United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-96-023
October 1996

Reregistration Eligibility Decision (RED)

Chlorpropham

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 0271 which includes the active ingredient chlorpropham. 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 also includes requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

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

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 (FQPA) became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in a tolerance is necessary, that tolerance too will be reassessed in the future pursuant tot eh requirements of FQPA.

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 Jean Holmes at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Margery Exton at (703) 308-8024.

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 Hgwy.
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

CHLORPROPHAM

LIST A

CASE 0271

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

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CHLORPROPHAM REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Ghulam Ali	Economic Analysis Branch
Steve Jarboe	Biological Analysis Branch
James Saulmon	Biological Analysis Branch

Environmental Fate and Effects Division

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Kathy Monk	Science Analysis and Coordination Staff
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Dave Anderson	Toxicology Branch I
Mary Clock	Risk Characterization and Analysis Branch
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Laura Morris	Occupational and Residential Exposure Branch
Karen Whitby	Risk Characterization and Analysis Branch
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Registration Division

Clarence Lewis	Fungicide-Herbicide Branch

Special Review and Reregistration Division

Judy Coombs	Reregistration Branch
Margery Exton	Reregistration Branch
Walter Waldrop	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
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

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
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
RUP	Restricted Use Pesticide
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.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

This Reregistration Eligibility Document (RED) addresses the eligibility for reregistration of pesticide products containing the active ingredient chlorpropham (isopropyl *m*-chlorocarbanilate).

BACKGROUND

Chlorpropham was registered in the United States in 1962 as a pre-emergence and post-emergence herbicide and as a plant growth regulator. It was originally registered for use on a variety of terrestrial food crops, nonfood crops, and ornamentals to control broadleaf weeds and grasses, and sprouting in stored potatoes. The Agency published an evaluation of existing data and identified data gaps in the December, 1987 Guidance for the Reregistration of Pesticide Products Containing Chlorpropham as the Active Ingredient (NTIS #PB88-169917). The 1987 guidance document (referred to as "Registration Standard") required additional data in the areas of product chemistry, residue chemistry, toxicology, ecological effects, and environmental fate. By 1990, the primary registrants had dropped all nationwide uses of chlorpropham except for sprout control on post-harvest stored potatoes. However, an additional 11 registrations for use within a particular county or state [registered under FIFRA Section 24(c)] remain today for use on spinach, Easter lilies, and ginkgo trees.

A Data Call-In (DCI) was issued in 1994 for chlorpropham requiring an analytical method to detect a metabolite of chlorpropham, 4-hydroxychlorpropham-O-sulfonic acid, and a residue study to test for that metabolite in meat and milk. The Agency is considering these data confirmatory to the decisions in this reregistration document.

REREGISTRATION ELIGIBILITY

The Agency has determined that the nationwide uses of chlorpropham on stored potatoes to inhibit sprouting as currently registered will not cause unreasonable risk to humans or the environment and this use is eligible for reregistration. However, there are four registrations first registered under Section 24(c) of FIFRA in the states of North Dakota, Oregon, and Washington that have an application rate that is not supported by field residue data. These products are eligible for reregistration, provided registrants of these products reduce their label application rates or submit additional field residue data to the Agency that support these higher rates.

In addition, there are currently seven chlorpropham registrations first registered under Section 24(c) of FIFRA restricted to particular states or counties for use on spinach, Easter lilies, and ginkgo trees. There are insufficient data to make a reregistration eligibility decision on these outdoor uses of chlorpropham. The Agency is requiring additional studies in the areas of residue chemistry, ecological effects, and environmental fate to maintain these uses.

There are sufficient data available to support the existing interim tolerance on spinach while new data are generated.

HEALTH EFFECTS

The chlorpropham Reference Dose (RfD) of 0.05 mg/kg bwt/day established by the Agency for a chronic dietary exposure risk assessment was based on the no effect level of 5 mg/kg bwt/day from a chronic feeding study with dogs. Dietary exposure to chlorpropham can be through either of it's two food uses - spinach or potatoes. The contribution to chronic dietary risk from spinach is negligible. The estimate for chronic dietary risk is driven by the primary use of chlorpropham on stored potatoes.

The current chlorpropham tolerance on stored potatoes is 50 ppm. The existing field data support a tolerance of 30 ppm. When risk was estimated based on tolerance level residues of 50 ppm, the RfD was exceeded for children 1 - 6 years of age. However, when risk was estimated assuming that 60% of all potatoes have chlorpropham residues at the revised tolerance value of 30 ppm , RfDs were not exceeded for any subgroup of the population. Estimated risk would be substantially lower if field residues were used rather than tolerance values.

Although chlorpropham is classified as a group E chemical (evidence of non-carcinogenicity for humans) according to the Agency's cancer classification guidelines, one of its metabolites, 3-chloroaniline, is structurally similar to a known carcinogen, 4-chloroaniline. There are no cancer data available on 3-chloroaniline. However, the Agency believes it is appropriate to use the cancer potency (Q_1^*) from 4-chloroaniline to gauge any potential risk from 3-chloroaniline. Based on the structure of the compounds, the Agency believes that 3-chloroaniline is probably, at most, equally as potent and not likely to be more potent than 4-chloroaniline.

Two risk scenarios were used in the dietary cancer risk assessment. One scenario would be more typical of the nationwide risk to chlorpropham as this chemical is currently used. This scenario assumes that the average public is exposed to 3-chloroaniline solely through residues on stored potatoes.

The second scenario, termed the "local milkshed" scenario, describes what could be a higher exposure in rural communities where cattle are fed potato peelings. This scenario assumes that residues of 3-chloroaniline would be present in beef liver based on a cattle diet of 75% treated potato waste and in milk at half the limit of detection. It further assumes that these food commodities are distributed locally.

The cancer risk assessment from the typical nationwide scenario resulted in a risk estimate of 3×10^{-6}. The resulting risk estimate from the local milkshed assessment was 4×10^{-6}. Both of these risk estimates exceed the 1×10^{-6} estimate of individual excess lifetime

cancer risk generally considered to be negligible. However, for the reasons noted below, the Agency believes these numbers may likely represent an overestimation of risk. (If new chlorpropham food uses are registered in the future which would increase the dietary exposure to 3-chloroaniline, the Agency may require additional data regarding the toxicity of 3-chloroaniline.)

- A study by Amdur *et al* (1991) showed that the substitution of aromatic amines such as aniline with an electron donating adduct such as chlorine in either the ortho (1) or para (4) position (e.g. 4-chloroaniline) relative to the amino group resulted in greater potency than observed for the parent compound, whereas substitution in the meta (3) position (e.g. 3-chloroaniline) was not likely to cause increased potency. Therefore, 3-chloroaniline would not be expected to be more potent than 4-chloroaniline.

- Rat metabolism studies detected 3-chloroaniline but no 4-chloroaniline.

- An oncogenicity study of chlorpropham in rats did produce an increase in testicular Leydig cell adenomas. These benign tumors were only observed at one excessive dose level (higher than he maximum tolerated dose). Yet none of the tumor types which have been observed in 4-chloroaniline data were present in the chlorpropham studies (i.e, the 3-chloroaniline that was present in the test was not observed having a similar mode-of-action effect).

The cancer dietary risk from spinach is likely to be small compared to potatoes because of its lower consumption and lower residues. However, if the spinach use is maintained, plant metabolism and possibly field residue studies analyzing for 3-chloroaniline may be required.

OCCUPATIONAL AND RESIDENTIAL EXPOSURE

Chlorpropham is not currently registered for residential use. Consequently, margins of Exposure (MOEs), a ratio of the estimated exposure level to the no observed effect level (NOEL) of 500 mg/kg/day from a 21-day dermal study, were only calculated for chlorpropham occupational handlers in high exposure potential scenarios. The resulting MOEs indicated only minimal concerns for occupational exposure to chlorpropham.

Minimum personal protective equipment for all occupational handlers is chemical resistant gloves. A restricted-entry interval of 12 hours has been established for the two uses (Easter lilies and spinach) which are within the scope of the Worker Protection Standard (WPS). Personal protective equipment required for persons who must enter areas that remain under a restricted-entry interval includes coveralls, chemical-resistant gloves, shoes, and socks. The Agency is requiring a respirator as PPE during application and ventilation of stored potatoes when chlorpropham is applied as an aerosol or through forced-air distribution.

The Agency is also establishing the following entry restriction for uses of chlorpropham on stored potatoes when it has been applied as an aerosol or through forced-air distribution:

> Do not enter or allow any person, other than a person equipped with the appropriate handler personal protective equipment including a respirator, to enter the treated area until the area has been ventilated for either a total of two (2) hours with fans or other mechanical ventilation or four (4) hours with windows, vents, or other passive ventilation or until such time as 10 complete air exchanges have occurred. The ventilation time may be interrupted, i.e., the time may be accumulated at sporadic intervals, such as 15 minutes of ventilation followed by a period with no ventilation, until the total required ventilation time has accumulated.

Chlorpropham products which are labeled for application to potatoes on a conveyor belt must contain the following statement:

> Following application, workers (e.g. baggers) must wear chemical-resistant gloves while potatoes are wet.

ENVIRONMENTAL FATE AND ECOLOGICAL EFFECTS

All data requirements for the indoor use of chlorpropham have been fulfilled. It was not necessary to perform a risk assessment for ecological effects for the indoor use of chlorpropham.

The three outdoor uses of chlorpropham (spinach, Easter lilies, and ginkgo trees) were registered as Special Local Needs under FIFRA Section 24(c) and are not being supported by the primary registrants of technical chlorpropham. In order to maintain these registrations, environmental fate and ecological effects data will have to be submitted.

TOLERANCE REASSESSMENT

Currently, there are raw agricultural tolerances for chlorpropham on post-harvest potatoes and soybeans listed under 40 CFR §180.181. There are also interim tolerances on multiple crops listed under 40 CFR §180.319. The Agency has reassessed the tolerance on post-harvest potatoes and determined that the tolerance value should be lowered from 50 ppm to 30 ppm.

The tolerance on soybeans and many of the interim tolerances will be proposed for revocation because their use sites are no longer supported by any registrant of chlorpropham. It should be noted that revoking these tolerances may impact the importation into the United States of corresponding food items bearing chlorpropham residues. Any interested party who

wishes to maintain a chlorpropham residue tolerance for importation purposes in the absence of a registered use should contact the Agency. In general, the Agency requires the same product chemistry and toxicology data to support an import tolerance as are required to support FIFRA registrations. The Agency also requires residue chemistry data representative of growing conditions in the exporting countries.

PRODUCT REREGISTRATION

Before reregistering the products containing chlorpropham, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSFs), and revised labeling to 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 may the Agency 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 chlorpropham. The document consists of six sections. Section I is the introduction. Section II describes chlorpropham, 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 chlorpropham. Section V discusses the reregistration requirements for chlorpropham. 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:** Chlorpropham
- **Chemical Name:** Isopropyl *m*-chlorocarbanilate, or CIPC
- **Chemical Family:** Carbamate
- **CAS Registry Number:** 101-21-3
- **OPP Chemical Code:** 018301
- **Empirical Formula:** $C_{10}H_{12}ClNO_2$
- **Molecular Weight:** 213.7
- **Trade and Other Names:** Spud Nic, Sprout Nip, Pin Nip, and Decco
- **Basic Manufacturer:** Aceto Agricultural Chemicals Corporation, Elf Atochem North America, Inc, and Pin Nip, Inc.

B. Use Profile

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

For Chlorpropham:

Type of Pesticide: Herbicide and plant growth regulator

Use Sites: Stored potatoes (indoor), spinach, Easter lilies, ginkgo trees

Target Pests: mouseear chickweed; used also in an integrated pest management method to decrease the incidence of Botrytis infection (a fungal disease) in Easter lilies.

Plant Regulator Uses: Inhibits sprouting in stored potatoes and controls fruiting in ginkgo trees.

Formulation Types Registered: 99% and 98% technical grade active ingredient; 36%, 46.5%, and 25% ai emulsifiable concentrate; 46% ai soluble concentrate; 49.65%, 78.5%, 78.6% and 78.41% ai ready-to-use.

Method and Rates of Application:

Equipment - sprayer, low pressure ground, aerosol generator, foaming apparatus, boom sprayer, and mist blower

Method and Rate - The maximum rates of application per commodity are:
Potato white/Irish: 0.0033 lbs a.i./cwt
Spinach: 1.001 lbs a.i./Acre
Easter lilies: 3.99 lbs a.i./Acre
Ginkgo trees: This rate has not been calculated. The label states to saturate the tree "to the point of runoff."
Apply as spray, low volume spray (concentrate), high volume spray (dilute), stored commodity fumigation, and stored commodity non-fumigation.

Timing - dormant, post-harvest, pre-bloom, and foliar

Use Practice Limitations:

- NPDES restrictions apply.
- There is a 30 day pre-harvest interval for spinach.
- Do not use on seed potatoes.
- Do not apply through any type of irrigation equipment.
- Proper ventilation required.

C. Data Requirements

Data requested in the 1987 Registration Standard for chlorpropham include studies on product chemistry, residue chemistry, toxicology, ecological effects, and environmental fate. These data were required to support the uses listed in the Registration Standard. Data requirements which are necessary to support reregistration for currently registered uses have been identified by the Agency and are listed in Appendix B.

D. Regulatory History

Chlorpropham was registered in the United States in 1962 as a pre-emergence and post-emergence herbicide and as a plant growth regulator. It was originally registered for use on a variety of terrestrial food crops, nonfood crops, and ornamentals to control broadleaf weeds and grasses, and sprouting in stored potatoes. The Agency published an evaluation of existing data and identified data gaps in the December, 1987 Guidance for the Reregistration of Pesticide Products Containing Chlorpropham (NTIS #PB88-169917). The 1987 guidance document (referred to as "Registration Standard") required additional data in the areas of product chemistry, residue chemistry, toxicology, ecological effects, and environmental fate. By 1990, the primary registrants had dropped all nationwide uses of chlorpropham except for sprout control on post-harvest stored potatoes. However, an additional 11 registrations for use within a particular county or state (registered under FIFRA 24(c)) remain today for use on spinach, Easter lilies, and ginkgo trees. Chlorpropham is used as an herbicide to control mouseear chickweed in spinach and in an integrated pest management method to decrease Botrytis infection on Easter lilies. As a plant growth regulator, chlorpropham is used to inhibit sprouting in stored potatoes and control fruiting in ginkgo trees.

