United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA 738-R-97-001 March 1997

Reregistration Eligibility Decision (RED)

4-Chlorophenoxy-acetic Acid (4-CPA)

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 4-CPA which includes the active ingredient 4-CPA acid. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Rubis at (703) 308-8184. Address any questions on required generic data to the Special Review and Reregistration Division representative Tom Luminello at (703) 308-8075.

Sincerely yours,

Lois A. Rossi, Director
Special Review
and Reregistration Division

Enclosures

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

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

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

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

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

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

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

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

4-CHLOROPHENOXYACETIC ACID

LIST B

CASE 2115

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

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4-CPA REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Phyllis Johnson	Biological Analysis Branch
George Keitt	Biological Analysis Branch

Environmental Fate and Effects Division

Curtis Laird	Ecological Effects Branch
Sharlene Matten	Science Analysis and Coordination Staff
James Hetrick	Environmental Fate and Groundwater Branch

Health Effects Division

William Smith	Reregistration Support Chemistry Branch
Mary Clock	Risk Characterization and Analysis Branch
John Leahy	Occupational and Residential Exposure Branch
Laura Morris	Occupational and Residential Exposure Branch
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Tom Luminello	Accelerated Reregistration Branch
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Office of Enforcement and Compliance Monitoring

Phyllis Flaherty	Agricultural Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (referred to as "the Agency") has completed an assessment of the potential human health and environmental risks associated with the pesticide uses of 4-chlorophenoxyacetic acid, hereafter referred to as "4-CPA." The Agency has determined that pesticide products containing this chemical as an active ingredient, labeled and used as specified in this Reregistration Eligibility Decision document (RED), will not cause unreasonable risk to humans or the environment. Therefore, the Agency has concluded that the products containing 4-CPA are eligible for reregistration.

4-CPA is used in the food industry as a plant growth regulator to restrict root growth during seed germination of mung beans. The product is used by preparing a diluted solution which is added to the water bath to soak the beans. The beans are soaked for several hours, then washed several times to remove the surface residues. The seeds are then germinated indoors for several days. After sprouting, the hulls and roots are discarded. The sprouted portion of the beans are packaged and sold for human consumption.

Studies suggest that 4-CPA has low subchronic mammalian toxicity, and with the exception of ocular irritation, has moderate to low acute toxicity. However, 4-CPA is a severe eye irritant when tested in rabbits and is a developmental toxin in rats. 4-CPA is considered practically non-toxic to fish and is not likely to pose environmental fate concerns under the present limited use pattern described above.

Before reregistering the products containing 4-CPA, 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.

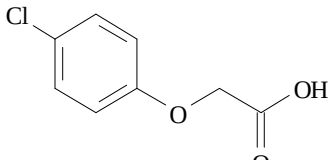
This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of 4-CPA. The document consists of six sections. Section I is the introduction. Section II describes 4-CPA, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for 4-CPA. Section V discusses the reregistration requirements for 4-CPA. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** 4-CPA
- **Chemical Name:** 4-chlorophenoxyacetic acid
- **Chemical Family:** phenoxy
- **CAS Registry Number:** 122-88-3
- **OPP Chemical Code:** 019401
- **Empirical Formula:** $C_8H_7ClO_3$
- **Structural Formula:**



4-CPA

- **Molecular Weight:** 186.6
- **Basic Manufacturer:** A. H. Marks and Company Ltd.

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the use of 4-CPA is in Appendix A.

For **4-CPA**:

Type of Pesticide: Plant growth regulator

Use Group and Site: Indoor Food Crop: Mung beans

Formulation Types Registered: soluble concentrate/liquid and crystals

Method and Rates of Application:

Equipment - Direct pour or closed delivery systems.

Method and Rate - 0.026 pounds of crystalline 4-CPA are dissolved in 1 liter of boiling water and added to 1150 gallons of water in which 3500 pounds of mung bean seeds are soaked.

