laboratory. At field sites in southern California, North Carolina, and Washington, ethephon dissipated with half-lives of about 7 to 25 days.

Ecological Effects

In dietary studies using the bobwhite quail and mallard duck, ethephon is practically nontoxic to slightly toxic on an acute basis, and practically nontoxic on a subacute basis. Acute oral studies using rats show that ethephon is slightly toxic to mammals. Other acute toxicity studies show that ethephon is practically nontoxic to coldwater fish, and practically nontoxic to slightly toxic to warmwater fish and freshwater invertebrates. Ethephon is practically nontoxic to shrimp, and slightly toxic to estuarine/marine mollusks. It is relatively nontoxic to honeybees. Regarding effects on terrestrial plants, ethephon reduces plant growth, resulting in reduced shoot lengths and weights.

Ecological Effects Risk Assessment

Ethephon is expected to have minimal effects on birds and mammals, as well as on fish, freshwater invertebrates, and marine and estuarine organisms.

Although minimal effects to aquatic and terrestrial plants (dry land) are expected, ethephon may pose a risk to semi-aquatic/wetland plants (including endangered semi-aquatic plants) when it is used on apples in North Carolina, cotton, tobacco, macadamia nuts, blackberries and pineapple. However, ethephon is a growth regulator and as such is not intended to be toxic to plants. Also, the magnitude of this risk is not high. Therefore, while the potential for risk to semi-aquatic plants exists, it is not extensive, arises only infrequently during periods of high exposure, and is geographically limited.

In response to Agency concerns about ethephon's risk to semi-aquatic plants, the registrant proposed as a risk mitigation measure to reduce the maximum use rate for blackberries and apples in North Carolina to 2.0 pounds per acre. They also provided information indicating that ethephon is used only occasionally at maximum rates when certain weather conditions exist, such as cool temperatures. Considering these factors, EPA believes that the risk to nontarget plants from use of ethephon will be limited.

Additional Data Required

EPA is requiring the following additional generic data for ethephon to confirm its regulatory assessments and conclusions: Product chemistry; Animal metabolism (poultry); Residue analytical method in plants and animals; Storage stability; Magnitude of the residue in plants (peppers, cantaloupes, grapes, wheat forage and hay, and cotton gin byproducts); Magnitude of the residue in processed sugarcane; Magnitude of the residue in poultry and ruminant; Batch equilibrium on the degradate of 2-hydroxy ethyl phosphonic acid; Acute and subchronic neurotoxicity.

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

Product Labeling Changes Required

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

Worker Protection

Personal Protective Equipment (PPE) for Handlers

PPE for handlers will be based on the toxicity of each end-use product (see PR Notice 93-7). If PPE is necessary for homeowner uses, it will be established during end-use product reregistration.

Entry Restrictions for Occupational-Use Products:

Worker Protection Standard (WPS) Uses

EPA is establishing a 48-hour restricted entry interval (REI), which increases to 72 hours in outdoor areas where average rainfall is less than 25 inches a year. PPE for WPS-permitted early entry into treated areas is coveralls over long-sleeved shirt and long pants, chemical-resistant gloves such as any waterproof gloves, chemical-resistant footwear plus socks, and chemical-resistant headgear for overhead exposures. In addition, protective eyewear is required since ethephon is in Toxicity Category I for eye irritation potential.

Non-WPS Uses

Products with uses outside the scope of the WPS must bear the following statement:

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

Entry Restrictions for Homeowner-Use Products

Ethephon products with directions for use by homeowners must bear the following statement:

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

Other Labeling Requirements

Reduce PPE when Engineering Controls are Used

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

User Safety Requirements

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

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

User Safety Statements

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

"Users should remove clothing immediately if pesticide gets inside."

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

Application Restrictions

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

Notification

"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."

Environmental Hazard

The following precautionary statement is required to address risks to wetlands:

"Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark."

For residential use sites (ornamental trees, shrubs, vines and herbaceous plants), the statement, "Do not apply directly to water" may be used instead of the statement above.

Spray Drift

The following language is required on each product label that can be applied aerially:

"AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR."

"The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions."

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

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

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

"Where states have more stringent regulations, they should be observed."

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

The following Aerial Drift Reduction Advisory Information must be contained in the product labeling:

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

Information on Droplet Size

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

Controlling Droplet Size

- "Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets."
- "Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure."
- "Number of nozzles - Use the minimum number of nozzles that provide uniform coverage."
- "Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential."
- "Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low- drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."

Boom Length

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

Application Height

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

Swath Adjustment

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

Wind

"Drift potential is lowest between winds speeds of 2 - 10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."

Temperature and Humidity

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

Temperature Inversions

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

Sensitive Areas

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

Residue Chemistry

The following label revisions must be added to pertinent end-use products:

- Product labels must be amended to reflect a maximum allowable use rate of 2 lb ai/A/season for application of ethephon to cotton.
- Label directions for apples, cranberries, carob, and olives that are for ornamental use only must be clearly designated as such.
- The 0.33 lb/gal SC/L label (264-263) must be amended to prohibit the harvesting of any treated pumpkins for human or animal consumption and must specify that treatments are to be made to pumpkins for seed production only.
- Labels must be amended to reduce the maximum use rate for blackberries and apples in N.C. to 2.0 lb per acre.

A table near the end of the RED document identifies the Food/Feed Use Patterns Subject to Reregistration for Ethephon. This table lists currently acceptable use sites, formulations, application rates, methods and equipment, pre-harvest and reentry intervals, and use limitations for ethephon products registered by the basic manufacturer. All ethephon end-use product labels must be amended to be consistent with the basic producer labels, as reflected in this table.

Regulatory Conclusion

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

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

For More Information

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

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also can be reached on the Internet via *FEDWORLD.GOV,* or obtained from EPA's gopher server, *EARTH1.EPA.GOV.*

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

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

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

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.