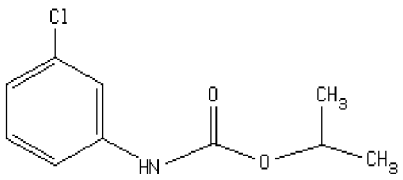
A Data Call-In (DCI) was issued in 1994 for chlorpropham requiring an analytical method to detect a metabolite of chlorpropham, 4-hydroxychlorpropham-O-sulfonic acid, and a residue study to test for that metabolite in meat and milk. These data are not due to the Agency until October, 1995. The Agency is considering these data confirmatory to the decisions in this reregistration document. Should a change in the Agency's regulatory position be warranted by the incoming data, a Federal Register Notice would be issued. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Description of Chemical

The molecular structure of chlorpropham is shown below:



Technical chlorpropham is an off-white to light brown solid with a melting point of 38-40 C. The solubility of chlorpropham in water at 25 C is 89 ppm. Chlorpropham is also soluble in ethyl and isopropyl alcohols, ketones, and aromatic solvents.

2. Manufacturing-use Products

- Two manufacturing use products registered to Aceto Agricultural Chemical Corporation (EPA Reg. Nos. 2749-102 and 2749-117).
- One manufacturing use product registered to Elf Atochem North American, Inc. (EPA Reg. No. 2792-67).
- One manufacturing use product registered to Pin Nip, Inc. (EPA Reg. No. 65726-2).

B. Human Health Assessment

1. Toxicology Assessment

a. Acute Toxicity

Table 1 summarizes acute toxicity results and categories for chlorpropham.

Table 1: Acute Toxicity Results and Categories for Chlorpropham

Test	Result	Category	MRID
Acute Oral LD_{50} (rat)	4 g/kg	III	41013703 41763601
Acute Dermal LD_{50} (rabbit)	> 5 g/kg	IV	41013704
Acute Inhalation LC_{50}	Requirement waived[1]	N/A	
Eye Irritation (rabbit)[2]	Mild Irritant	III	41013705 41763301
Dermal Irritation (rabbit)[2]	Mild Irritant	IV	41013706 41763501
Skin Sensitization (guinea pig)[2]	Negative	N/A	41013707 41763401

1 The requirement for an acute inhalation study was waived (memos dated 11/9/88 and 11/26/90). Chlorpropham technical cannot be prepared and tested in a respirable form.
2 This study is not required for the technical grade active ingredient.
N/A = not applicable

Chlorpropham displayed a low level of toxicity in acute tests. Studies using technical chlorpropham showed an oral LD_{50} of 4 g/kg in rats (Category III Toxicity) and a dermal LD_{50} in excess of 5 g/kg in rabbits (Category IV Toxicity). The data requirement for an inhalation study in rats was waived. (Technical chlorpropham cannot be prepared and tested in a respirable form.) Chlorpropham produced mild eye and dermal irritation in rabbits (Category III and IV Toxicity, respectively). Chlorpropham was negative in a study for dermal sensitization in guinea pigs.

b. Subchronic Toxicity

A 21-day dermal study was conducted with male and female New Zealand white rabbits. Chlorpropham was applied to intact skin at dose levels of 0, 100, 500, or 1000 mg/kg/day for 6 hours/day, 7 days/week. On three occasions some animals were exposed for 24 hours. All dose levels produced dermal irritation consisting of erythema, edema, cracking, and scaling. Histopathological findings in the skin included minimal acanthosis, hyperkeratosis, and focal inflammatory cells. The only systemic effect was a dose-related increase in reticulocytes in blood of both sexes that was significant at the highest dose of 1000 mg/kg/day. Hematology revealed no other indications of anemia. An increase in spleen weight (relative to brain weight) at the high dose was possibly related to the increase in reticulocytes. The effect on reticulocyte count was consistent with hematological findings of erythrocyte destruction/loss in longer-term studies. The NOEL for dermal effects was less than the lowest dose of 100 mg/kg/day, and the LOEL was 100 mg/kg/day. The NOEL for systemic toxicity was 500 mg/kg/day, and the LOEL was 1000 mg/kg/day based on the increase in reticulocyte count (MRID 41899901).

A 90-day feeding study with rats and a 28-day dog study were supplementary. The subchronic feeding study requirements are satisfied by the two-year rat and 60-week dog studies.

c. Chronic Toxicity

A 60-week study was conducted with male and female beagle dogs. Chlorpropham was orally administered in the diet at dose levels of 0, 5, 50, 350, or 500 mg/kg/day. The diets containing 350 or 500 mg/kg/day were unpalatable, causing marked reductions in food consumption and body weight gain during the initial weeks of the study.

Food consumption returned to normal by the dogs adapting to the diet or manipulation of the test material concentration; however, body weight gain of the 350 and 500 mg/kg/day dose groups remained depressed throughout the study. Anemia was evident at the two highest dose levels. Erythrocyte count, hemoglobin, and hematocrit were reduced, and mean corpuscular volume (MCV) was increased. Changes in thyroid function and morphology were prominent effects of treatment. Doses of 50 mg/kg/day and above resulted in increased thyroid weight with associated histopathological changes. The thyroid showed moderate to marked changes characterized by irregular shaped follicles lined by medium to high cuboidal epithelium; follicles contained clear to pale stained colloid. Serum T_3 and T_4 levels were reduced at 350 and 500 mg/kg/day. Thyroid response to TSH was depressed at these dose levels. Cholesterol was increased at 350 and 500 mg/kg/day. The NOEL was 5 mg/kg/day. The LOEL was 50 mg/kg/day based on evidence of thyroid effects at this dose level (MRID 42189501).

In a two-year chronic toxicity/carcinogenicity study, male and female Sprague-Dawley rats were fed diets at dose levels of 0, 30, 100, 500, or 1000 mg/kg/day of chlorpropham. Survival was not adversely affected by treatment. In fact, survival showed a dose-related increase with increasing dose. Body weight gain was reduced at the two highest dose levels. Indications of erythrocyte destruction or loss were evident at 100 mg/kg/day and higher. Erythrocyte count, hematocrit, and hemoglobin were decreased. Hematopoiesis in bone marrow and splenic hemosiderosis were increased. Additional compensatory changes or consequences of the anemia were observed at 500 mg/kg/day and above. The findings included increased reticulocyte count, increased hematopoiesis (liver, spleen, bone marrow), increased spleen weight, pigment accumulation in liver and kidney tubules, and presence of bilirubin in urine. At the two highest doses, blood was dark with a brown tint suggestive of methemoglobinemia (but unconfirmed). Morphological study of erythrocytes revealed crenated and polychromatic cells at the two highest dose levels. Crenated cells (associated with erythrocyte destruction) were most marked early in treatment whereas polychromatic cells (associated with compensation) were most marked later in the study. Cholesterol levels were increased at 500 and 1000 mg/kg/day. The NOEL was 30 mg/kg/day, and the LOEL was 100 mg/kg/day based on the hematological effects (MRID 42754701).

d. Carcinogenicity

In a two-year chronic toxicity/carcinogenicity study, male and female Sprague-Dawley rats were fed diets at dose levels of 0, 30, 100, 500, or 1000 mg/kg/day of chlorpropham. Survival showed a dose-related increase with increasing dose. Body weight gain was reduced at the two highest dose levels. Indications of hemolytic anemia were evident at 100 mg/kg/day and higher. The only neoplastic lesion related to treatment was benign testicular Leydig cell tumor. The incidence showed a dose-related trend and was significantly increased (pair-wise comparison) at the highest dose. The incidence of focal hyperplasia of Leydig cells showed a similar dose-response relationship (MRID 42754701).

An 18-month carcinogenicity study was conducted with male and female CD-1 mice. Chlorpropham was administered in the diet at dose levels of 0, 100, 500, or 1000 mg/kg/day of chlorpropham. Survival of males was reduced at the highest dose of 1000 mg/kg/day. Doses of 500 and 1000 mg/kg/day were associated with hematological and hematopoietic organ changes indicative of erythrocyte destruction or loss. Hematopoiesis (spleen, liver, bone marrow), hemosiderosis (spleen), and bone marrow cellularity were increased in severity and/or incidence at 500 and 1000 mg/kg/day. Dark eyes and a bluish tint of the skin in these animals were suggestive of methemoglobinemia (but unconfirmed). Related compensatory findings observed at the high dose only included elevated reticulocyte count, MCH, and MCHC and increased spleen and liver weights. No neoplastic lesions were related to treatment (MRID 42530301).

On July 20, 1994, the Agency classified chlorpropham in Group E (evidence of non-carcinogenicity for humans). The classification was supported by the following evidence: 1) a lack of carcinogenic potential demonstrated in mice and 2) the increase in benign Leydig cell tumors in rats occurred only at an excessive dose.

e. Developmental Toxicity

A developmental toxicity study was conducted with pregnant Sprague Dawley rats administered doses of 0, 100, 350, or 1000 mg/kg/day of chlorpropham by gavage on days 6 through 19 of gestation. Dams were sacrificed on day 20 of gestation. Doses of 350 and 1000 mg/kg/day were maternally toxic. Dams in these dose groups experienced clinical signs, reduced body weight gain, and enlarged

spleens. Clinical signs included salivation, urogenital staining, and red staining around the mouth, nares, and eyes. A single fetal effect was associated with the high dose group. These fetuses had an increased incidence of rudimentary 14th rib. No other litter or fetal effects were related to treatment. The NOEL for maternal toxicity was 100 mg/kg/day, and the LOEL was 350 mg/kg/day based on clinical signs and reduced weight gain. The developmental toxicity NOEL was 350 mg/kg/day, and the LOEL was 1000 mg/kg/day based on the increased incidence of 14th rib (MRID 00093921).

A developmental toxicity study was conducted with New Zealand white rabbits given doses of 0, 125, 250, or 500 mg/kg/day of chlorpropham by gavage on days 6 through 18 of gestation. Does were sacrificed on day 29 of gestation. The high dose of 500 mg/kg/day was maternally toxic producing clinical signs including cold ears, anorexia, reduced fecal output, and blood stained urine. The high dose affected litter size by increasing embryo resorptions and post-implantation loss. The NOEL was 250 mg/kg/day and the LOEL was 500 mg/kg/day for both maternal and developmental toxicity (MRID 00129940).

f. Reproductive Toxicity

A two-generation reproduction study was conducted with Sprague-Dawley-derived CD rats. Chlorpropham was administered in the diet at concentrations of 0, 1000, 3000, or 10,000 ppm. These levels were equivalent to 50, 150, and 500 mg/kg/day, respectively. Body weight gain by adults (F_0 and F_1) and lactating pups (F_1 and F_2) of both generations was depressed at 500 mg/kg/day. Growth was also depressed at 150 mg/kg/day in the F_1 generation post-weaning. Changes in spleen, bone marrow, and other organs were observed at 150 mg/kg/day and above in weanlings or adults of the F_1 generation. Spleens of weanlings had a dark red appearance grossly. In adults, spleen weight was increased and brown pigment granules were observed in reticuloendothelial cells of the spleen. Similar pigmentation was seen in liver Kupffer cells and kidney convoluted tubule epithelium. Bone marrow hyper cellularity was also observed in F_1 adults. These effects were consistent with findings of other studies showing hematotoxicity (i.e., erythrocyte loss or destruction). Reproductive indices were unaffected by treatment. A decrease in ovary weight was observed in F_1 (all doses) and F_2 (2 highest doses) weanlings but was unaccompanied by gross or microscopic changes. The ovary was normal in F_1 adults. The NOEL for systemic toxicity was 50 mg/kg/day, and the LOEL was 150 mg/kg/day based on effects

on growth and histopathological changes in the spleen, bone marrow, liver and kidney. The NOEL for reproductive toxicity was the highest dose tested, 500 mg/kg/day (MRID 00129545).

g. Mutagenicity

A gene mutation assay in mammalian cells was conducted using the L5178Y (TK+/-) mouse lymphoma cell line. Complete toxicity occurred at chlorpropham concentrations of 1000 µg/ml and greater with or without metabolic activation (PCB-induced rat liver S9). Concentrations of 13 to 75 µg/ml were tested without metabolic activation; growth was 41 to 100% of control cultures. Concentrations of 13 to 100 µg/ml were tested with metabolic activation; growth was 8 to 52% of control cultures. Chlorpropham had no effect on mutation frequency with or without metabolic activation (MRID 00129938).

Chlorpropham was tested for cytogenetic effects in vitro using Chinese hamster ovary cells. Metaphase cells were collected 10 and 20 hours after treatment. Concentrations of 149 µg/ml and higher were cytotoxic. Concentrations tested ranged from 10 to 160 µg/ml with or without metabolic activation (PCB-induced rat liver S9). Chlorpropham was presumptively positive with metabolic activation at moderately toxic doses (120, 140 µg/ml). Chlorpropham was negative without metabolic activation, but this portion of the assay was incompletely performed (i.e., single trial; no 10-hr evaluation) (MRID 41846701).

Chlorpropham was tested in an in vitro transformation assay using Syrian hamster embryo cells. Six concentrations of chlorpropham (5-30 µg/ml) were tested in a continuous (7-day) exposure regimen. Five concentrations (85-115 µg/ml) were tested for 24 hours, which included a 7-day refeeding regimen. Chlorpropham was positive for producing morphological transformations. Both the continuous exposure and the 24-hour exposure resulted in a significant increase in the frequency of transformations (MRID 41845501).