Timing - Bean are soaked 5-8 hours before sprouting. Seeds are well rinsed in water and allowed to germinate.

Use Practice Limitations: Do not feed treated hulls or bean parts to livestock.

C. Data Requirements

Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

D. Regulatory History

A pesticide product formulated with 4-CPA as an active ingredient was first registered in the United States in October 1969. It was registered for use as a plant growth regulator for mung beans and later as a fruiting bloom set for tomatoes.

A Data Call-In was issued in December 1984 for 4-CPA requiring chronic toxicology data. A Data Call-In was issued in June 1987 to investigate possible Dioxin\Furan formation during the manufacturing process.

Under Phase 4 of reregistration, a Data Call-In was issued in June 1991 for data to characterize the chemistry, human toxicity, and environmental fate of 4-CPA. Another Data Call-In was issued in June 1994 to allow other end use product manufacturers a chance to support the tomato use. As a result, the products labeled for use on tomatoes were voluntarily cancelled, leaving two products labeled for use on mung beans.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

4-CPA is an odorless, light-colored powder with a melting point of 158-160°C. It is stable at elevated temperatures (54°C) and on exposure to metals, but degrades (30% loss in 24 hours) on exposure to sunlight.

All pertinent generic chemistry data requirements except preliminary analysis are satisfied for the La Choy 4-CPA product. These data for preliminary analysis have been required of the registrant and will be due to the Agency after the next production of the La Choy technical. However, all data requirements are outstanding for the TGAIs of the other registrant's 4-CPA product. Provided that the registrant submits the data required in the June

1994 for the TGAIs of their products as confirmatory data, the Agency has no objections to the reregistration of 4-CPA with respect to product chemistry data requirements. These product chemistry data are due June, 1995.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on 4-CPA is adequate and will support reregistration eligibility. The Agency required data on acute, subchronic feeding, and developmental toxicology as well as mutagenicity studies. The results of the subchronic studies in two species showed no adverse systemic effects. 4-CPA was shown to be a developmental toxin causing decreases in fetal body weights and inducing skeletal variations in rats. Because of the lack of overt toxicity in subchronic dietary studies, the low volume/minor use status and the lack of acute dietary exposure concerns of 4-CPA, described below, the Agency waived the chronic toxicity, carcinogenicity, and reproductive effects studies normally required for food-use chemicals.

a. Acute Toxicity

Table 1. Summary of acute toxicity data on 4-CPA

Test	Results	Category
Oral LD_{50}--rat	2,703 mg/kg	III
Dermal LD_{50}--rabbit	>2,000 mg/kg	III
Inhalation LC_{50}--rat	>5.25 mg/L	IV
Eye irritation--rabbit	severe irritation	I
Dermal irritation--rabbit	non-irritating	IV
Dermal sensitization-- guinea pig	non-sensitizing	--

In an acute oral toxicity study in rats, the LD_{50} was 2,703 mg/kg (guideline 81-1; MRID 41837001). Clinical signs of toxicity were staggered gait, hypoactivity, and absent pain reflex. An acute dermal toxicity study with rabbits found the LD_{50} was greater than 2,000 mg/kg (guideline 81-2; MRID 42522601). In an acute inhalation toxicity study with rats, 4-CPA had an LC_{50} greater than 5.25 mg/L (guideline 81-3; MRID 42968201).

In rabbits, 4-CPA was a severe eye irritant (guideline 81-4; MRID 42339101). 4-CPA was non-irritating in a primary dermal irritation study with rabbits (guideline 81-5; MRID 42306801). No sensitization occurred in a dermal sensitization study with guinea pigs (guideline 81-6; MRID 42339102).

b. Subchronic Toxicity

In a 13-week oral toxicity study, 4-CPA was given to Crl:CD BR VAF/Plus rats at doses of 0, 100, 2000, or 8000 ppm in the diet (0, 6.6, 132, or 517 mg/kg/day for males; 0, 8.0, 153, or 626 mg/kg/day for females). The NOEL was 2000 ppm. The LOEL was 8000 ppm, based on decreased body weight gain in both sexes, decreased food consumption in females, increased urine volume in females, and increased incidence of slight hepatic lymphohistiocytic infiltrates and slight individual hepatocellular necrosis in males (guideline 82-1; MRID 42902501).