Two potential metabolites of chlorpropham were evaluated in the Salmonella typhimurium mutation assay using tester strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538. The compounds tested were isopropyl 5-chloro-2-hydroxycarbanilate and isopropyl 3-chloro-4-hydroxycarbanilate. Both tested negative with and without metabolic activation (PCB-induced rat liver S9) in all strains (MRID 00126733 and 00126734).

h. Metabolism

The pharmacokinetics of chlorpropham was evaluated in male and female Sprague-Dawley rats following a single intravenous dose (0.5 mg/kg), single oral low dose (5 mg/kg), single oral high dose (200 mg/kg), or repeated oral low doses (5 mg/kg/day for 15 days). With all dosing regimens, chlorpropham was rapidly absorbed and essentially completely metabolized prior to excretion in urine with small amounts in feces. Within 24 hours 82-92% of the radiolabel was recovered in the urine and 3-5 % in the feces. Peak excretion at the low dose occurred at 4-12 hours (49-62% of the dose) and at the high dose between 8-24 hours (59-64% of the dose). Less than 0.3% of doses were recovered at C^{14}-CO_2 over a three day period. The approximate half-life of chlorpropham was 8 hours at the low dose and 9 hours at the high dose in males and females. Three major metabolic routes were proposed: (1) hydroxylation at the 4'-position and conjugation, (2) oxidation of the isopropyl side chain to form isopropanol and isopropinate moieties; (3) decarbamilation to form 3-chloroaniline followed by N-acetylation, 4'-hydroxylation, and conjugation (MRID 42006901).

i. Other Toxic Endpoints: Neurotoxicity

Chlorpropham was tested for acute delayed neurotoxicity. Adult domestic hens were given 0, 1250, 2500, or 5000 mg/kg as a single oral dose. The LD_{50} was shown to be greater than 5000 mg/kg in a preliminary study. TOCP was the positive control. Chlorpropham did not show any potential for producing delayed neurotoxicity. No mortality, clinical signs, or histopathology was associated with any dose level. The study was a limit test using the maximum dose (5000 mg/kg) required in testing for acute delayed neurotoxicity (MRID 00093915).

j. World Health Organization Review

Chlorpropham was evaluated at the Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide Residues (JMPR) in 1963 and 1965, but no Acceptable Daily Intake (ADI) was allocated. The toxicology and residue chemistry of chlorpropham is scheduled to be evaluated by the JMPR in September of 1995. An ADI may be set as a consequence of this evaluation.

k. Reference Dose (RfD) for Chronic Oral Exposure

The Agency established 0.05 mg/kg/day as the RfD for chlorpropham, based on the results of a one-year feeding study in dogs (MRID 42189501). The NOEL from the dog study was 5 mg/kg/day and an uncertainty factor of 100 was used to derive the RfD for chlorpropham.

2. Exposure Assessment

a. Dietary Exposure

The summaries of residue chemistry data listed below are based on the post-harvest application use on stored potatoes. Additional data will be required if the spinach use is maintained.

Plant Metabolism: The qualitative nature of the residue in stored potato treated post-harvest is adequately understood. The parent chlorpropham was found to be the major residue, representing 96% of the total radioactive residues (TRR), in potato stored for 52 weeks following treatment with [^{14}C]chlorpropham at 2.4x the maximum registered rate. Although this indicates that little metabolism of chlorpropham occurs in stored potato, some metabolites of chlorpropham were detected (each at <1.3% of TRR), indicating that chlorpropham may metabolize through hydroxylation of the aniline ring or the isopropyl side chain, with subsequent conjugation with carbohydrates or amino acids. Decarbanilation also occurs, forming 3-chloroaniline. The regulated metabolite (1-hydroxy-2-propyl-3-chlorocarbanilate) was not detected, but an oligosaccharide conjugate of this metabolite was detected at 0.03% TRR. The 3-chloroaniline metabolite and its glucose conjugate were also identified at a combined level of 0.58% TRR.

The Agency has determined that the metabolite 1-hydroxy-2-propyl-3-chlorocarbanilate does not need to be included in the tolerance expression for potato. The Agency also judged that the tolerance expression in potatoes should *not* include the 3-chloroaniline compound, but that a risk assessment for this metabolite should be included in the RED document. This risk assessment should be performed using anticipated residues of 3-chloroaniline along with the Q* associated with 4-chloroaniline. The Agency recognized that this latter assumption may overestimate the risk associated with 3-chloroaniline, but believed that no reliable information exists at this time to refute or provide a more reasonable assumption.

In order to maintain the spinach use, a plant metabolism study is required.

Animal Metabolism: The qualitative nature of the residue in poultry is adequately understood for the purposes of the limited use of chlorpropham. The qualitative nature of the residue in ruminants is adequately understood.

The metabolism of chlorpropham in ruminants and poultry is proposed to proceed through oxidation to 4-hydroxychlorpropham or degradation to 3-chloroaniline. The hydroxychlorpropham is then further metabolized to 4-hydroxychlorpropham-O-sulfonic acid or 4-hydroxychlorpropham-O-glucuronide and the aniline is further metabolized to 3-chloro-4-hydroxyaniline-O-sulfonic acid. The 3-chloroaniline metabolite was not detected in fat, kidney, or milk, but was identified in beef liver at 11% TRR.

The Agency has determined that the residues to be regulated in animal commodities are chlorpropham and the metabolite 4-hydroxychlorpropham-O-sulfonic acid. The Agency has judged that, although 3-chloroaniline will *not* be included in the tolerance expression, the dietary risk assessment would include the 3-chloroaniline metabolite.

Residue Analytical Methods-Plants and Animals: The Pesticide Analytical Manual (PAM) Vol. II lists several methods as available for the enforcement of chlorpropham tolerances in plant commodities and milk. The PAM Vol. I method for chlorinated pesticides is listed as Method I and an infrared (IR) method is listed as Method II. The limit of detection for Method II is 1 ppm. Methods A, B, and D are spectrophotometric methods involving conversion of chlorpropham to 3-chloroaniline. PAM notes that propham, monuron, diuron, linuron, and any other compound forming a volatile aniline on hydrolysis will also be determined in these procedures. Method C is a gas chromatographic method with electron capture detection and involves conversion of chlorpropham to bromochloroaniline. Method E is a thin layer chromatography (TLC) method and Method F is similar to Method II.

Data collection and enforcement methodology should include hydrolysis steps in order to detect free and conjugated side-chain modified metabolites, such as 1-hydroxy-2-propyl-3-chlorocarbanilate and 3-chloroaniline. A gas chromatographic method with nitrogen-

phosphorus detection has been submitted for the determination of chlorpropham and 3-chloroaniline in potato commodities. The limits of detection are estimated to range from 0.05 to 0.08 ppm for potato, potato pulp, potato peel, and processed wet peel; from 0.05 to 0.38 ppm for granules and dried potato peel; and from 0.05 to 0.45 ppm for potato chips. The registrant has submitted an acceptable laboratory validation of this method on potatoes. EPA's Beltsville laboratory has performed an acceptable tolerance method validation (TMV) and the Agency is awaiting minor changes in the method protocol description from the registrant. A method for spinach is required.

An enforcement analytical method capable of adequately detecting the residues of concern (chlorpropham and the metabolite 4-hydroxychlorpropham-O-sulfonic acid) in animal commodities must be developed and validated using radiolabeled samples from the goat metabolism study.

The FDA PESTDATA database of 8/93 (PAM Vol. I, Appendix II) indicates that chlorpropham is completely recovered (>80%) using FDA multi-residue method protocols D (Section 232.4) and E (Section 212.1/232.1, nonfatty matrices and Section 211.1/232.1, fatty matrices).

Storage Stability: All data requirements pertaining to chlorpropham storage stability *per se* have been evaluated and deemed adequate. Residues of chlorpropham *per se* are stable during frozen storage at -4C in potato and wet potato peel for at least 13 months, in potato chips for at least 8 months, in potato granules for at least 9 months, and in processed dry peels for at least 12 months. Data on spinach will be required if the use is supported.

No storage stability data are available for animal commodities. A data requirement for a ruminant feeding study remains outstanding. Unless tissue and milk samples from the feeding study are analyzed within two weeks of sample collection, storage stability data for residues of chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid in animal commodities will be required.

Magnitude of the Residue in Plants: All data requirements pertaining to the magnitude of chlorpropham residue in stored potato have been evaluated and deemed adequate.

Data pertaining to 3-chloroaniline residues in potato have also been submitted. However, the Agency has determined that the tolerance

expression will consist of chlorpropham only, and *not* the 3-chloroaniline metabolite. Instead, the magnitude of the 3-chloroaniline residue in potatoes will be incorporated into the risk assessment: adequate magnitude of the 3-chloroaniline residue data for a risk assessment have been submitted.

Adequate magnitude of the residue data are available to support the interim tolerance on spinach. However, if the spinach use is to be supported, an FFDCA Sect. 408 tolerance would need to be established. Therefore, residue data on spinach, including a decline study, are needed.

Magnitude of the Residue in Processed Food/Feed: All data requirements pertaining to the magnitude of chlorpropham residue in processed potato commodities have been evaluated and deemed adequate.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs: A data requirement for a ruminant feeding study remains outstanding. Since potato commodities are not significant poultry feed items, a poultry feeding study is not required and tolerances for poultry commodities will not be necessary.

The maximum theoretical dietary burden of chlorpropham for ruminants is estimated to be 940 ppm (dry matter basis) based on a diet consisting of 75% processed potato waste consisting of 88.6% dry matter.

Confined/Field Rotational Crops: Rotational crop studies are not required to support use of chlorpropham on stored potato. Confined rotational crop data will be required to support the spinach use. Field rotational crop data may be necessary pending the results of the confined rotational crop data.

b. Dietary Exposure Assessment Summary

A dietary exposure assessment is needed for residues of chlorpropham and its 3-chloroaniline metabolite as a result of treatment of food and feed commodities with chlorpropham. Therefore, the Agency has estimated residues of both chlorpropham *per se* and the 3-chloroaniline metabolite which was detected in certain commodities during the plant and animal metabolism studies. These estimates are described in more detail below.

Exposure Assessment for Chlorpropham *per se*: The reassessed tolerances for chlorpropham in potato and processed potato commodities have been used to estimate dietary risk from chlorpropham and 3-chloroaniline. Reassessment of the tolerances associated with meat and milk products is not possible at this time since feeding studies with cattle ("Magnitude of the Residue in Ruminants") have not yet been performed by the registrant. When this information becomes available, the current tolerances associated with these commodities will be reassessed. Part IV of this document provides a summary of these reassessed tolerances as well as the current tolerances for those commodities for which adequate information is not available. This information was used by the Agency to estimate dietary risks associated with chlorpropham and 3-chloroaniline.

Exposure Assessment for 3-Chloroaniline: The Agency decided that the potential carcinogenic risk due to the 3-chloroaniline metabolite should be assessed. Since no data are available on the cancer potency of the 3-chloroaniline metabolite, this risk was calculated using the cancer potency factor (i.e., the Q_1^*) available for the 4-chloroaniline isomer. The Agency recognized that using the Q_1^* value for 4-chloroaniline in place of an actual Q_1^* for 3-chloroaniline may likely overestimate the risk associated with 3-chloroaniline.

The Agency developed anticipated residues for use in assessing the dietary risk of the 3-chloroaniline metabolite under two scenarios: a "typical" risk scenario which represents an estimate of exposure on a national basis and an upper bound estimate to represent consumers in a local milkshed. In each case, field trial studies and potato processing studies were reviewed to provide estimates of 3-chloroaniline concentrations following actual post-harvest fumigation of stored potatoes. To provide exposure estimates for populations residing in a local milkshed, metabolism study data were used along with certain assumptions regarding the percent of the potato crop which is treated and the livestock dietary burden. The major differences in the assumptions used in these two scenarios are highlighted in table 2.

Table 2: Exposure Scenarios for Cancer Risk Assessment

Risk Scenario	Beef and Milk
Local Milkshed Case	• Beef and dairy cow diet assumed to consist of 75% and 50% processed potato waste, respectively; 3-chloroaniline assumed to be present in milk at 1/2 the Limit of Detection
Typical Case	• Assumes that no exposure occurs through beef and milk.

The anticipated residues under the local milkshed and typical cases are presented in columns (1) and (2) of table 3, respectively. Anticipated residues in potatoes are assumed to be equivalent in both the typical and local milkshed scenario, whereas actual residues in meat and milk are assumed only in the milkshed scenario because distribution of processed potato waste for livestock feeding purposes will most likely occur on a local basis in the vicinity of the processing plant.

Table 3: Anticipated Residue Values for 3-Chloroaniline

Summary of Anticipated Residue Values for Dietary Risk Assessment Under Local Milkshed and Typical Case Exposure Scenarios for Use in DRES Analysis (Assumed 60% of Potatoes Treated)		
Food Name/Food Form	**3-Chloroaniline Anticipated Residue (ppm)**	
	(1) Local Milkshed Case Risk Scenario	**(2) Typical Case Risk Scenario**
Potatoes(White)--Whole Raw	0.059	0.059
Cooked -not further specified	0.059	0.059
Cooked-fresh baked	0.059	0.059
Potatoes(White)--Unspecified		
Cooked-fresh baked	0.059	0.059
Potatoes(White)--Peeled		
Cooked-not further specified	0.018[a]	0.018[a]
Cooked-fresh baked	0.018[a]	0.018[a]
Cooked-fresh boiled	0.018[a]	0.018[a]
Cooked-fresh fried	0.041	0.041[b]
Potatoes(White)--Dry		
Raw-fresh or not further specified	0.059	0.059
Cooked-fresh or canned	0.059	0.059

Summary of Anticipated Residue Values for Dietary Risk Assessment Under Local Milkshed and Typical Case Exposure Scenarios for Use in DRES Analysis (Assumed 60% of Potatoes Treated)		
Food Name/Food Form	**3-Chloroaniline Anticipated Residue (ppm)**	
	(1) Local Milkshed Case Risk Scenario	**(2) Typical Case Risk Scenario**
Potatoes(White)--Peel Only		
Cooked-fresh baked	0.958[c]	0.958[c]
Beef(Organ Meats)--Liver		
Cooked-fresh fried	0.039	--[e]
Cooked-fresh or canned	0.039	--[e]
Milk--Non-fat Solids		
Raw-fresh or not further specified	0.002[d]	--[e]
Cooked-not further specified	0.002[d]	--[e]
Cooked-canned	0.002[d]	--[e]
Milk--Fat Solids		
Raw-Fresh or not further specified	0.002[d]	--[e]
Cooked-not further specified	0.002[d]	--[e]
Cooked-canned	0.002[d]	--[e]
Milk Sugar(Lactose)		
Cooked-not further specified	0.002[d]	--[e]
Cooked-canned	0.002[d]	--[e]

[a] The registrant did not supply adequate magnitude of the residue data for concentrations of 3-chloroaniline in peeled potatoes. However, an article appearing in *Pesticide Science* demonstrates that approximately 70% of the radioactivity is present in the skin of the tuber (Coxon, DT and A Filmer, 1985, *Pesticide Science* 16:355-63). Thus, the ppm values shown here were calculated by assuming that 70% of the residues are present in 5% of the potato (which represents peel). The calculation also assumes that 60% of the potatoes are treated with chlorpropham.

[b] The registrant did not peel the potatoes prior to frying them and determining 3-chloroaniline concentrations. The Agency calculated the anticipated residues in fresh fried potatoes by assuming that (i) 70% of the residues are present in the peel; (ii) the peel represents 5% of the whole tuber weight; (iii) 95% of the fresh fried potatoes (french fries and potato chips) are peeled prior to processing. The calculation also assumes that 60% of the potatoes are treated with chlorpropham.

[c] This value is assumed to equal the value for processed dry peel.