4-CPA was given to beagle dogs for 13 weeks in the diet at 0, 20, 100, or 500 ppm (0, 0.8, 3.3, or 18.6 mg/kg/day for males; 0, 0.8, 4.0, or 17.4 mg/kg/day for females). The NOEL was 500 ppm. The only effect found was decreased body weight gain and food consumption during the first four weeks at the highest dose, which may have been related to palatability (guideline 82-1; MRID 42968301).

c. Developmental Toxicity

4-CPA was administered to Crl:CD BR VAF/Plus rats by gavage at 0, 150, 300, 600, or 1000 mg/kg/day on gestation days 6-15. The NOELs for maternal and developmental toxicity were 150 mg/kg/day. The maternal LOEL, 300 mg/kg/day, was based on tremors, uncoordinated movements, recumbent posture, languidness, cold body, and decreased body weight gain. The highest dose also showed increased mortality. Fetal body weights were decreased at 600 and 1000 mg/kg/day. Skeletal variations were seen at the developmental LOEL of 300 mg/kg/day and at higher doses. The skeletal variations manifested as increased unossified sternebrae, seventh cervical ribs, and misaligned sternebrae (guideline 83-3; MRID 42322602).

d. Mutagenicity

4-CPA tested in an in vitro mammalian mutation assay did not induce forward mutations in mouse lymphoma cells (guideline 84-2; MRID 41837004).

In the Ames Salmonella/mammalian-microsome reverse mutation assay, 4-CPA was not mutagenic, with and without activation (guideline 84-2; MRID 41837002). Also, this chemical was not clastogenic in an in vivo mouse micronucleus assay (guideline 84-4; MRID 41837003).

e. Reference Dose

A Reference Dose (RfD) of 0.006 mg/kg/day has been established, based on the NOEL of 500 ppm highest dose tested (HDT) in the subchronic toxicity study in dogs. The uncertainty factor is 3000, including factors of 10 for inter-species extrapolation, 10 for intra-species variability, 10 for extrapolation from subchronic to chronic exposure, and 3 for the lack of reproductive toxicity data.

2. Exposure Assessment

a. Dietary Exposure

An acute dietary risk assessment is not required since no acute dietary toxicity end-point of concern has been identified, but we have an RfD for chronic exposure.

Tolerances are expressed as the combined residues of 4-chlorophenoxyacetic acid (4-CPA) and its metabolite 4-chlorophenol (4-CP) in/on mung bean sprouts at 2.0 ppm and in/on tomatoes at 0.05 ppm (40 CFR §180.202). Tolerances for residues of 4-CPA in animal commodities have not been established and are not needed because the mung beans are not a feed item. No food/feed additive tolerances have been established nor are they needed because there are no animal feed items associated with mung beans. An adequate enforcement method is available for the determination of residues of 4-CPA and 4-CP in/on plant commodities.

The Agency has concluded that the 4-CP metabolite of 4-CPA, present in the residue at less than 1%, is not of risk concern and no longer needs to be regulated. The Agency will propose under a separate Federal Register notice that 4-CP be excluded from the tolerance expression (guideline 171-4(a); MRID 42819602).

The registrant has submitted a petition (PP#2E04120) for a reduction in the tolerance for mung bean sprouts to 0.2 ppm. Data submitted by the registrant indicate that residues will not exceed this level when 4-CPA is used on sprouting mung beans according to label instructions. Therefore, the Agency will amend the existing tolerance from 2 ppm to a level of 0.2 ppm through proposed and final notices in the Federal Register. The Agency used the existing tolerance level in its dietary risk assessment, described below, since it represents a conservative estimate of total residues of 4-CPA, both free and conjugated, and the proposed revision was not final at the time of the assessment.

The established tolerance on tomatoes will be revoked. No other party has expressed an interest in supporting this use and all registrations for

tomato uses are cancelled.

Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on a mung bean sprout metabolism study. The residue of concern in mung bean sprouts is 4-CPA, both free and conjugated.

Animal Metabolism

Because there are no animal feed items associated with mung bean sprouts, animal metabolism studies are not required (guideline 171-4(b)).

Residue Analytical Methods - Plants and Animals

An adequate enforcement method is available for determination of residues of 4-CPA and the metabolite 4-CP in/on plant commodities. The Pesticide Analytical Method (PAM) Vol. II lists a GC method with microcoulometric detection and a detection limit of 0.02 ppm (Method I; Sec. 180.202).

Residue data submitted in response to the Phase 4 Data Call-In and in support of the petition (PP#2E04120) for a reduction in the established tolerance for the combined residues of 4-CPA and 4-CP in/on mung bean sprouts were collected using two residue analytical methods for determining the residue analytical methods for determining residues of 4-CPA (Method C 023.00) and 4-CP (Method 024.00). Both 4-CPA and 4-CP are isolated by liquid/liquid extraction, cleaned up by ion exchange, and separated and quantitated by HPLC using a C-18 column and UV detection (225 nm). The limit of detection of these methods is 10 ppb. The registrant indicated (in their petition for a reduced tolerance) that these methods were suitable for enforcement purposes. However, the present limited use of 4-CPA does not merit expenditure of further resources on an independent laboratory validation and Agency method validation trial for inclusion in PAM Vol II.

Although the existing analytical methods do not release and measure residues of conjugated 4-CPA, they are considered adequate for enforcement and data collection because of the limited use of the pesticide.

Analytical methods for animal commodities are not required since there are no animal feed items associated with mung beans and no direct animal uses of 4-CPA.

The Agency required that 4-CPA and its metabolites be tested

through multiresidue method Protocol B. The FDA PESTDATA data base dated January 1994 (PAM Vol. I, Appendix I) indicates that 4-CPA is completely recovered (>80%) using multiresidue method PAM Vol. I Section 402 using the E2 extraction procedure but that there is only a small recovery (<50%) when the E1 extraction procedure is used. PAM Vol. I Section 402 is the multiresidue method for acids and phenols and corresponds to what was previously designated Protocol B (guideline 171-4(c); MRID 43326801).

Storage Stability

Residue data for 4-CPA from the magnitude of the residue studies are supported by adequate storage stability data. Residues of 4-CPA are stable in/on mung bean sprouts stored at -15° C for 69 days and in canned mung bean sprouts stored frozen for 57 days.

Storage stability data for residues of the metabolite 4-CP will not be required as the Agency has determined that these residues should no longer be regulated (guideline 171-4(e); MRID 43326801).

Magnitude of the Residue in Plants

The data for magnitude of the residue in/on mung bean sprouts are adequate for tolerance reassessment. The magnitude of the residue studies from the original petition for the mung bean sprouts tolerance (PP#360) are not considered here because the raw agricultural commodity was not analyzed and there were problems with the analytical method used to generate the residue data (guideline 171-4(k); MRID 42551004).

Data are not available for the tomato use. The established tolerance will be revoked because the use is cancelled.

Magnitude of the Residue in Processed Food/Feed

The data for magnitude of the residue in processed food/feed have been evaluated and are adequate for mung bean sprouts. Mung bean sprouts are considered a raw agricultural commodity in Table II (June 1994) of Subdivision O of the Pesticide Assessment Guidelines, and thus there is no need to establish a food additive tolerance.

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

Data pertaining to magnitude of the residue in milk, meat, poultry, and eggs are not required because there are no animal feed items associated

with mung beans (guideline 171-4(j)).