[d] Although 3-chloroaniline was not detected in milk during the metabolism study, these local milkshed case assumptions are calculated using the one-half the Limit of Detection value.

[e] The concentrations are assumed to be zero, since under typical risk scenario animals are not assumed to consume potato waste.

c. Occupational and Residential

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

Acute Toxicity: Studies for acute toxicity indicate that chlorpropham is classified as category III for acute oral toxicity, category IV for acute dermal toxicity, category IV for skin irritation potential, and category III for eye irritation potential. It is not classified as a skin sensitizer. Inhalation toxicity data were waived because chlorpropham technical cannot be prepared and tested in a respirable form. Based on acute toxicity, the criteria for performing an exposure assessment are not met.

Short Term and Intermediate Toxicity: Short term toxicity is evaluated based on exposure to the test substance for 1 to 7 days. The Agency determined that the primary route of occupational exposure is dermal. The chlorpropham toxicology database does not include a short term study with a NOEL derived from dermal exposure. Neither does the database include a dermal absorption study.

Intermediate term toxicity is evaluated based on exposure to the test substance for 1 week to several months. The 21-day dermal study discussed previously regarding subchronic toxicity produced a NOEL value of 500 mg/kg/day (MRID 41899901). The effects in this study were increased reticulocytes and possibly an increase in spleen weight (relative to brain weight). The Agency decided that the intermediate toxicity is of concern and warranted assessing the potential for exposure to handlers or persons entering treated sites post-application. Therefore, this NOEL value was used in the occupational risk assessment.

Potential for Handler Exposure: The Agency has determined that there is potential exposure to mixers, loaders, applicators, or other handlers during usual use patterns associated with chlorpropham. The Agency is specifically concerned about potential exposures to workers who mix and load liquids and/or apply chlorpropham using low pressure sprayers (i.e. hand held sprayers and groundboom sprayers). Exposure data are not available for the indoor application of chlorpropham on potatoes (sprayed while the potatoes are on washer-rollers or through a forced-air

distribution method). In the indoor (potato) setting, workers wear full-face oxygen-supplied respirators since there is little oxygen in potato storage chambers during application (citation of information from registrant). Further, a closed-delivery system is employed for the forced-air distribution use. Due to the nature of the indoor use practices, worker exposure in the indoor (potato) setting is not expected to exceed that of workers involved in the outdoor crop treatment of Easter lilies or spinach.

Potential for Post-Application Exposure: The Agency has determined that there is potential exposure to persons entering treated sites after application is complete. The Agency has some concerns about both post-application dermal exposures in all use sites and post-application inhalation exposures following the forced-air distribution application at stored potato sites.

Handler Exposure Assessment: Because chlorpropham has intermediate toxicity concerns and the potential for exposure to handlers exists, an occupational exposure assessment for handlers (for outdoor uses) was performed. However, there are no data available to evaluate the potential exposure to handlers during the application of chlorpropham into indoor potato storage facilities.

Table 4 below presents the assumptions that were used in the occupational exposure assessment for handlers.

Table 4: Occupational Exposure Assessment for Handlers

Scenario	Dermal Exposure (mg/lb ai)	Max. Label Rate[a]	Daily Max. Treated	Daily Dermal Dose (mg/kg/day)[b]
Mixer/Loader				
Groundboom Mixer/Loader	0.2[c]	4 lb ai/A	80 acres	0.9
Applicator				
Groundboom	0.02[d]	4 lb ai/A	80 acres	0.09

Scenario	Dermal Exposure (mg/lb ai)	Max. Label Rate[a]	Daily Max. Treated	Daily Dermal Dose (mg/kg/day)[b]
Mixer/Loader/Applicator				
Low Pressure Handwand	52.0[e]	4 lb ai/A	1 acre	3.0

[a] Oregon state registration (OR 91001200) for Easter lilies.

[b] Daily Dermal Dose (mg/kg/day) =

$$\frac{\text{Exposure (mg/lb ai)} * \text{Max. Label Rate (lb ai/acre)} * \text{Max Treated (acres)}}{70 \text{ kg}}$$

[c] Dermal exposure is based on PHED clothing scenario for long pants, long-sleeved shirt, and no gloves. A 50 percent protection factor was applied to the no glove data for the use of chemical resistant gloves. It was assumed that 50% of the total dermal exposure was exposure to the hands [i.e., total dermal exposure = 0.3 mg/lb ai, hand exposure = 0.15 mg/lb ai (which becomes 0.075 mg/lb ai after the 50% reduction in dermal exposure due to gloves) and the remaining dermal exposure = 0.15 mg/lb ai). The PHED grades for this scenario are acceptable and the number of replicates per body part are 14+. High confidence in exposure data.

[d] Dermal exposure is based on PHED clothing scenario for long pants, long-sleeved shirt, and no gloves. A 50 percent protection factor was applied to the no glove data for the use of chemical resistant gloves. It was assumed that 50 percent of the total dermal exposure (0.02 mg/lb ai) was for the hand exposure. The PHED grades for this scenario are A, B, and C and the number of replicates per body part are 6+. Low to medium confidence in exposure.

[e] Dermal exposure is based on PHED clothing scenario for long pants, long-sleeved shirt, and no gloves. A 50 percent protection factor was applied to the no glove data for the use of chemical resistant gloves. A 50 percent protection factor was applied to the actual hand exposure data because 102 mg/lb ai of the 103 mg/lb ai total dermal exposure was for the non-protected hands. Low to medium confidence in exposure data.

Post-Application Exposures and Assumptions: Post-application exposure data were not required in the Guidance for the Reregistration of Pesticide Products Containing Chlorpropham issued in December, 1987. At that time, no toxicological criteria had been triggered for chlorpropham. A rough estimate of the exposure to post-application workers was made based on the exposure values available in the handler assessment. These rough estimates were used to assess the risk to workers posed by post-application exposure. However, there are no data available to evaluate the potential post-application exposures to chlorpropham following an application into indoor potato storage facilities, since technical chlorpropham cannot be formulated into a material that is respirable by laboratory animals.

3. Risk Assessment

a. Dietary

Acute Dietary Risk The endpoint selected for acute dietary risk assessment was based on the findings observed in a developmental toxicity study in the rabbit (MRID 00129940). The effects of concern were increased resorption and post implantation loss (LOEL 500 mg/kg). The NOEL was 250 mg/kg/day. The primary source of dietary exposure to chlorpropham is via potatoes (the tolerance for which is hereby being revised from 50 ppm to 30 ppm). No feed/food additive tolerances have been established. It is anticipated that acute dietary exposure will be significantly lower than 2.5 mg/kg/day, which is the exposure that would trigger a concern based on effects noted at the LOEL. The basis for this is the relatively high NOEL in conjunction with the fact that it is used on so few crops (i.e., potatoes at 30 ppm and spinach at 0.3 ppm). Therefore, an acute dietary risk assessment was not necessary.

Chronic Dietary Risk: The chronic dietary analysis used a Reference Dose (RfD) of 0.05 mg/kg bwt/day, based on an NOEL of 5 mg/kg bwt/day and an uncertainty factor of 100. The NOEL is taken from a chronic toxicity study in dogs (MRID 42189501) which demonstrated thyroid toxicity in males and females and other effects at 50 mg/kg bwt/day (RfD/Peer Review Report of Chlorpropham, 10/24/94).

USDA Pesticide Data Program Summary of 1992 Data (PDP data) show that chlorpropham residues are found on 60% of potatoes. Since all treated potatoes would be expected to have detectable concentrations (the limit of detection for the PDP data is less than or equal to 13 ppb), the Agency estimated that 60% of the potatoes are treated. This information was corroborated by information supplied by the National Potato Council.

Although the existing tolerance of chlorpropham on potatoes is 50 ppm, current data indicate that the tolerance should be reduced to 30 ppm and expressed in terms of chlorpropham *per se*. Therefore, the dietary risk from potatoes in this risk analysis was conducted assuming potato residues at both the 50 ppm and 30 ppm tolerance levels.

Three DRES chronic analyses for chlorpropham were conducted in order to estimate risk resulting from different potato residue values and interim tolerances. For each analysis, both Theoretical Maximum

Residue Contributions (TMRCs) and Anticipated Residue Contributions (ARCs) were calculated for the overall U.S. population and 22 population subgroups. The TMRCs assume that 100% of all crops are treated and have chlorpropham residues. The ARCs assume that only 60% of all potatoes are treated and have chlorpropham residues. The exposure estimates were then compared to the RfD for chlorpropham to calculate estimates of chronic dietary risk.

A comparison of Analysis I and II shows that the contribution to chronic dietary risk from spinach (which is only one of many existing interim tolerances) is negligible. The chronic dietary risk estimate is driven by the level of the potato residue. Since tolerance levels represent upper bound residue limits, the chronic dietary risk estimates would be lower if refined (average) residues were used in these calculations. However, the U.S. population and all DRES subgroups have exposures for chronic dietary risk below the RfD in the analysis assuming reassessed (30 ppm) tolerance level residues are on 60% of all potatoes (see table 10). Therefore, the development of more refined anticipated residues was not required. The three analyses are shown below.

ANALYSIS I

The TMRCs (table 5) and ARCs (table 6) for the overall U.S. population and children (1-6 years) were calculated in analysis I using a potato tolerance of 50 ppm and all current interim tolerances.

Table 5: Assuming tolerance level residues on 100% of crops.

Subgroup	Exposure(mg/kg/day)	% Reference Dose
U.S. population	0.058	116
Children (1-6)	0.115	231

Table 6: Assuming tolerance level residues on 60% of potatoes; 100% on all other crops.

Subgroup	Exposure(mg/kg/day)	% Reference Dose
U.S. population	0.035	70
Children (1-6)	0.070	141

ANALYSIS II

In analysis II, the TMRCs (table 7) and ARCs (table 8) for the overall U.S. population and children (1 - 6 years) were calculated based solely on the potato tolerance value of 50 ppm. (All existing interim tolerances were excluded.)

Table 7: Assuming tolerance level residues on 100% of potatoes.

Subgroup	Exposure(mg/kg/day)	% Reference Dose
U.S. population	0.057	115
Children (1-6)	0.114	229

Table 8: Assuming tolerance level residues on 60% of potatoes.

Subgroup	Exposure(mg/kg/day)	% Reference Dose
U.S. population	0.035	69
Children (1-6)	0.069	139

ANALYSIS III

The TMRCs (table 9) and ARCs (table 10) for the overall U.S. population and children (1-6 years) were calculated in analysis III based solely on a revised potato tolerance value of 30 ppm. (All existing interim tolerances were excluded.)

Table 9: Assuming revised tolerance level residues on 100% of potatoes.

Subgroup	Exposure(mg/kg/day)	% Reference Dose
U.S. population	0.035	69
Children (1-6)	0.069	139

Table 10: Assuming revised tolerance level residues on 60% of potatoes.

Subgroup	Exposure(mg/kg/day)	% Reference Dose
U.S. population	0.021	42
Children (1-6)	0.042	85

Dietary Cancer Risk: No data are currently available on the cancer potency of the 3-chloroaniline metabolite. Therefore, the dietary cancer risk for the 3-chloroaniline metabolite has been estimated using the cancer potency factor (Q^*_1) of 6.38×10^{-2} $(mg/kg/day)^{-1}$ for the 4-chloroaniline or para-chloroaniline isomer.

Anticipated residues for the 3-chloroaniline used in this risk assessment are listed in table 3 of this document. Since average residues are usually considered appropriate for carcinogenic risk estimates and the term "local milkshed" applies primarily to local use of livestock feed, the upper bound anticipated residues provided for potatoes marketed for human food were not used in estimating carcinogenic risk from 3-chloroaniline.

Two risk scenarios were developed in the dietary cancer risk assessment. One scenario would be more typical of a nationwide risk to chlorpropham as this chemical is currently used. This scenario used anticipated residues for potatoes (0.059 ppm) and assumed no residues in meat and milk commodities. It is assumed in this scenario that no significant quantities of processed potato waste having chlorpropham residues are fed to cattle. The upper bound carcinogenic risk from this scenario is 3×10^{-6}.

The second scenario, termed the "local milkshed" scenario, used anticipated residues for potatoes (0.059 ppm), a limit of detection residue for milk of 0.002 ppm and a residue of 0.039 for beef liver. This scenario assumes that processed potato waste is fed locally to livestock and that food commodities derived from these livestock are distributed locally. The upper bound carcinogenic risk from this scenario is 4×10^{-6}.

Characterization of Dietary Cancer Risk: The estimated dietary cancer risk as described above, exceeds the 1×10^{-6} estimate of individual excess lifetime cancer risk generally considered to be negligible. However, the Agency believes the risk may be overestimated. The

Agency evaluated the weight-of-the-evidence for the carcinogenic potential of chlorpropham and concluded that chlorpropham should be classified as Group E. Nonetheless, due to the structure activity relationship of the chlorpropham metabolite, 3-chloroaniline, to 4-chloroaniline (which has a cancer potency factor Q_1*), the Agency expressed concern for potential carcinogenicity of 3-chloroaniline. Therefore, the 4-chloroaniline Q_1* was used as a surrogate for 3-chloroaniline to gauge any potential risk from 3-chloroaniline.

Substitution of aromatic amines such as aniline with an electron donating adduct such as chlorine in either the ortho (1) or para (4) position relative to the amino group has been shown to result in greater cancer potency than observed for the parent compound (Amdur *et al.,* 1991). Substitution in the meta (3) position is not likely to cause increased potency. There is no way to quantify how much less potent this metabolite may be. Therefore, the use of the Q_1* from a para (4) substituted aniline (4-chloroaniline) to estimate the cancer risk from a meta (3) substituted aniline (3-chloroaniline) was generally agreed by OPP toxicologists to potentially overestimate the risk. However, in the absence of a Q_1* for 3-chloroaniline, OPP used the best available cancer potency factor, i.e., the 4-chloroaniline Q_1*. Additional factors which are also believed to potentially contribute to overestimation of the dietary cancer risk include:

- While 3-chloroaniline was identified in the Sprague-Dawley rat as a metabolite of chlorpropham (MRID 42006901), 4-chloroaniline was not.

- There is a lack of target or site concordance between chlorpropham and 4-chloroaniline in carcinogenicity studies. The Agency concluded that chlorpropham should be classified as Group E (evidence of non-carcinogenicity for humans). This classification was supported by: 1) a lack of carcinogenic potential demonstrated in mice and 2) the increase in benign Leydig cell tumors in Sprague-Dawley rats which occurred only at a dose in excess of the maximum tolerated dose.