Confined/Field Rotational Crops

Confined and field rotational crop studies are not required. The registered use of 4-CPA on mung beans as a soak treatment does not lend itself to subsequent crop rotation as the mung beans are treated and harvested entirely indoors (guidelines 165-1 and 165-2).

b. Occupational and Residential

As described previously, 4-CPA is a plant growth regulator formulated as a soluble concentrate liquid (containing 100 percent a.i.). The 4-CPA product is applied to mung beans in a soak tank. 4-CPA is first mixed in boiling water, then the dissolved solution is poured into the soak tank. 4-CPA is applied at 0.008 lb ai/1,000 lb mung beans.

A short and intermediate term (1-7 days) occupational exposure assessment is not required because of a high maternal and developmental toxicity LOEL [300 mg/kg/day].

The products containing 4-CPA are intended primarily for occupational use. The registered use is not likely to involve application at residential sites.

At this time, the registered use of 4-CPA is outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS), due to the industrial setting for application of the pesticide.

3. Risk Assessment

a. Dietary

Based upon the review of the toxicology data base for 4-CPA, there is no endpoint of concern identified for acute dietary exposure. Therefore, an acute dietary risk assessment was not conducted.

The Agency used a RfD of 0.006 mg/kg/day for its Dietary Risk Evaluation System (DRES) chronic exposure analysis. This RfD is based upon the NOELs of 18.58 and 17.41 mg/kg bwt/day for males and females, respectively, from the subchronic toxicity study in dogs described above. An uncertainty factor of 3000 was applied.

(1) Residues

4-CPA residues included in this dietary analysis were from 4-CPA's uses on mung bean sprouts and tomatoes since there currently are established tolerances for these two commodities. The Agency used tolerance values established in 40 CFR § 180.202 and the Office of Pesticide Program's Tolerance Index System (TIS): mung beans at 2.0 ppm and tomatoes at 0.05 ppm. As discussed above the Agency intends to make the following changes in the tolerance statement: first, the tolerances are to be based upon 4-CPA residues only because the 4-CP metabolite has been determined to not be of toxicological concern; second, the tolerance for mung beans will be reduced from 2.0 ppm to 0.2 ppm; and, third, the tolerance for tomatoes will be revoked since there is no corresponding U.S. registration for use on this commodity. There are no proposed or pending tolerances for 4-CPA. Mung beans have no associated animal feed items, therefore, there are no meat, milk, egg and poultry tolerances.

(2) Chronic Exposure

In the DRES chronic analysis, tolerance level residues were used to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. The exposure estimates were then compared to the RfD for 4-CPA to calculate estimates of chronic dietary risk.

Although uses on tomatoes have been voluntarily canceled, the tolerances have not been revoked at the time of this analysis. Therefore, tomatoes - whole, tomatoes - juice, tomatoes - puree, tomatoes - paste, and tomatoes - catsup were included in this DRES analysis at the tolerance level of 0.05 ppm. In addition, although the Agency intends to reduce the tolerance for mung beans from 2.0 ppm to 0.2 ppm, this analysis was conducted using the currently published tolerance of 2.0 ppm. Anticipated residues and percent crop treated data were not required and therefore, not used in this analysis because of the results presented below.

The results (TMRC and % RfD) of the DRES chronic analysis for the U.S. population and two most sensitive subgroups are displayed in Table 2.

Table 2. Population subgroup chronic dietary analysis for 4-CPA

Subgroup	Exposure (TMRC) (mg/kg/day)	%RfD

U.S. Population	8.60×10^{-5}	1.43
Children (1-6 years old)	1.57×10^{-4}	2.62
Children (7-12 years old)	1.34×10^{-4}	2.24

The U.S. population and all of the DRES population subgroups have TMRCs for chronic dietary risk well below the RfD when published tolerances are considered. Therefore, it appears that chronic dietary risk is not of concern for this chemical.

b. Occupational

The Agency believes that the potential for exposure to 4-CPA during pesticide handling operations exists, but is low. Further, the toxicological criteria for requiring an exposure assessment were not triggered. An endpoint of 300 mg/kg/day (LOEL) was identified for short term and intermediate term occupational exposure. A risk assessment was not required because of this high LOEL and the potentially low worker exposure associated with the growing of mung beans.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has waived most of the ecotoxicity data requirements for the reregistration of the mung bean use, because the use is carried out entirely indoors, resulting in practically no exposure to non-target organisms. The Agency concludes that the available data, summarized below in Table 3, are adequate for determining the ecological toxicity and labeling of this chemical. No further data are required for labeling or for ecological risk characterization.

Table 3. Ecological Effects Toxicology Data

Available Toxicity Findings

Species	Test Material	Results	MRID	Toxicity Category
Rat	4-CPA (100 % ai)	LD_{50} = 2703 (2191 - 3335) mg/kg	418370-01	Practically Non-toxic
Bluegill Sunfish	4-CPA, Diethanol-amine salt (2 % ai)	96-Hr LC_{50} = > 180 ppm	ABL Test No. 657	Practically Non-toxic

The above data indicate that 4-CPA, 100% active ingredient (ai) is practically non-toxic to small mammals on an acute oral basis (MRID 41837001) and 4-CPA, diethanolamine salt, in a 2% formulation, is practically non-toxic to warm water fish (ABL Test No. 657).

The fish test is considered a supplemental study because it is based on a summary report for a related formulation. However, considering the unique use pattern, this study provides enough useful information for characterizing the toxicity of 4-CPA.

2. Environmental Fate

a. Environmental Fate Assessment

Hydrolysis data were the only data required to support the indoor use (e.g., root suppression of mung bean sprouts) of 4-CPA. From an acceptable study, parent 4-CPA was stable ($t_{1/2}$ > 30 days) to abiotic hydrolysis in three buffer solutions (guideline 161-1; MRID 42819601). No additional environmental fate data are required to support the use of 4-CPA on mung beans.

4-CPA is expected to be mobile in soil and aquatic environments because it will be an anion (dissociated carboxylic acid) in most environments. The soil partitioning coefficient (K_d) for 4-CPA cannot be estimated from structural analysis. Disposal of 4-CPA-treated water, after treatment of mung beans, should be in compliance with a NPDES permit.

3. Exposure and Risk Characterization

a. Exposure and Risk Characterization

Because the use of 4-CPA on mung beans is limited in scope and is completely indoors, the Agency has not performed a risk characterization for nontarget organisms. The presently registered use provides for essentially no exposure to nontarget organisms. Further, the disposal of wastes will be

into landfills or publicly-owned sewage treatment facilities, thereby precluding exposure to nontarget organisms. Therefore, the use of 4-CPA on mung beans is unlikely to pose a risk to nontarget organisms.

b. Endangered Species

As discussed above, the presently registered use provides for virtually no exposure to endangered species. Therefore, risks to such organisms are unlikely.

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 4-CPA as an 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 4-CPA. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of 4-CPA, 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 use of 4-CPA and to determine that 4-CPA can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing 4-CPA as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of 4-CPA 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 4-CPA, 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 4-CPA, the Agency has sufficient information on the health effects of 4-CPA and on its potential

for causing adverse effects in fish and wildlife and the environment. The Agency has determined that 4-CPA products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing 4-CPA for the mung bean use are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that the mung bean use of 4-CPA is eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for 4-CPA. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

Existing tolerances of 2.0 ppm and 0.05 ppm are currently established for 4-CPA and its metabolite 4-chlorophenol in or on mung beans and tomatoes, respectively, per 40 CFR §180.202. The Agency will amend the tolerance expression to include only 4-CPA, reduce the tolerance on mung beans to 0.2 ppm, and revoke the tolerance on tomatoes for the reasons discussed above.

2. Endangered Species Statement

The Agency has no concerns about the exposure of threatened and endangered species to 4-CPA.