- The Q_1* for 4-chloroaniline was derived from a National Toxicology Program two-year carcinogenicity study in F344/N rats. In this study, 4-chloroaniline was administered by gavage at 0, 2, 6, or 18 mg/kg for 103 weeks. The Q_1* was based on spleen sarcoma incidences in male rats.

- Mutagenicity testing indicates that 3-chloroaniline and 4-chloroaniline are mutagenic in *in vitro* tests. These mutagenicity test have about a 50 to 70 percent correlation (depending on how the data are compared) with carcinogenicity studies in rats and/or mice. The 3-chloroaniline structure is less reactive than 4-chloroaniline because of the position of the chlorine on the benzene ring. Thus, 3-chloroaniline would be expected to be less carcinogenic. However, there is no adequate way to quantitate this structure activity relationship at this time.

Cancer dietary risk from spinach is considered to be insignificant because of the small dietary contribution from spinach and negligible residues.

b. Occupational and Residential

At this time, there are no products containing chlorpropham intended for residential use. Therefore, the Agency is not conducting a residential risk assessment.

Handler Risk: Margins of Exposure (MOEs), a ratio of the estimated exposure level to the NOEL of 500 mg/kg/day from a 21-day dermal study, were only calculated for occupational handlers in high exposure potential scenarios. The resulting MOEs are all greater than 100, indicating only minimal concerns. Table 11 provides the MOEs for mixer/loader and applicator exposure scenarios for outdoor uses.

Table 11: Margins of Exposure for Chlorpropham Handlers

Scenario	Dermal Exposure (mg/lb ai)	Max. Label Rate[a]	Daily Max. Treated	Daily Dermal Dose (mg/kg/day)[b]	MOE[c]
Mixer/Loader					
Groundboom Mixer/Loader	0.2[d]	4 lb ai/A	80 acres	0.9	556
Applicator					
Groundboom	0.02[e]	4 lb ai/A	80 acres	0.09	5,556

Scenario	Dermal Exposure (mg/lb ai)	Max. Label Rate[a]	Daily Max. Treated	Daily Dermal Dose (mg/kg/day)[b]	MOE[c]
Mixer/Loader/Applicator					
Low Pressure Handwand	52.0[f]	4 lb ai/A	1 acre	3.0	167

[a] Oregon state registration (OR 91001200) for Easter lilies.

[b] Daily Dermal Dose (mg/kg/day) =

$$\frac{\text{Exposure (mg/lb ai)} * \text{Max. Label Rate (lb ai/acre)} * \text{Max Treated (acres)}}{70 \text{ kg}}$$

[c] Intermediate MOE = NOEL (500 mg/kg/day)/Daily Dermal Dose (mg/kg/day).

[d] Dermal exposure is based on PHED clothing scenario for long pants, long-sleeved shirt, and no gloves. A 50 percent protection factor was applied to the no glove data for the use of chemical resistant gloves. It was assumed that 50 percent of the total dermal exposure was to the hands [i.e., total dermal exposure = 0.3 mg/lb ai, hand exposure = 0.15 mg/lb ai (which becomes 0.075 mg/lb ai after the 50% reduction in dermal exposure due to gloves) and the remaining dermal exposure = 0.15 mg/lb ai]. The PHED grades for this scenario are acceptable and the number of replicates per body part are 14+. There is a high confidence in this exposure data.

[e] Dermal exposure is based on PHED clothing scenario for long pants, long-sleeved shirt, and no gloves. A 50 percent protection factor was applied to the no glove data for the use of chemical resistant gloves. It was assumed that 50 percent of the total dermal exposure (0.02 mg/lb ai) was for the hand exposure. The PHED grades for this scenario are A, B, and C and the number of replicates per body part are 6+. There is low to medium confidence in this exposure data.

[f] Dermal exposure is based on PHED clothing scenario for long pants, long-sleeved shirt, and no gloves. A 50 percent protection factor was applied to the no glove data for the use of chemical resistant gloves. A 50 percent protection factor was applied to the actual hand exposure data because 102 mg/lb ai of the 103 mg/lb ai total dermal exposure was for the non-protected hands. The PHED grades are B, C, and E, and the number of replicates ranged from 25 to 95. There is low to medium confidence in this exposure data.

Risk from Post-Application Exposures: The Agency has determined that post-application exposures do not appear to pose an unreasonable risk to individuals entering treated areas, provided entry is not permitted immediately following application. Therefore, for all uses within the scope of the WPS (spinach and Easter lilies), a restricted-entry interval (REI) of 12 hours is required and personal protective equipment for workers who enter the treated area before the REI is expired.

The 12-hour post-application entry restriction for chlorpropham does not apply to uses outside the scope of the WPS for agricultural chemicals. The predicted degree of exposure by such uses do not warrant the same risk mitigation measures required for users covered by the WPS.

For forced-air distribution applications, the Agency is prohibiting entry until either a total of two hours of mechanical ventilation (fans, etc.) or four hours of passive ventilation (windows, vents, etc.) have occurred. The ventilation time may be interrupted, i.e., the time may be accumulated at sporadic intervals, such as 15 minutes of ventilation following by a period with no ventilation, until the total required ventilation time has accumulated. This entry prohibition is due to concerns about exposures to airborne aerosols composed of chlorpropham and inert ingredients in chlorpropham aerosol-generator formulations.

Additional Occupational Exposure Studies: Requirements for handler and post-application exposure studies are addressed in Subdivision U and K of the Pesticide Assessment Guidelines, respectively. The Agency's review of the complete toxicology data submitted to support reregistration indicates that additional exposure studies are not required at this time.

C. Environmental Assessment

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

The oral toxicity data acceptable for the indoor use are listed below:

Species	% ai	LD_{50} or LC_{50}	Fulfills Guideline
Mallard	99	> 2000 mg/kg	No

The study is classified as supplemental because data on dose levels tested, number of birds tested per level, and mortality/dosage were not reported. In addition, only females were tested. The data indicate that technical chlorpropham is practically nontoxic to waterfowl (No MRID number, Hudson et al. 1970, HCOSTA01).

The acceptable avian dietary toxicity study is listed below:

Species	% ai	LD_{50} or LC_{50}	Fulfills Guideline
Bobwhite	98	> 5620 ppm	Yes

This study indicates that chlorpropham is practically nontoxic to upland game birds on a subacute basis (MRID 42490401).

(2) Mammals

Acute Toxicity Testing with the TGAI produced an LD_{50} of 4.1 g/kg and 4.8 g/kg in male and female rats, respectively. These data characterize chlorpropham as practically nontoxic to mammals on an acute basis (MRID 41013703).

Chronic Toxicity A two generation rat reproduction study produced a reproductive NOEL > 10,000 ppm and a systemic NOEL of 1000 ppm. The systemic LOEL was 3000 ppm (MRID 0129545).

(3) Insects

Insect testing was not required for chlorpropham's indoor use. However, an acceptable study was submitted and is listed below.

Species	% ai	Results	Fulfills Guideline
Apis mellifera	Unknown	4.9% mortality at 36.26 μg/bee	Yes

This study fulfills the guideline requirement for an acute contact toxicity test with honey bees. The study is sufficient to characterize chlorpropham as practically nontoxic to honey bees when bees are exposed to direct treatment (MRID 00018842).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

Fish Acute The fish acute toxicity data that are acceptable for use in a hazard assessment are listed in the following table:

Species	% ai	LC_{50} (ppm)	Fulfills Guidelines
Bluegill sunfish	Unknown	6.3	No[a]
Rainbow trout	Unknown	3.0	No[a]
Bluegill sunfish	99%	6.8	Yes
Rainbow trout	99%	5.7	Yes

[a] These studies were found to be useful only as supplemental data due to inadequate reporting and protocol deviations (MRID 00037279).

Based upon the available data, the guideline requirements for acute testing of the technical grade active ingredient have been satisfied. There is sufficient information available to characterize technical chlorpropham as moderately toxic to both cold and warmwater freshwater fish (MRIDs 40208603 and 40208604).

(2) Freshwater Invertebrates

Invertebrate Acute The minimum data required for establishing the acute toxicity of chlorpropham to freshwater invertebrates are the results from a 48-hour study with the technical material (preferably on first instar *Daphnia magna*, or early instar amphipods, stone flies, or may flies).

The aquatic invertebrate toxicity data that are acceptable for use in a hazard assessment are listed below:

Species	% ai	EC_{50}	Fulfills Guideline
Daphnia magna	98	3.7 ppm	Yes

The guideline requirement for the acute testing of the technical grade active ingredient on aquatic invertebrates has been satisfied. Chlorpropham may be characterized as moderately toxic to freshwater invertebrates. The NOEC is 0.77 ppm (MRID 42507601).

c. Toxicity to Plants

No studies were required to support the registration for the indoor use. No studies were evaluated for phytotoxicity. However, it is known that chlorpropham has phytotoxic effects in plants, suppressing transpiration and respiration and inhibiting root and epicotyl growth. At

the cellular level, chlorpropham disrupts the normal cell division, strongly inhibits RNA and protein synthesis, interferes with oxidative phosphorylation and photosynthesis, and inhibits the activity of beta-amylase.

2. Environmental Fate

a. Environmental Fate Assessment

Only hydrolysis data have been required to support the indoor use of this chemical on stored potatoes. Hydrolysis data indicate that chlorpropham is stable to hydrolysis at an environmental pH. Since it is unlikely to be exposed to other routes of degradation indoors, it is likely to persist indoors.

b. Environmental Fate and Transport

A study of chlorpropham in aqueous buffer solutions at pH 4, 7, and 9 demonstrated that chlorpropham does not hydrolyze or degrade in water.

3. Exposure and Risk Characterization

No risk assessment was performed for the indoor use of this chemical. If the SLN registrations for spinach, Easter lilies, and ginkgo trees are to be maintained, additional ecological effects and environmental fate data are required. These additional studies are listed in part V of this document.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

1. Eligibility Decision

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing chlorpropham as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to evaluate the risks associates with the primary indoor use on stored potatoes.

The data are insufficient to make a reregistration eligibility decision for the chlorpropham outdoor uses on spinach, Easter lilies, and ginkgo trees. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of chlorpropham, and lists the submitted studies that the Agency found acceptable.

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, and the data identified in Appendix B. It should be understood that the Agency may take appropriate regulatory action in the future, and/or require the submission of additional data to support the registration of products containing chlorpropham, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

2. Eligible and Ineligible Uses

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of chlorpropham on potatoes and to determine that the indoor potato use of chlorpropham as currently registered does not result in unreasonable adverse effects to humans and the environment, if used according to the labels as amended by this RED.

The data are insufficient to make a reregistration eligibility decision for the chlorpropham outdoor uses on spinach, Easter lilies, and ginkgo trees. Further studies in the areas of ecological effects, environmental fate, and residue chemistry must be submitted to the Agency to support these uses. The reregistration of particular products is addressed in Section V of this document.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.181: The tolerances listed in 40 CFR §180.181 for post-harvest potatoes and soybeans are currently expressed in terms of the combined residues of chlorpropham and 1-hydroxy-2-propyl-3-chlorocarbanilate. The tolerance expression for post-harvest potatoes will be revised to reflect residues of chlorpropham *per se*. Sufficient data were

available to assess the adequacy of the established tolerance for post-harvest potatoes. The data indicate that the tolerance may be reduced from 50 ppm to 30 ppm. The following treatment rates should not be exceeded:

- aerosol fog at 0.022 lbs ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lbs ai/1000 lbs potato; or

- aerosol fog at 0.033 lbs ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lbs ai/1000 lbs potato.

Because the soybean use is no longer being supported, the soybean tolerance of 0.2 ppm will be proposed for revocation.

Tolerances Listed Under 40 CFR §180.319 (interim tolerances): The tolerances listed in 40 CFR §180.319 for chlorpropham are expressed in terms of residues of chlorpropham *per se*.

Insufficient data are available to assess the adequacy of the interim tolerances for milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep. Data from a ruminant feeding study are due to the Agency by October, 1995. Subsequent to the review of that data, appropriate tolerance levels for these commodities will be determined and the interim tolerances will be revoked. Tolerances for combined residues of chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid in these commodities will then be proposed under 40 CFR §180.181.

Because the use of chlorpropham on the following crops is no longer being supported, the corresponding interim tolerances will be proposed for revocation: alfalfa, alfalfa hay, beans (dry and succulent), blackberries, blueberries, carrots, clover, clover hay, cranberries, garlic, grass, grass hay, onions, peas (dry and succulent), raspberries, rice grain, safflower seed, sugar beet roots and tops, and tomatoes. Additional data are required to support the interim tolerance for chlorpropham on spinach. A tolerance under 40 CFR §180.181 must be proposed.

The Agency has determined that tolerances for poultry commodities are not required since potato commodities are not a significant poultry feed item. Therefore, the interim tolerances for eggs, and the fat, meat, and meat byproducts of poultry will be proposed for revocation.

Processed Food (40 CFR §185) and Feed (40 CFR §186) Tolerances: No food/feed additive tolerances have been established for chlorpropham. An adequate potato processing study has been conducted for chlorpropham. The study indicates that chlorpropham residues in potato peels are 2.4 times higher than the residues for the entire raw potato. The concentration of chlorpropham in peels suggests that an additional (higher) pesticide tolerance (under FFDCA Sect. 409) might be needed for processed potato waste, a cattle feed item. Such tolerances are only necessary when residues in ready-to-eat processed food or animal feed appreciably exceed the raw food tolerance.

Although chlorpropham concentrates in potato peels, the Agency believes for various reasons that residues in processed potato waste are not likely to appreciably exceed the reassessed raw agricultural tolerance of 30 ppm. Therefore, a processed feed tolerance is not required under FFDCA Sect. 409. The Agency is requiring residue data from processed potato waste to confirm this presumption.

The Agency does not find it necessary to make a determination whether processed potato waste is ready to eat in this situation because calculated residues of chlorpropham in this commodity do not significantly exceed the FFDCA 408 reassessed tolerance. Listed below are the Agency's assumptions regarding and calculation of an expected processed potato waste residue.