3. Personal Protective Equipment (PPE) for Handlers (Mixers/Loaders/Applicators)

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

- If the Agency 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.

- If the Agency 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, the Agency 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 the end-use product.

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

The Agency has no special concerns about the effects of this active ingredient under the current use pattern. Little exposure is expected and the toxicological data do not suggest a need for active-ingredient-based PPE, with the exception of requiring eye protection for the product which contains 100% active ingredient because of the corrosive effects observed in the acute study. PPE for the product containing 0.0015% 4-CPA will be based on the acute toxicity of the end-use product.

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 4-CPA for the above eligible use has been reviewed and determined to be substantially complete. Additional preliminary analysis data are required and are due to the Agency at the next production of the La Choy product.

Additional product chemistry data are required of the Luigino product. These requirements have been issued in the Data Call-In of June 1994. These data are due June 1995.

2. Labeling Requirements for Manufacturing-Use Products

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

Directions For Use:

"Only for formulation into a Plant Growth Regulator for the following use: mung bean."

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

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

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

The following label statement is required on all manufacturing-use products (PR Notice 93-10):

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specially identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Product chemistry and acute toxicology data are required. However, since the end use product is nearly 100% technical material, and the registrant so chooses, they may rely on some of the data generated for the TGAI and cite those MRIDs.

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; Attachment E) 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

Personal Protective Equipment (PPE) for Handlers (Mixer/Loaders and Applicators)

At this time there are no engineering control requirements, such as closed systems, currently required on labeling for 4-CPA products. Due to the potential for eye irritation (Toxicity Category 1), the Agency is requiring that handlers of the 100% 4-CPA product wear protective eyewear. However, there are no other special toxicological concerns about 4-CPA that warrant the establishment of active-ingredient-based handler PPE requirements. Therefore, the PPE for handlers will be based on the acute toxicity of the end-use product. Due to the potential for eye irritation (Toxicity Category 1), the Agency is requiring that handlers wear protective eyewear.

To protect handlers of the 100% 4-CPA product, the following language must be located on the label:

"Applicators and other handlers must wear goggles."

Entry Restrictions for Occupational-Use Products

All of the registered uses of 4-CPA are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Therefore, there are no reentry restrictions. The Agency is requiring the following labeling statements to be located on all end-use products containing 4-CPA that are intended primarily for occupational use:

Application Restrictions:

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

User Safety Requirements:

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

User Safety Recommendations:

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

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

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

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

VI. APPENDICES

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 Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES											
BEAN SPROUTS, MUNG					Use Group: INDOOR FOOD						
Soak., Seed., 1150 gal tank.	Cr	NA	3 ppm[1]	*	NA	NA	3 ppm	NA	NA	NA	CAL G16 G95
Tank size unspec.	SC/L	NA	0.3 ppm[2]	*	NA	NA	0.3 ppm	NA	NA	NA	CAL

[1] Standard procedure: 9-12 grams of crystalline 4-CPA are dissolved in 1 liter of boiling water and added to 1150 gal of water to soak 3500 lb of mung bean seeds.

[2] 2 fl oz of product are added to each 3 1/3 qt of seed soak solution. Volume of soak solution depends on amount of seed per batch.

LEGEND

HEADER ABBREVIATIONS

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

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

PRL	: PRESSURIZED LIQUID
RTU	: LIQUID-READY TO USE
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

CAL : Do not contaminate water, food or feed.
G16 : Do not feed treated seed to livestock.
G95 : Do not feed to livestock.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 2115 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 2115 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of 4-CPA

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	I	**42025301**
61-2A	**Start. Mat. & Mnfg. Process**	I	**42025301**
61-2B	**Formation of Impurities**	I	**42025301**
62-1	**Preliminary Analysis**		
62-2	**Certification of limits**		
62-3	**Analytical Method**		
63-2	**Color**	I	**124265**
63-3	**Physical State**	I	**124265**
63-4	**Odor**	I	**42363301**
63-5	**Melting Point**	I	**124265**
63-6	**Boiling Point**		
63-7	**Density**	I	**42363301**
63-8	**Solubility**	I	**124265**
63-9	**Vapor Pressure**	I	**42363301**
63-10	**Dissociation Constant**	I	**42363301**
63-11	**Octanol/Water Partition**	I	**42018501**
63-12	**pH**	I	**42363301**
63-13	**Stability**	I	**42363301**
63-14	**Oxidizing/Reducing Action**		

Data Supporting Guideline Requirements for the Reregistration of 4-CPA

REQUIREMENT		USE PATTERN	CITATION(S)
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	I	**41837001**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	I	**42522601**
81-3	**Acute Inhalation Toxicity - Rat**	I	**42968201**
81-4	**Primary Eye Irritation - Rabbit**	I	**42339101**
81-5	**Primary Dermal Irritation - Rabbit**	I	**42306801**
81-6	**Dermal Sensitization - Guinea Pig**	I	**42339102**
82-1A	**90-Day Feeding - Rodent**	I	**42902501**
82-1B	**90-Day Feeding - Non-rodent**	I	**42968301**
83-3A	**Developmental Toxicity - Rat**	I	**42322602**
84-2A	**Gene Mutation (Ames Test)**	I	**41837002**
84-2B	**Structural Chromosomal Aberration**	I	**41837004**
84-4	**Other Genotoxic Effects**	I	**41837003**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	I	**42819601**
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	I	**42819602**
171-4C	**Residue Analytical Method - Plants**	I	**43326801**
171-4E	**Storage Stability**	I	**43326801**
171-4K	**Crop Field Trials**	I	**42551004**

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of 2115

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

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

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41837002 Lawlor, T. (1990) Mutagenicity Test on 4-Chlorophenoxyacetic Acid in the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames Test) with a Confirmatory Assay: Lab Project Number: 12447-0-401R. Unpublished study prepared by Hazleton Laboratories America, Inc. 33 p.

41837003 Murli, H. (1991) Mutagenicity Test on 4-Chlorophenoxyacetic Acid in vivo Micronucleus Assay: Lab Project Number: 12447-0-455PO. Unpublished study prepared by Hazleton Washington, Inc. 23 p.

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42306801 Glaza, S. (1992) Primary Dermal Irritation Study of 4-Chlorophenoxyacetic Acid in Rabbits: Lab Project Number: HWI 20200490. Unpublished study prepared by Hazleton Wisconsin, Inc. 21 p.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

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

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

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

The Attachments to this Notice are:

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

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 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 160.3(a)(6)].

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

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

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory

performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

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

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

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

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most

circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

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

4-CPA DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 4-CPA.

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 4-CPA. 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 4-CPA 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 4-CPA are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 4-CPA 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 4-CPA products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact C.P. Moran at (703) 308-8590.

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

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

RE: **4-CPA**

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

Item 1-4. Already completed by EPA.

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

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

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

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

Items 8-11. Self-explanatory.

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

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

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

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

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

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

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

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

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

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

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also

submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

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

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency

(**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

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

Items 10-13. Self-explanatory.

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

EPA'S BATCHING OF 4-CHLOROPHENOXYACETIC ACID 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 4-chlorophenoxyacetic acid as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that

choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Two products were found which contain 4-chlorophenoxyacetic acid as the active ingredient. Both products have been placed into the "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. The following table identifies the products addressed in this document.

Table 1 (No batch)

EPA Reg. No.	% 4-Chlorophenoxyacetic acid	Formulation Type
8906-1	99.99	Solid
62469-1	0.0015	Liquid

Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

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

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

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

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "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 E. List of Available Related Documents

The following is a list of available documents related to 2115. 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 2115 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. 2115 RED Fact Sheet
4. PR Notice 86-5
5. PR Notice 91-2 - pertains to the Label Ingredient Statement