Calculation of Expected Residues for Processed Potato Waste: The Agency protocol for conducting potato processing studies does not completely reflect commercial practices because data on actual processing waste do not need to be generated. Because processed potato waste contains more water than raw potatoes, a dilution factor must be used in calculating expected processed potato waste residues (see Table II update in the Agency's Pesticide Reregistration Rejection Rate Analysis: Residue Chemistry Follow Up, June, 1994). The added water arises, at least in part, from washing potatoes during processing. Therefore, the calculation of expected processed potato waste residues takes into account the following components:

- 24.5 ppm = the highest residue of chlorpropham on raw potatoes in the potato field trial
- 2.4X = the average concentration factor in potato peels from the processing study
- the assumption that the dry matter content of potato peels is the same as that for whole raw potatoes

- 0.12/0.2 = a dilution factor based upon the ratio of the dry matter contents (as percentages) of processed potato waste to whole raw potatoes

The expected residue in potato waste is calculated as follows:

24.5 X 2.4 X 0.12/0.2 = 35.28 ppm

This 35.28 ppm chlorpropham expected residue in processed potato waste is not significantly above the reassessed 30 ppm raw potato tolerance (the factor is 1.2). The Agency believes that even this 35.28 ppm estimate is conservative since there are a variety of additional factors which would tend to decrease the estimate of chlorpropham levels in processed potato waste. These factors are listed below:

- Processed potato waste is comprised not solely of peel, but also of culled potatoes, clarifier and other wastes, culled french fries/processed products, etc. These items would be expected to have lower chlorpropham concentrations than peel and would thus tend to lower the chlorpropham residues found in the processed waste product.

- Potatoes processed commercially are expected to undergo a more rigorous washing than the gentle rinsing used in the processing study evaluated by the Agency. This washing step is expected to further decrease chlorpropham residues.

- Per industry sources, potatoes are almost exclusively peeled by means of a "steam-peeling" procedure, rather than the simple hand peeling used in the evaluated processing study. This added heat may accelerate chlorpropham loss/degradation.

- The Agency utilizes the highest average field trial (HAFT) in calculations when more than one field trial has been submitted. Since the Agency only has one relevant chlorpropham field trial from a single location, the highest reported concentration (24.5 ppm) was used. If average residues were considered, the concentration in the livestock feed would likely be significantly lower.

A summary of chlorpropham tolerance reassessments is presented in Table 12.

Table 12: Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.181			
Potatoes (POST-H)	50	30	Potato
Soybeans	0.2	Revoke	No registered uses
Tolerances listed under 40 CFR §180.319 (interim tolerances)			
Alfalfa	20	Revoke	No registered uses
Alfalfa hay	50	Revoke	No registered uses
Beans (dry and succulent)	0.3	Revoke	No registered uses
Blackberries	0.3	Revoke	No registered uses
Blueberries	0.3	Revoke	No registered uses
Carrots	0.1	Revoke	No registered uses
Cattle, fat	0.05	To be determined	To be determined following ruminant feeding study
Cattle, mbyp	0.05	To be determined	To be determined following ruminant feeding study
Cattle, meat	0.05	To be determined	To be determined following ruminant feeding study
Clover	20	Revoke	No registered uses
Clover hay	50	Revoke	No registered uses
Cranberries	0.3	Revoke	No registered uses
Eggs	0.05	Revoke	Tolerances for poultry commodities are not required.
Garlic	0.1	Revoke	No registered uses
Goats, fat	0.05	To be determined	To be determined following ruminant feeding study
Goats, mbyp	0.05	To be determined	To be determined following ruminant feeding study
Goats, meat	0.05	To be determined	To be determined following ruminant feeding study
Grass	20	Revoke	No registered uses
Grass hay	50	Revoke	No registered uses
Hogs, fat	0.05	To be determined	To be determined following ruminant feeding study
Hogs, mbyp	0.05	To be determined	To be determined following ruminant feeding study
Hogs, meat	0.05	To be determined	To be determined following ruminant feeding study

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Horses, fat	0.05	To be determined	To be determined following ruminant feeding study
Horses, mbyp	0.05	To be determined	To be determined following ruminant feeding study
Horses, meat	0.05	To be determined	To be determined following ruminant feeding study
Milk	0.05	To be determined	To be determined following ruminant feeding study
Onions	0.1	Revoke	No registered uses
Peas (dry and succulent)	0.3	Revoke	No registered uses
Poultry, fat	0.05	Revoke	Tolerances for poultry commodities are not required.
Poultry, mbyp	0.05	Revoke	Tolerances for poultry commodities are not required.
Poultry, meat	0.05	Revoke	Tolerances for poultry commodities are not required.
Raspberries	0.3	Revoke	No registered uses
Rice grain	0.1	Revoke	No registered uses
Safflower seed	0.1	Revoke	No registered uses
Sheep, fat	0.05	To be determined	To be determined following ruminant feeding study
Sheep, mbyp	0.05	To be determined	To be determined following ruminant feeding study
Sheep, meat	0.05	To be determined	To be determined following ruminant feeding study
Spinach	0.3	To be determined	Spinach
Sugar beet roots	0.1	Revoke	No registered uses
Sugar beet tops	0.3	Revoke	No registered uses
Tomatoes	0.1	Revoke	No registered uses

It should be noted that revoking the above tolerances may impact the importation into the United States of corresponding food items bearing chlorpropham residues. Any interested party who wishes to maintain a chlorpropham residue tolerance for importation purposes in the absence of a registered use should contact the Agency. In general, the Agency requires the same product chemistry and toxicology data to support an import tolerance as are required to support FIFRA registrations. The Agency also requires residue chemistry data representative of growing conditions in the exporting countries.

2. Codex Harmonization

There are no Codex Maximum Residue Limits (MRLs) established or proposed for residues of chlorpropham. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

3. Restricted Use Classification

Chlorpropham as currently registered does not trigger the criterion for a restricted use classification.

4. Reference Dose

The Agency established a Reference Dose (RfD) of 0.05 mg/kg bwt/day for a chronic dietary exposure risk assessment based on the no effect level from a chronic feeding study in dogs. This RfD was not exceeded for any subgroup of the U.S. population in the scenario where residues on 60% of all U.S. potatoes were assumed to be at the reassessed potato tolerance value of 30 ppm.

5. Cancer Risk

Chlorpropham *per se* has been tested for carcinogenicity and determined to be a group E chemical (evidence of non-carcinogenicity for humans) according to the Agency's cancer classification guidelines. However, 3-chloroaniline, one of chlorpropham's metabolites, is structurally similar to a known carcinogen, 4-chloroaniline. Since there are no cancer data available on 3-chloroaniline, the Agency believed it appropriate to perform a risk assessment using 4-chloroaniline's cancer potency (Q_1^*) to gauge any potential risk from 3-chloroaniline.

The resulting values from the extrapolated risk assessment were in the range of 3 to 4 x 10^{-6}. These risk estimates exceed the 1 x 10^{-6} estimate of individual excess lifetime cancer risk generally considered to be negligible. However, the Agency believes this assessment is an overestimation of risk for 3-chloroaniline for the reasons discussed in chapter III of this document. In addition, the uncertainties inherent in performing this risk assessment, based on the potency of a structural analog rather than the compound present, are great. The Agency believes it is not likely that 3-chloroaniline as a metabolite of chlorpropham is posing a risk of regulatory concern.

6. Endangered Species Statement

The primary use of chlorpropham on stored potatoes is an indoor use. This use is unlikely to result in harm to federally listed threatened or endangered species. However, if the outdoor uses of chlorpropham are maintained, the Agency will address those uses in the Endangered Species Protection Program, a developing program to identify all pesticides whose use may cause adverse impacts on endangered and threatened species. This program is designed to implement mitigation measures that will address the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in the future. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

7. Worker Protection Requirements

Uses Within the Scope of the Worker Protection Standard: The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the labels of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-residential) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food and feed crops). Of the current chlorpropham use sites, only spinach and Easter lilies are within the scope of the WPS.

Those uses that are outside the scope of the WPS include uses:

- on the portions of agricultural plants that have been harvested, such as on stored potatoes, and
- on plants, such as ginkgo trees, that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit.

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

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

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

Personal Protective Equipment/Engineering Controls for Handlers

WPS and nonWPS Uses: At this time, there are no engineering control requirements, such as closed systems, currently required on labeling for chlorpropham products.

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

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

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

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

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.
- The more stringent choice for each type of PPE (i.e., body wear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There are special toxicological concerns from dermal exposure to chlorpropham that warrant the establishment of active-ingredient-based handler PPE requirements. The MOEs were calculated as being acceptable for both WPS and nonWPS handlers based on an adjustment simulating the wearing of chemical-resistant gloves by handlers. A requirement for chemical-resistant gloves is being required as minimum (baseline) PPE for all occupational handlers.

For applications of chlorpropham as an aerosol, the Agency is requiring use of a respirator for handlers who must enter an enclosed treated site during either application or the ventilation period. Although inhalation data were waived because technical chlorpropham cannot be prepared and tested in a respirable form, the existing toxicology data indicate there are no special inhalation concerns based on extrapolations from oral data. The Agency believes it prudent to require a respirator when entering during application or ventilation to minimize exposure.

The type of respirator must be specified on each chlorpropham end-use product labeled for application through an aerosol generator. The type of respirator required depends on the product ingredients other than chlorpropham. Since the vapor pressure of chlorpropham is low, a NIOSH/MSHA dust/mist filtering respirator is sufficiently protective for chlorpropham aerosols. However, if other ingredients in the end-use product (either actives or inerts) have a high vapor pressure (eg. methanol), a respirator with an organic-vapor absorbing component (cartridge or canister) plus a dust/mist filtering component is required.

Post-Application/Entry Restrictions

WPS Uses:

Entry Restrictions for Occupational-Use Products (WPS Uses): At this time, some registered uses of chlorpropham are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS.

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

For occupational end-use products containing chlorpropham as an active ingredient, the Agency is establishing a 12-hour restricted-entry interval for each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The basis for this requirement is that chlorpropham is categorized as toxicity category III for eye irritation potential and toxicity category IV for acute dermal toxicity and for skin irritation potential, and EPA has no special concerns about other adverse effects (NOEL for intermediate-term exposures based on a 21-day dermal study in rabbits).

Early-Entry PPE: The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and the requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-

entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

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

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

Since chlorpropham is classified as category III for eye irritation potential and as category IV for acute dermal toxicity and for skin irritation potential, and EPA has no special concerns about other adverse effects, the PPE required for early entry is: coveralls, chemical-resistant gloves, shoes, and socks.

Post-Application/Entry Restrictions

NonWPS Uses

At this time some registered uses of chlorpropham are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

For forced-air distribution applications (due to inhalation concerns), the Agency is prohibiting entry except to persons equipped with the appropriate handler PPE until either a total of two hours of mechanical (fans, etc.) ventilation or four hours of passive (windows, vents, etc.) ventilation has occurred, or until such time as 10 complete air exchanges have occurred. The ventilation time may be interrupted, i.e., the time may be accumulated at sporadic intervals, such as 15 minutes of ventilation followed by a period with no ventilation, until the total required ventilation time has accumulated.

Chlorpropham products which are labeled for application to potatoes on a conveyor belt must contain the following statement:

> Following application, workers (e.g. baggers) must wear chemical-resistant gloves while potatoes are wet.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

Registrants are required to submit the following generic data to support the use of chlorpropham on stored potatoes.

171-4(k) Cropfield Trials - This data requirement applies to end use products with a label which does not conform to the residue trial scenarios evaluated in support of the potato tolerance. The two scenarios for which the Agency has adequate residue data are listed below.

Scenarios

- Aerosol fog at 0.022 lbs ai/1000 lbs (0.0022 lbs ai/cwt) potato in each of two applications 90 days apart followed by direct spray at 0.0104 lbs ai/1000 lbs (0.00104 lbs ai/cwt) potato; or

- Aerosol fog at 0.033 lbs ai/1000 lbs (0.0033 lbs ai/cwt) potato and a second aerosol fog 140 days later at 0.017 lbs ai/1000 lbs (0.0017 lbs ai/cwt) potato.

Registrants whose products are labeled with post-harvest potato treatment rates and timing other than the above or which do not prohibit treatment which could result in higher residues are required to submit additional residue data to maintain their registration.

However, registrants may chose instead to modify their labels to conform to the above scenarios or submit additional information showing why residues on potatoes treated with their product would not be expected to be greater than the reassessed potato tolerance.

171-4(l) Processed food - a commercial-scale study measuring residues in processed potato waste using standard industry practices;

potatoes treated at maximum label rates; protocol to be submitted to the Agency for review and approval.

Registrants are required to submit the following generic data to support any of the three existing outdoor uses of chlorpropham (spinach, Easter lilies, ginkgo trees).

71-1(a)	Avian Oral LD_{50} (with the bobwhite quail)
71-2(b)	Avian Dietary LC_{50} (with the mallard duck)
122-1(a)	Seed Germination/Seedling Emergence
122-1(b)	Vegetative Vigor
122-2	Aquatic Plant Growth
161-2	Photodegradation in Water
161-3	Photodegradation on Soil
162-1	Aerobic Soil Metabolism
162-2	Anaerobic Soil Metabolism
163-1	Mobility/Adsorption/Desorption
163-2	Laboratory Volatility
164-1	Terrestrial Field Dissipation
165-4	Accumulation in Fish

The following chronic studies are being held in reserve to support any of the three outdoor uses, pending environmental fate data.

71-4(a)	Avian Reproduction (with the bobwhite quail)
71-4(b)	Avian Reproduction (with the mallard duck)
72-4(a)	Early Life-Stage Fish
72-4(b)	Life-cycle Aquatic Invertebrate
72-5	Life-Cycle Fish

Registrants are required to submit the following generic data to support the existing spinach use of chlorpropham.

165-1	Confined Rotational Crop
171-4(a)	Plant Metabolism (only for spinach; levels of chlorpropham and 3-chloroaniline must be quantified)
171-4(c)	Residue Analytical Methods (to determine chlorpropham, 3-chloroaniline and any other residue of concern)
171-4(e)	Storage Stability (for chlorpropham, 3-chloroaniline, and any other residue of concern)
171-4(k)	Crop Field Trials (Two trials with two independent plots treated at 1x and 2x rates OR three trials)

The following study is being held in reserve to support the existing spinach use of chlorpropham, pending the results of guideline 165-1.

165-2 Field Rotational Crop

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

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

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (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.

Since manufacturing use registrants may not support the uses of chlorpropham on spinach, Easter lilies, or ginkgo trees, end use registrants may be required to conduct the data listed under the Manufacturing-Use Products section above to maintain their registrations. Within 90 days, registrants will have to commit to generate the data, volunteer to cancel their products, or comply with Agency requirements by selecting other appropriate options in the Data Call In.

2. Labeling Requirements for End-Use Products

Occupational/Residential Labeling

PPE Requirements for Pesticide Handlers

Sole-active-ingredient end-use products that contain chlorpropham must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain chlorpropham must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

WPS and nonWPS uses

Minimum (baseline) PPE requirements -- The minimum (baseline) PPE for all WPS and nonWPS uses of chlorpropham is:

Applicators and other handlers must wear:
--chemical-resistant gloves*,

* The glove statement for {active ingredient} is the statement established through the instructions in Supplement Three of PR Notice 93-7.

In addition, for all chlorpropham products that bear use-directions for generating an aerosol in an aerosol generator or for using a forced-air distribution method of application, the following PPE restriction applies:

--From the start of application and continuing until the ventilation requirements listed on this labeling have been completed, for entry into the enclosed treated area, handlers must wear a long-sleeve shirt, long pants, shoes and socks, and a respirator. The following type of respirator is appropriate to mitigate chlorpropham inhalation exposure when the end-use product does not contain an inert ingredient which has a low vapor pressure:

- A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TX-21C).

If the end-use product contains an inert, such as methanol, which has a low vapor pressure, the type of respirator appropriate to mitigate the inhalation concerns for that end-use product is:

- A respirator with either an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).

If the enclosed area contains less than 19.5 percent oxygen, the respirator must be one of the following types:

- A supplied-air respirator (MSHA/NIOSH approval number prefix TC-19C) OR a self-contained breathing apparatus (SCBA) (MSHA/NIOSH approval number prefix TX-13F).

Actual end-use product PPE requirements -- The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) personal protective equipment, if any, specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in labeling -- The personal protective equipment must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Entry Restrictions

Sole-active-ingredient end-use products that contain chlorpropham must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain chlorpropham must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use

WPS uses

Restricted-entry interval -- A 12-hour restricted entry interval (REI) is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products (see tests in PR Notices 93-7 and 93-11). This REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

Early-entry personal protective equipment (PPE) --

The PPE required for early entry is:
--coveralls,
--chemical-resistant gloves,
--shoes plus socks

Handler PPE, in addition to chemical resistant gloves, will be established at the time of product reregistration based on the toxicity of the end-use product. However, at a minimum, PPE for handlers involved in chlorpropham application for WPS uses will be established at an equivalent protection level (i.e. long-sleeves, long pants, shoes and socks).

Placement in labeling -- The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early entry PPE statement required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions --

For aerosol or forced-air distribution applications:
"Do not enter or allow any person, other than a person equipped with the appropriate handler personal protective equipment including the appropriate respirator, to enter the treated area until the area has been ventilated. Ventilation may be for either a total of two (2) hours with fans or other

mechanical ventilation or four (4) hours with windows, vents, or other passive ventilation, or until such time that there have been 10 complete air exchanges. The ventilation time may be interrupted, i.e., the time may be accumulated at sporadic intervals, such as 15 minutes of ventilation followed by a period with no ventilation, until the total required ventilation time has accumulated."

Chlorpropham products which are labeled for application to potatoes on a conveyor belt must contain the following statement:
Following application, workers (e.g. baggers) must wear chemical-resistant gloves while potatoes are wet.

Placement in labeling --

If WPS uses are also on label: Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box and place the appropriate nonWPS entry restriction in that box.

If no WPS uses are on label: Add the appropriate nonWPS entry restriction to the labels of all end-use products, except products primarily intended for residential use, in a section in the Directions For Use with the heading: "Entry Restrictions:"

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing chlorpropham 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."

Engineering controls

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

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."

The Agency is requiring the following labeling statement to be placed on all chlorpropham end-use products which are labeled for use on ginkgo trees. This statement is considered adequate to preclude the possibility of residues in ginkgo nuts (a food item) since ginkgos are grown primarily as ornamentals in the United States.

"Do not use on ginkgo trees which produce ginkgo nuts destined for human consumption."

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."

Residue Chemistry Labeling Requirements

Unless registrants conduct additional residue data under guideline 171-4(k), end use product labels must conform to the residue trial scenarios presented below or show why potatoes treated according to their label would not be expected to have residues above the reassessed tolerance of 30 ppm.

Scenarios

- Aerosol fog at 0.022 lbs ai/1000 lbs (0.0022 lbs ai/cwt) potato in each of two applications 90 days apart followed by direct spray at 0.0104 lbs ai/1000 lbs (0.00104 lbs ai/cwt) potato; or
- Aerosol fog at 0.033 lbs ai/1000 lbs (0.0033 lbs ai/cwt) potato and a second aerosol fog 140 days later at 0.017 lbs ai/1000 lbs (0.0017 lbs ai/cwt) potato.

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 chlorpropham 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

The uses in Appendix A were evaluated for reregistration. Appendix A does not include changes in application rates, frequency, timing of application, restricted entry intervals, etc. that may be required by this document.

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
POTATO, WHITE/IRISH				Use Group: INDOOR FOOD									
Stored commodity fumigation., Postharvest., Aerosol generator.	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS			
	RTU	NA	UC 7 lb 4.2K cwt	* *	NS	NS	NS	NS	NS	NS			C04
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS			C93
Stored commodity non-fumigation., Postharvest., Aerosol generator.	EC	NA	.02143 lb 20 cwt	*	NS	NS	NS	NS	NS	NS			
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS			
	RTU	NA	UC 7 lb 4.2K cwt	* *	NS	NS	NS	NS	NS	NS			C04
	RTU	NA	8 lb 2.4K cwt	*	NS	NS	NS	NS	NS	NS	ND		
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	ND		C04
	RTU	NA	8 lb 2.4K cwt	*	NS	NS	NS	NS	NS	NS	OR		
Stored commodity non-fumigation., Postharvest., Foaming apparatus.	EC	NA	.08698 lb 80 cwt	*	NS	NS	NS	NS	NS	NS			C04
Stored commodity non-fumigation., Postharvest., Not on label.	RTU	NA	8 lb 2.4K cwt	*	NS	NS	NS	NS	NS	NS	WA		
Stored commodity non-fumigation., Postharvest., Sprayer.	EC	NA	.02143 lb 20 cwt	*	NS	NS	NS	NS	NS	NS			
	EC	NA	.02143 lb 20 cwt .08698 lb 80 cwt	* *	NS	NS	NS	NS	NS	NS			C04
SPINACH				Use Group: TERRESTRIAL FOOD CROP									
Broadcast., Dormant., Low pressure ground sprayer.	EC	NA	1.001 lb A	*	1	NS	1 lb	NS	NS	NS	DE		CAE, H01(30)
	EC	NA	1.001 lb A	*	1	NS	1 lb	NS	NS	NS	MD		CAE, H01(30)
	EC	NA	1.001 lb A	*	1	NS	1 lb	NS	NS	NS	NJ		H01(30)
	EC	NA	1.001 lb A	*	NS	NS	NS	NS	NS	NS	VA		CAE, H01(30)
Low volume spray (concentrate)., Dormant., Low pressure ground sprayer.	EC	NA	1.001 lb A	*	NS	NS	NS	NS	NS	NS	NJ		H01(30)

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. Dose	Max. # Apps Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES (con't)											
SPINACH (con't)				Use Group: TERRESTRIAL FOOD CROP (con't)							
	EC	NA	1.001 lb A	*	NS NS	NS NS	NS	NS	VA		CAE, H01(30)
NON-FOOD/NON-FEED											
ORNAMENTAL AND/OR SHADE TREES				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL							
Spray., Foliar., Mist blower.	EC	NA	UC	*	NS NS	NS NS	NS	NS	DC		C46
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL NON-FOOD CROP							
Directed spray., Bulbs., Ground.	EC	NA	3.99 lb A	*	NS NS	NS NS	NS	1	CA		
High volume spray (dilute)., Prebloom., Boom sprayer.	EC	NA	3.99 lb A	*	1 NS	NS NS	NS	NS	OR		
	EC	NA	3.99 lb A	*	NS NS	NS NS	NS	1	CA		

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

EC	: EMULSIFIABLE CONCENTRATE
RTU	: LIQUID-READY TO USE

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

C04 : Proper ventilation required.
C46 : Do not apply through any type of irrigation system.
C93 : Do not apply directly to water.
CAE : Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

CA : California
DC : District of Columbia
DE : Delaware
MD : Maryland
ND : North Dakota
NJ : New Jersey
OR : Oregon
VA : Virginia
WA : Washington

GUIDE TO APPENDIX B

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

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
Aceto Agricultural Chemical Corporation 98% T (2749-102)			
61-1	**Chemical Identity**	ALL	42183703, 42915101
61-2A	**Start. Mat. & Mnfg. Process**	ALL	42183703, 42752201
61-2B	**Formation of Impurities**	ALL	42183703, 42752201, 42915101
62-1	**Preliminary Analysis**	ALL	42183702, 42796301
62-2	**Certification of limits**	ALL	42183703, 42796301
62-3	**Analytical Method**	ALL	42796301
63-2	**Color**	ALL	42737401, 42183701
63-3	**Physical State**	ALL	42737401, 42183701
63-4	**Odor**	ALL	42737401, 42183701
63-5	**Melting Point**	ALL	42737401, 42183701
63-6	**Boiling Point**		N/A - Not required, TGAI/MP is solid at room temperature.
63-7	**Density**	ALL	42737401, 42183701
63-8	**Solubility**	ALL	42737401, 42754301, 42183701
63-9	**Vapor Pressure**	ALL	42772401,42183701
63-10	**Dissociation Constant**	ALL	42737402,42183701
63-11	**Octanol/Water Partition**	ALL	42737401, 42754401, 42183701

REQUIREMENT		USE PATTERN	CITATION(S)
63-12	**pH**	ALL	42737401, 42183701
63-13	**Stability**	ALL	42741101, 42183701
63-14	**Oxidizing/Reducing Action**	ALL	42741101, 42737401
63-15	**Flammability**		N/A - See requirement 63-6.
63-16	**Explodability**	ALL	42741101, 42737401
63-17	**Storage stability**	ALL	42823001, 43178101
63-18	**Viscosity**		N/A - See requirement 63-6.
63-19	**Miscibility**		N/A - See requirement 63-6.
63-20	**Corrosion characteristics**	ALL	42817301
63-21	**Dielectric breakdown volt**		N/A
64-1	**Submittal of Samples**		N/A
Aceto Agricultural Chemical Corporation 98% T (2749-117)			
61-1	**Chemical Identity**	ALL	DATA GAP
61-2A	**Start. Mat. & Mnfg.Process**	ALL	DATA GAP
61-2B	**Formation of Impurities**	ALL	DATA GAP
62-1	**Preliminary Analysis**	ALL	DATA GAP
62-2	**Certification of limits**	ALL	DATA GAP
62-3	**Analytical Method**	ALL	DATA GAP
63-2	**Color**	ALL	DATA GAP
63-3	**Physical State**	ALL	DATA GAP
63-4	**Odor**	ALL	DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Chlorpropham

REQUIREMENT		USE PATTERN	CITATION(S)
63-5	**Melting Point**	ALL	DATA GAP
63-6	**Boiling Point**	ALL	N/A
63-7	**Density**	ALL	DATA GAP
63-8	**Solubility**	ALL	DATA GAP
63-9	**Vapor Pressure**	ALL	DATA GAP
63-10	**Dissociation Constant**	ALL	DATA GAP
63-11	**Octanol/Water Partition**	ALL	DATA GAP
63-12	**pH**	ALL	DATA GAP
63-13	**Stability**	ALL	DATA GAP
63-14	**Oxidizing/Reducing Action**	ALL	DATA GAP
63-15	**Flammability**	ALL	DATA GAP
63-16	**Explodability**	ALL	DATA GAP
63-17	**Storage stability**	ALL	DATA GAP
63-18	**Viscosity**	ALL	N/A
63-19	**Miscibility**	ALL	N/A
63-20	**Corrosion characteristics**	ALL	DATA GAP
63-21	**Dielectric breakdown volt**		N/A
64-1	**Submittal of Samples**		N/A
Elf Atochem North America, Inc. 99% TGAI 2792-67			
61-1	**Chemical Identity**	ALL	42598801
61-2A	**Start. Mat. & Mnfg. Process**	ALL	42598801

Data Supporting Guideline Requirements for the Reregistration of Chlorpropham

REQUIREMENT		USE PATTERN	CITATION(S)
61-2B	**Formation of Impurities**	ALL	42598801
62-1	**Preliminary Analysis**	ALL	42822602, 42873601
62-2	**Certification of limits**	ALL	42598801
62-3	**Analytical Method**	ALL	42864501
63-2	**Color**	ALL	42058903
63-3	**Physical State**	ALL	42058903
63-4	**Odor**	ALL	42058903
63-5	**Melting Point**	ALL	42058903
63-6	**Boiling Point**		N/A
63-7	**Density**	ALL	42058903,42675601
63-8	**Solubility**	ALL	42058903,42675601
63-9	**Vapor Pressure**	ALL	42058903,42864502
63-10	**Dissociation Constant**	ALL	42744301
63-11	**Octanol/Water Partition**	ALL	42855101
63-12	**pH**	ALL	42058903
63-13	**Stability**	ALL	42855102
63-14	**Oxidizing/Reducing Action**	ALL	42675602
63-15	**Flammability**	ALL	N/A
63-16	**Explodability**	ALL	42807401
63-17	**Storage stability**	ALL	42058903
63-18	**Viscosity**		N/A

REQUIREMENT		USE PATTERN	CITATION(S)
63-19	**Miscibility**		N/A
63-20	**Corrosion characteristics**	ALL	42966001
63-21	**Dielectric breakdown volt**		N/A
64-1	**Submittal of Samples**		N/A
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A,C	DATA GAP
71-1B	**Acute Avian Oral - Quail/Duck TEP**		N/A
71-2A	**Avian Dietary - Quail**	A,C	42490401
71-2B	**Avian Dietary - Duck**	A,C	DATA GAP
71-3	**Wild Mammal Toxicity**		N/A
71-4A	**Avian Reproduction - Quail**	A,C	RESERVED
71-4B	**Avian Reproduction - Duck**	A,C	RESERVED
71-5A	**Simulated Field Study**		N/A
71-5B	**Actual Field Study**		N/A
72-1A	**Fish Toxicity Bluegill**	A,C	40208603, 00037279
72-1B	**Fish Toxicity Bluegill - TEP**		N/A
72-1C	**Fish Toxicity Rainbow Trout**	A,C	40208604
72-1D	**Fish Toxicity Rainbow Trout- TEP**		N/A
72-2A	**Invertebrate Toxicity**	A,C	42507601
72-2B	**Invertebrate Toxicity - TEP**		N/A

Data Supporting Guideline Requirements for the Reregistration of Chlorpropham

REQUIREMENT		USE PATTERN	CITATION(S)
72-3A	**Estuarine/Marine Toxicity - Fish**		N/A
72-3B	**Estuarine/Marine Toxicity - Mollusk**		N/A
72-3C	**Estuarine/Marine Toxicity - Shrimp**		N/A
72-3D	**Estuarine/Marine Toxicity Fish- TEP**		N/A
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**		N/A
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**		N/A
72-4A	**Early Life Stage Fish**	A,C	RESERVED
72-4B	**Life Cycle Invertebrate**	A,C	RESERVED
72-5	**Life Cycle FisH**	A,C	RESERVED
72-6	**Aquatic Organism Accumulation**	A,C	RESERVED
72-7A	**Simulated Field - Aquatic Organisms**		N/A
72-7B	**Actual Field - Aquatic Organisms**		N/A
122-1A	**Seed Germination/Seedling Emergence**	A,C	DATA GAP
122-1B	**Vegetative Vigor**	A,C	DATA GAP
122-2	**Aquatic Plant Growth**	A,C	DATA GAP
123-1A	**Seed Germination/Seedling Emergence**	A,C	RESERVED

REQUIREMENT		USE PATTERN	CITATION(S)
123-1B	**Vegetative Vigor**	A,C	RESERVED
123-2	**Aquatic Plant Growth**	A,C	RESERVED
124-1	**Terrestrial Field**		N/A
124-2	**Aquatic Field**		N/A
141-1	**Honey Bee Acute Contact**	A,C	00018842
141-2	**Honey Bee Residue on Foliage**		N/A
141-5	**Field Test for Pollinators**		N/A
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,L	41013703, 41763601
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,L	41013704
81-3	**Acute Inhalation Toxicity - Rat**		N/A
81-4	**Primary Eye Irritation - Rabbit**	A,L	41013705, 41763301, N/A - Not required for the technical grade active ingredient.
81-5	**Primary Dermal Irritation - Rabbit**	A,L	41013706, 41763501, N/A - Not required for the technical grade active ingredient.
81-6	**Dermal Sensitization - Guinea Pig**	A,L	41013707, 41763401, N/A - Not required for. the technical grade active ingredient
81-7	**Acute Delayed Neurotoxicity - Hen**	A,L	00093915
82-1A	**90-Day Feeding - Rodent**		41863101, 41899301
82-1B	**90-Day Feeding - Non-rodent**		N/A
82-2	**21-Day Dermal - Rabbit/Rat**	A,L	41899901

Data Supporting Guideline Requirements for the Reregistration of Chlorpropham

REQUIREMENT		USE PATTERN	CITATION(S)
82-3	**90-Day Dermal - Rodent**		WAIVED
82-4	**90-Day Inhalation - Rat**		N/A
82-5A	**90-Day Neurotoxicity - Hen**		N/A
82-5B	**90-Day Neurotoxicity - Mammal**		N/A
83-1A	**Chronic Feeding Toxicity - Rodent**	A,L	42754701
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,L	42189501
83-2A	**Oncogenicity - Rat**	A,L	42754701
83-2B	**Oncogenicity - Mouse**	A,L	42530301
83-3A	**Developmental Toxicity - Rat**	A,L	00093921
83-3B	**Developmental Toxicity - Rabbit**	A,L	00129940
83-4	**2-Generation Reproduction - Rat**	A,L	00129545
84-2A	**Gene Mutation (Ames Test)**	A,L	00126733, 00129938, 00126734, 41846701
84-2B	**Structural Chromosomal Aberration**	A,L	41845501
84-4	**Other Genotoxic Effects**		N/A
85-1	**General Metabolism**	A,L	42006901
85-2	**Dermal Penetration**		N/A
86-1	**Domestic Animal Safety**		N/A
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**		N/A
132-1B	**Soil Residue Dissipation**		N/A

REQUIREMENT		USE PATTERN	CITATION(S)
133-3	**Dermal Passive Dosimetry Exposure**		N/A
133-4	**Inhalation Passive Dosimetry Exposure**		N/A
231	**Estimation of Dermal Exposure at Outdoor Sites**		N/A
232	**Estimation of Inhalation Exposure at Outdoor Sites**		N/A
233	**Estimation of Dermal Exposure at Indoor Sites**		N/A
234	**Estimation of Inhalation Exposure at Indoor Sites**		N/A
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**		N/A
161-1	**Hydrolysis**	A,C	00114729
161-2	**Photodegradation - Water**	A,C	DATA GAP
161-3	**Photodegradation - Soil**	A,C	DATA GAP
161-4	**Photodegradation - Air**		N/A
162-1	**Aerobic Soil Metabolism**	A,C	DATA GAP
162-2	**Anaerobic Soil Metabolism**	A,C	DATA GAP
162-3	**Anaerobic Aquatic Metabolism**		N/A
162-4	**Aerobic Aquatic Metabolism**		N/A
163-1	**Leaching/Adsorption/Desorption**	A,C	DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Chlorpropham

REQUIREMENT		USE PATTERN	CITATION(S)
163-2	**Volatility - Lab**	A,C	DATA GAP
163-3	**Volatility - Field**		RESERVED
164-1	**Terrestrial Field Dissipation**	A,C	DATA GAP
164-2	**Aquatic Field Dissipation**		N/A
164-3	**Forest Field Dissipation**		N/A
164-5	**Long Term Soil Dissipation**	A	RESERVED
165-1	**Confined Rotational Crop**	A	DATA GAP
165-2	**Field Rotational Crop**		RESERVED
165-3	**Accumulation - Irrigated Crop**		N/A
165-4	**Bioaccumulation in Fish**	A,C	00035997, 00035998, DATA GAP
165-5	**Bioaccumulation - Aquatic NonTarget**		RESERVED
166-1	**Ground Water - Small Prospective**		N/A
166-2	**Ground Water - Small Retrospective**		N/A
166-3	**Ground Water - Irrigated Retrospective**		N/A
201-1	**Droplet Size Spectrum**		N/A
202-1	**Drift Field Evaluation**		N/A
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	A,L	42085601, DATA GAP

Data Supporting Guideline Requirements for the Reregistration of Chlorpropham

REQUIREMENT		USE PATTERN	CITATION(S)
171-4B	**Nature of Residue - Livestock**	A,L	00114700, 00114701, 00114739, 42112201 42130401
171-4C	**Residue Analytical Method - Plant**	A,L	00035896, 00045294, 00045295, 00114710 00114715, 00114718, 00114739, 00114741 00114751, 00114785, 42123101, 42653401 42778901, DATA GAP
171-4D	**Residue Analytical Method - Animal**	A,L	00115388, DATA GAP
171-4E	**Storage Stability**	A,L	00054672, 42660101, 42958301, 4305360l DATA GAP
171-4F	**Magnitude of Residues - Potable H2O**		N/A
171-4G	**Magnitude of Residues in Fish**		N/A
171-4H	**Magnitude of Residues - Irrigated Crop**		N/A
171-4I	**Magnitude of Residues - Food Handling**		N/A
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**		N/A
171-4K	**Crop Field Trials**		
	<u>Root and Tuber Vegetables Group</u>		
	-Potato	L	00083155, 00114695, 00114718, 00114741 00114747, 00114750, 00114777, 00114785 00114795, 42566801, 42610301, 42653601 42653801, 42653901

REQUIREMENT		USE PATTERN	CITATION(S)
	Leafy Vegetable (except Brassica) Group		
	-Spinach	A	00114710, 00114715, 00114794, DATA GAP
171-4L	**Processed Food - Potato**	L	DATA GAP
171-5	**Reduction of Residues**		N/A
171-6	**Proposed Tolerance**		N/A
171-7	**Support for Tolerance**		N/A
171-13	**Analytical Reference Standard**		N/A

GUIDE TO APPENDIX C

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

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

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

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

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

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

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
00035896	Wiedmann, J.L.; Pensyl, J. (1975) Proposed Regulatory Method for CIPC Residue (CIPC + Metabolite III): BR 19718. Method dated May 2, 1975. (Unpublished study received May 8, 1975 under 4F1429; submitted by PPG Industries, Inc., Barberton, Ohio; CDL: 093811-D)
00035997	Ecke, G.G. (1976) Qualitative Investigation of CIPC Metabolites in Bluegill Sunfish: Final Report: BR 20315A. (Unpublished study received Sep 21, 1976 under 748-161; submitted by PPG Industries, Inc., Barberton, Ohio; CDL:095292-E)
00035998	Smith, K.S. (1976) Report: Bluegill Sunfish Tissue Residue Levels following Exposure to 14C-CIPC: Laboratory No. 6E-1100A. (Unpublished study received Sep 21, 1976 under 748-161; prepared by Cannon Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, Ohio; CDL:095292-F)
00037279	Reinert, H.K.; Parke, G.S.E. (1975) Report: Static 96-Hour Toxicity Study of PPG Industries, Incorporated Sample CIPC Technical in Bluegill Sunfish and Rainbow Trout: Laboratory No. 5E-8034. (Unpublished study received Sep 21, 1976 under 748-161; prepared by Cannon Laboratories, Inc., submitted by PPG Industries, Inc., Barberton, Ohio; CDL:095292-AA)
00045294	PPG Industries, Incorporated (1969) General Analytical Method for Determining CIPC Residues in Crops Designated in the Summary Table as Being Analyzed by MF (Ext.). (Unpublished study received Dec 31, 1970 under 1F1119; CDL:093430-D)
00045295	PPG Industries, Incorporated (1968) General Analytical Method for Determining CIPC Residues in Crops Designated in the Summary Table as Being Analyzed by the MF (TCH-Dist) Method. (Unpublished study received Dec 31, 1970 under 1F1119; CDL:093430-E)
00054672	Dave, B. (1977) Residue Data of CIPC on Potatoes. (Unpublished study received Aug 26, 1977 under 4581-EX-30; submitted by Pennwalt Corp., Philadelphia, Pa.; CDL:231831-T)
00083155	Gard, L.N. (1959) Determination of isopropyl~N~-(3-chlorophenyl) carbamate residues in potatoes treated for sprout inhibition. Journal of Agricultural and Food Chemistry 7(5):339-341. (Also~In~unpublished submission received Dec 1, 1959 under PP0234; submitted by Columbia-Southern Chemical Corp., Pittsburgh, Pa.; CDL:090262-G)

BIBLIOGRAPHY

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). 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 4; 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 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 4).

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

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

This Notice is divided into six sections and five 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:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form
Attachment 3	-	Requirements Status And Registrant's Response Form
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The 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.

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.

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 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)].

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice 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.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the 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 (Attachment 2) and the Requirements Status and Registrant's Response Form (Attachment 3). The Data Call-In Response Form must be submitted as part of every response to this Notice. 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 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(s) 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 choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

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

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

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

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

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

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

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

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

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the 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 option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 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.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), 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. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

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

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

must be included as well as a full description of any problems encountered since the last progress report.

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

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

Option 2, Agreement to Share in Cost to Develop Data --

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

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its

discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept 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. 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(7) " *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(7), 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 EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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

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 ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

D. REQUESTS FOR DATA WAIVERS

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

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used

for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

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

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

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

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

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

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

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

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

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

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

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

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

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

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

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; or,

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.

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.

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 Federal Insecticide, Fungicide, and Rodenticide 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(s) 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 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 (Attachment 2) and a completed Requirements Status and Registrant's Response Form (Attachment 3) and any other documents required by this Notice, and should be submitted to the contact person 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 (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Chlorpropham DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

DATA REQUIRED BY THIS NOTICE

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Margery Exton at (703) 308-8024.

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

Margery Exton, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Chlorpropham

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

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

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 suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

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

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

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

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

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

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

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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

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

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites

TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

*See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

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

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

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

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data"

that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

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

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

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

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

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless

modified by the Agency in writing, the data requirement as stated in the Notice governs.

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

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

Remove this page and insert the list of registrants here.

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) NOTICES ISSUED BY THE AGENCY

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

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

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

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

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

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

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the

Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

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

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

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not

submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

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

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

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

CHLORPROPHAM DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Chlorpropham. 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 Chlorpropham 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 Chlorpropham are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Chlorpropham 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 Chlorpropham 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 Jean Holmes at (703) 308-8008.

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

Jean Holmes
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: **Chlorpropham**

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.

REMOVE THIS PAGE AND INSERT PART A OF THE PDCI HERE.

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.

Remove this page and insert the list of registrants here.

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient chlorpropham (Isopropyl N-(3-chlorophenyl) carbamate), the Agency has batched products that can be considered similar in terms 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., liquid, wettable powder, aerosol, 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 date 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 general 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 if the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by the Agency 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 it's EPA Registration Number. If more than one confidential statement of formulation (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 requirement, 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 that 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 Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1,4,5, or 6. However, a registrant should know that choosing not to participate in a batch does not

preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient chlorpropham.

Table 1

Batch	EPA Reg. No.	Active Ingredient	Formulation Type
1	2749-102	chlorpropham ...98.0%	solid
	2749-117	chlorpropham ...98.0%	solid
	2792-67	chlorpropham ...98.0%	solid
2	2749-70	chlorpropham ...36.0%	liquid
	34704-613	chlorpropham ...36.0%	liquid
	CA93000800	chlorpropham ...36.0%	liquid
	DC90000100	chlorpropham ...36.0%	liquid
	DE91000100	chlorpropham ...36.0%	liquid
	MD91000800	chlorpropham ...36.0%	liquid
	NJ91001200	chlorpropham ...36.0%	liquid
	OR91001200	chlorpropham ...36.0%	liquid
	VA91000400	chlorpropham ...36.0%	liquid
3	2749-264	chlorpropham ...46.5%	liquid
	2792-41	chlorpropham ...49.65%	liquid
	ND82002100	chlorpropham ...46.5%	liquid
	OR85004700	chlorpropham ...46.5%	liquid
	WA82006500	chlorpropham ...46.5%	liquid
4	34704-614	chlorpropham ...78.5%	liquid
	65726-1	chlorpropham ...78.6%	liquid
	WA82007600	chlorpropham ...78.5%	liquid
	WA92004100	chlorpropham ...78.5%	liquid

Table 2 lists the product the Agency was unable to batch. These products were either considered not to be similar to other products for purposes of acute toxicity or the Agency lacked sufficient information for decision making. The registrants of these products are responsible for meeting the acute toxicity data requirements for these products.

Table 2

EPA Reg. No.	Active Ingredient	Formulation Type
2792-40	chlorpropham...25%	liquid
34704-612	chlorpropham...46%	liquid
ND85000900	chlorpropham...78.41%	liquid

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

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

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date

Name and Title (Please Type or Print)

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

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

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

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jean Holmes at (703)-308-8008.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for Chlorpropham.

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

1. Health and Environmental Effects Science Chapters.

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

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria