United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-98-005
November 1998

Reregistration Eligibility Decision (RED)

DCPA

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 DCPA which includes the active ingredient Dimethyl tetrachloroterephthalate. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1995 contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the date of receipt of this letter. The second set of required responses is due 8 months from the date of receipt 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 to the 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 Venus Eagle at (703) 308-8045. Address any questions on required generic data to the Special Review and Reregistration Division representative Jill Bloom at (703)308-8019.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

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

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

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

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

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

DCPA

LIST A

CASE 0270

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

TABLE OF CONTENTS

DCPA REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Ghulam Ali	Economic Analysis Branch
Dennis Szuhay	Biological Analysis Branch

Environmental Fate and Effects Assessment

Akiva Abramovitch	Environmental Fate and Groundwater Branch
Michael Davy	Environmental Risk Characterization Branch
Janice Jensen	Policy and Special Projects Staff
Sharlene Matten	Science Analysis and Coordination Staff
Daniel Rieder	Environmental Risk Characterization Branch
Stephanie Syslo	Environmental Risk Characterization Branch

Health Effects Assessment

Kathryn Boyle	Risk Characterization and Analysis Branch
Jeff Evans	Occupational and Residential Exposure Branch
Peg Perreault	Occupational and Residential Exposure Branch
William Smith	Reregistration Support Chemistry Branch
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Linda Taylor	Toxicology Branch II
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Registration Support Risk Assessment

Tom Ellwanger	Registration Support Branch
Joanne Miller	Fungicide-Herbicide Branch
Eugene Wilson	Fungicide-Herbicide Branch

Risk Management

Judith Coombs	Reregistration Branch
Margery Exton	Reregistration Branch
Eric Feris	Reregistration Branch
Sherell Sterling	Reregistration Branch
Walt 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
FQPA	Food Quality Protection 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
μg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
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 © 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.
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 DCPA (dimethyl tetrachloroterephthalate) which is commonly known by the trade name "Dacthal."

BACKGROUND

DCPA, an herbicide, was originally registered under FIFRA in 1958 for use on turf grasses for the selective preemergence control of crabgrass and other assorted weeds. Today, there are 72 FIFRA Section 3 registrations and 11 FIFRA Section 24(c) registrations - totaling 83 product registrations. DCPA is used for selective preemergence weed control on ornamental turf and plants, strawberries, seeded and transplanted vegetables, cotton, and field beans.

A Registration Standard was issued for DCPA in June of 1988. At that time, the Agency required additional data in the areas of product chemistry, residue chemistry, environmental fate, toxicology, and ecological effects to continue the registration of pesticide products containing DCPA as an active ingredient. The DCPA technical grade active ingredient was subject to a 1987 Data Call-In requiring analysis for possible dioxin/furan contamination. A DCI was also issued on September 28, 1992 requiring DCPA occupational exposure monitoring data. This RED document represents a complete review of the data which has been submitted in response to the Registration Standard and both the 1987 dioxin/furan and 1992 DCPA DCIs.

REREGISTRATION ELIGIBILITY

The Agency is unable to make an eligibility decision for the use of DCPA on turf at this time. The Agency has identified several risks of regulatory concern, and will be undertaking a full benefits assessment before determining whether this use is eligible for reregistration. The risks of concern include carcinogenic risk to children playing on lawns post-treatment, carcinogenic risk through contaminated drinking water, chronic risks to wild mammalian species, including endangered species, and acute risks to freshwater and estuarine mollusks, including endangered species. The Agency will refine the risk estimates associated with the turf use, since a final report regarding groundwater contamination associated with the use of DCPA on turf is expected during the summer of 1996.

The Agency has determined that all remaining currently registered uses of DCPA, with the labeling changes required in Section V of this document, do not pose an unreasonable risk to humans or the environment and are eligible for reregistration.

HEALTH EFFECTS

The Agency's Carcinogenicity Peer Review Committee within the Office of Pesticide Programs has classified DCPA as a Group C (possible human) carcinogen. The estimated Q_1^* (a

measure of carcinogenic potential) of DCPA is 0.00149 $(mg/kg/day)^{-1}$. Dietary risk from exposure to DCPA and its two metabolites, tetrachloroterephthalic acid (TPA) and monomethyl tetrachloroterephthalic acid (MTP) was assessed using anticipated residues and percent crop treated data for multiple crops.

In the absence of a complete database on the metabolites, the Agency is assuming that the carcinogenic potential of the metabolites is the same as the parent compound. Therefore, the Q_1^* for DCPA is also used for its metabolites.

The resulting upper bound carcinogenic risk estimate for dietary exposure was 3.5×10^{-7}. The Agency generally considers dietary risks of 1×10^{-6} and less to be negligible, and thus does not pursue risk reduction measures for such risks. Based on this risk assessment, the Agency concludes that DCPA does not pose a significant cancer risk to the overall U.S. population from dietary exposure as currently registered.

The manufacturing process of DCPA produces several known contaminants. Of those of toxicological concern are hexachlorobenzene (HCB) and congeners (structurally related chemicals) of polyhalogenated dibenzo-p-dioxins/dibenzofurans (dioxins/furans). Carcinogenic risk was assessed for dietary exposure to HCB and dioxin/furans using Q_1^*s of 1.02 $(mg/kg/day)^{-1}$ and 1×10^5, respectively. Resulting dietary risk estimates are 7.1×10^{-7} for HCB and 7×10^{-8} for dioxin/furans. The Agency concludes that neither HCB nor dioxin/furans pose a significant cancer risk to the overall U.S. population through dietary exposure resulting from DCPA product use.

A chronic dietary risk assessment was performed to examine the most sensitive non-cancer endpoint observed for DCPA, which includes effects in the lungs, liver, thyroid, and thyroid hormones in rats of both sexes as well as the eyes of females rats. A Reference Dose (RfD) of 0.01 mg/kg/day was calculated using a 1.0 mg/kg/day No Observed Effect Level (NOEL) from a chronic rat study and an uncertainty factor of 100 to account for inter-species extrapolation and intra-species variability. When anticipated residues were used as well as percent of crop treated data, risk estimates did not exceed a level of concern for the general population or any population subgroup.

Chronic dietary (non-cancer) risk was also assessed for exposure to 2,3,7,8-TCDD and HCB resulting from DCPA product use. An RfD of 0.000001 ug/kg/day was calculated for 2,3,7,8-TCDD based on a LOEL of 0.001 ug/kg/day from a three generation feeding study in rats. An RfD of 0.0008 mg/kg/day was calculated for HCB based on a NOEL of 0.08 mg/kg/day from a 130-week feeding study in rats. Neither of the resulting risk estimates exceeded a level of concern for the general population or any subgroup.

Because one of DCPA's metabolites, TPA, is a frequently detected pesticide residue in groundwater, both chronic and carcinogenic risk estimates were calculated to assess exposure to DCPA and its metabolites through drinking water. The data from five geographic regions were

used to generate exposure scenarios. The greatest contamination was found at a turf site in New York, where the annual average contamination of DCPA and its metabolites was approximately 50 ppb. Exposure to this contamination level resulted in the highest risk estimates for both cancer and non-cancer risk.

The individual excess lifetime cancer risk estimate associated with the turf site is 1.7×10^{-6}. The Agency is undertaking a risk-benefit assessment to determine whether the turf use is eligible for reregistration. The groundwater contamination and cancer risk estimates associated with this use will be evaluated in context of the benefits of DCPA use on turf.
Once the benefits assessment has been completed, the Agency will make a final decision regarding the eligibility for reregistration of DCPA use on turf. The Agency will announce the eligibility decision through a Federal Register Notice, as an amendment to this document.

The second highest carcinogenic risk estimate is based on data from Suffolk County, New York. The risk estimate from that site is 9.7×10^{-7}. DCPA's registrant has voluntarily withdrawn from selling the product in Suffolk, New York. Exposure values from all other sites resulted in risks below the Agency's cancer benchmark of 1×10^{-6}.

Chronic drinking water risk is expressed as a percent of the RfD. The chronic drinking water risk estimate was 11 percent of the RfD at this site. Based on these estimates, the Agency concludes that DCPA and its metabolites do not currently pose a significant cancer or chronic non-cancer risk from non-turf uses to the overall U.S. population from exposure through contaminated drinking water.

OCCUPATIONAL AND RESIDENTIAL EXPOSURE

DCPA is currently registered for commercial and residential use. Risk assessments were performed to assess the individual excess lifetime cancer risk from DCPA and HCB resulting from occupational and residential exposure to DCPA. The Agency will not generally allow non-dietary risks to exceed 10^{-4}, except in cases where EPA has determined that benefits exceed the risks.

Risk was estimated for occupational exposures to both DCPA and HCB. The highest risk for both commercial applicators and private applicators is associated with the use of the wettable powder formulation. For the commercial applicator, the highest risk for DCPA was estimated to be 7.5×10^{-5} and for HCB (in DCPA) to be 1.9×10^{-4}. The Agency is requiring mixer/loader/applicators using DCPA wettable powders to wear a dust-mist respirator fitted with a TC-21 filter to mitigate this risk. Wearing a dust-mist respirator reduces the risks to 4.0×10^{-5} and 1.3×10^{-4} for DCPA and HCB respectively.

For the private applicator, the highest risk for DCPA was estimated to be 1.6×10^{-6} and for HCB (in DCPA) to be 4.6×10^{-6}.

Risks to children playing on a treated lawn were assessed for exposure to DCPA and HCB. The risks from DCPA and HCB to children playing on an irrigated lawn are 5.6 x

10^{-7} and 3.9 x 10^{-7}, respectively. The risks from DCPA and HCB to children playing on non-irrigated lawns are 2.0 x 10^{-6} and 2.7 x 10^{-6}, respectively. The Agency is conducting a risk/benefit assessment to determine whether the turf use is eligible for reregistration. However, in the interim, the Agency is requiring that residential lawns be watered after DCPA product use and that reentry not occur until sprays have dried, in an effort to mitigate risks to children.

Risk from exposure to DCPA and HCB through worker reentry into a cucumber field was assessed. Harvesting cucumbers immediately after application resulted in risk estimates of 1.8 x 10^{-4} for DCPA and 3.2 x 10^{-4} for HCB. Delayed reentry periods only minimally reduced risk estimates. However, the Agency believes that the worker exposures are overestimates. These scenarios were based solely on a foliar dissipation study, not on dermal exposure studies. DCPA's registrant is a member of a task force which will address dermal exposure for hand labor tasks required by various crops, such as cucumber harvesting. The risk assessment will be refined when the task force submits it dermal exposure data.

ENVIRONMENTAL FATE AND ECOLOGICAL EFFECTS

Ecological effects risk assessments indicate that there may be a concern for endangered mammals and mollusks exposed to DCPA. Since the Agency is developing an Endangered Species Protection Program designed to minimize harm to endangered species from pesticide use, the Agency is not requiring specific mitigation measures in this document.

The Agency concludes that non-turf uses of DCPA, labeled and used as specified in this document, will not pose unreasonable risks to birds, insects, fish and estuarine species, or nontarget plants. However, the Agency is requiring additional data in the areas of avian toxicity and reproduction, vegetative vigor, and seedling emergence to confirm these conclusions. The Agency has concerns regarding chronic risks to mammalian species and acute risk to mollusk species as a result of DCPA use on turf. Once the benefits assessment on turf has been completed, the Agency will determine whether this use is eligible for reregistration.

The Agency has concerns about contamination of groundwater by DCPA soil metabolites. The registrant has voluntarily agreed to limit the manufacture of DCPA technical grade active ingredient for use within the United States to current production levels. This will help to ensure that groundwater contamination rates do not significantly increase in the future. Since DCPA is produced intermittently, the production limit will be set at the average of the last three production campaigns, allowing for a 5% variance. The Agency will enforce this production cap through review of manufacture data which the registrant is required to submit under FIFRA, Section 7. The registrant will produce no more than the agreed upon limit every 3 calendar years, beginning in January, 1997.

A final report regarding leaching of DCPA and its metabolites to groundwater is due to the Agency during the summer of 1996. Once that data has been reviewed, the Agency will reassess potential drinking water risk and evaluate the need for additional groundwater protection

measures.

The Agency is continuing to require all DCPA products to bear a groundwater advisory statement. Through the reregistration process, the Agency has also identified concerns for the contamination of surface water by DCPA. Consequently, the Agency is requiring all DCPA products to bear a surface water advisory statement as well.

TOLERANCE REASSESSMENT

Sufficient data were available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.185(a) and §180.185(b) for those crops for which the use of DCPA is being supported. New tolerances will be needed for parsley, cowpea (forage and hay), and cotton gin, byproducts under §180.185 and §180.185(b). The registrant is being required to submit residue data on parsley, cowpea (forage and hay), and cotton gin, byproducts. However, in lieu of tolerances on cowpea commodities, the registrant may restrict the use of DCPA on beans to those varieties that are used for human consumption only.

Tolerances for animal commodities have not been established. The available ruminant metabolism and poultry feeding studies indicated that tolerances may be needed. The need for tolerances for animal commodities will be determined following review of the required data on poultry metabolism and ruminant feeding studies.

During the Agency's reregistration process, the registrant decided not to support the use of DCPA on lettuce, soybeans, corn, and rutabagas. The use of DCPA on these four crops has been voluntarily cancelled. Normally, once a pesticide use is no longer registered in the U.S., the related pesticide residue tolerance is no longer needed. It is the Agency's policy to propose revocation of a tolerance following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. The Agency has the responsibility under FFDCA to revoke a tolerance on the grounds that the Agency cannot conclude that the tolerance is protective of public health.

However, in the case of DCPA, the Agency is not seeking revocation of these tolerances, as it normally would under the above policy. The registrant is supporting rotational crop tolerances for these four commodities, thereby allowing DCPA residues which result from use on registered crops previously grown in the same field. The reassessed tolerances will be determined once field rotational crop residue data has been submitted to the Agency and reviewed. Subsequently, the tolerances of DCPA on these four commodities may be significantly reduced.

The Agency recognizes, however, that interested parties may want to retain a tolerance which is higher than the rotational crop tolerance (yet to be determined) in the absence of a U.S. registration, to allow legal importation of treated food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, the Agency requires the same product chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are

required to support U.S. food use registrations and any resulting tolerances. In addition, the Agency requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that the Agency requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance.

Parties interested in supporting an existing DCPA tolerance as an import tolerance should ensure that all of the data noted above are available to the Agency, so that the Agency may determine whether maintenance of the tolerance would be protective of the public health.

PRODUCT REREGISTRATION

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

I. INTRODUCTION

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of DCPA. The document consists of six sections. Section I is the introduction. Section II describes DCPA, 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 DCPA. Section V discusses the reregistration requirements for DCPA. 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(s) are covered by this Reregistration Eligibility Decision:

!	**Common Name:**	DCPA, or chlorthal dimethyl
!	**Chemical Name:**	Dimethyl tetrachloroterephthalate
!	**Chemical Abstracts Index Name:**	1,4-Benzenedicarboxylic acid, 2,3,5,6-tetrachloro-,dimethyl ester
!	**Chemical Family:**	Chlorinated Benzoic Acids
!	**CAS Registry Number:**	1861-32-1
!	**OPP Chemical Code:**	078701
!	**Empirical Formula:**	$C_{10}H_6Cl_4O_4$
!	**Trade and Other Names:**	Dacthal®
!	**Basic Manufacturer:**	ISK Biosciences 5966 Heisley Road, #8000 Mentor, Ohio USA 44061-8000

B. Use Profile

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

Type of Pesticide: A pre-emergent herbicide used to control annual grasses and broadleaf weeds.

Use Sites: Terrestrial Food Crops: beans, beans (succulent, snap), beets, broccoli, Brussels sprouts, cabbage, cauliflower, cole crops, collards, cress (garden) cucumber, eggplant, garlic, kale, melons (cantaloupe, honeydew, and water), mustards, onion, peas (southern), pepper, radish, squash (all or unspecified), strawberry, sweet potato, tomato, turnip, and yam.

Terrestrial Food and Feed Crops: beans, beans (dried-type), bean (mung), beans (succulent, lima) beans (succulent, snap), beets, eggplant, mustard, peas (southern), pepper, potato (white/irish), tomato, turnip, and yam.

Terrestrial Feed Crops: alfalfa

Terrestrial Non-Food and Outdoor Residential Sites: ornamental and/or shade trees, ornamental herbaceous plants, ornamental lawns and turf, ornamental nonflowering plants, ornamental woody shrubs and vines.

Weeds Controlled: Broadleaves: black nightshade, burning nettle, carpetweed, cheeseweed, common chickweed, common lambsquarters, dodder, field pansy, Florida pusley, groundcherry, nodding spurge, prostrate knotweed, prostrate spurge, purple deadnettle, purslane, redroot pigweed, whombic copperleaf, spotted deadnettle, spotted spurge, and Virginia copperleaf.

Grasses: annual bluegrass, barnyardgrass, browntop panicum, goosegrass, green foxtail, Johnsongrass (free seed), large crabgrass, lovegrass, sandbur, smooth crabgrass, witchgrass, and yellow foxtail.

Weeds Suppressed: Broadleaves: annual sowthistle, curley dock (from seed), henbit, ladysthumb, London rocket, nettleleaf goosefoot, polypogon, shepherdspurse, silversheath knotweed, wild buckwheat, and witchweed.

Grasses: giant foxtail, littleseed canarygrass, rabbitfoot fall panicum, Texas panicum, and vaseygrass.

Formulation Types Registered: All currently registered DCPA products are single active ingredient (AI) Formulations:
20.7% AI emulsifiable concentrate
54.9% AI flowable concentrate
1.15% to 10% AI granular
6% AI soluble concentrate/liquid
25% and 75% AI wettable powder
20.7%, 75%, and 90% AI formulation intermediates

Method and Rates of Application:

Emulsifiable Concentrate Formulations: Apply to agricultural crops at planting, transplant, post-emergence, or post-transplant as soil treatment using sprayer or

sprinkler can at .125 gal product/1000 square feet; or apply to strawberries in early fall or early spring as soil treatment using sprayer or sprinkler can at .1016 gal product/1000 square feet; apply to ornamental plants in early spring, late spring, late fall, late winter, post-emergence, or post-transplant as soil treatment using sprayer or sprinkler can at .125 gal product/1000 square feet; or apply to ornamental lawns and turf in early fall or late summer as soil treatment using sprayer or sprinkler can at .1693 gal product/1000 square feet.

Flowable Concentrate Formulations: Apply to ornamental plants in early spring, early fall, or late summer via irrigation at up to 12 lb AI/A; or apply (e.g. to ornamental lawns and turf) in early spring, early summer, or early fall as soil treatment using sprayer at up to 15 lb AI/A.

Granular Formulations: Apply to agricultural crops at planting or post-plant as broadcast or soil treatment using spreader or sprinkler can at up to 10 lb AI/A; or apply at planting, post-emergence, foliar, at layby, or at transplant using spreader or shaker can at .2 lb AI/1000 square feet; or apply at planting, at transplant, post-plant, post-transplant, or seed bed using spreader or shaker can at up to 10.5 lb AI/A; or apply at planting as broadcast using spreader, sprayer, or shaker can at 10 lb AI/A; apply at planting, transplant, or post-transplant as soil treatment using spreader at 11 lb AI/A; or apply as foliar broadcast at .2 lb AI/A; or apply to ornamental plants at planting, early spring, late summer, fall, early fall, or nurserystock as broadcast using spreader or shaker can at .2 to .347 lb AI/1000 square feet; or apply as broadcast at up to 10 lb AI/A; or apply to ornamental lawns and turf in late summer, early fall, or late fall as soil treatment using spreader or shaker can at up to 15 lb AI/A.

Wettable Powder Formulations: Apply to agricultural crops at planting, early spring, layby, foliar, or transplant as soil treatment (includes soil incorporation) using aircraft, spreader, shaker can, or irrigation at up to 10.5 lb AI/A; or apply to strawberries early spring, summer, early fall, or transplant using soil incorporate via spreader or aircraft or use irrigation at up to 9 lb AI/A; or apply to ornamental plants in spring, late summer, or late fall as broadcast using sprayer, or apply in April, early spring, late summer, nurserystock, or transplant as soil treatment via aircraft, or sprayer, or use irrigation at up to 12 lb AI/A; or apply to ornamental lawns and turf in late summer or early fall as broadcast using sprayer, or as soil treatment via aircraft, or sprayer, or use irrigation at up to 15 lb AI/A.

Use Practice Limitations: (these do not apply to all uses on all products)

* Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).
* Do not apply directly to water or wetlands.
* Do not apply directly to water.

* Do not apply through any type of irrigation system.
* Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).
* Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
* Do not feed clippings to livestock.
* Do not feed treated foliage to livestock or graze treated areas.
* Do not feed treated screenings or hay to livestock.
* Do not graze livestock in treated areas.
* Do not graze or feed forage, silage or fodder (stubble) from treated fields to dairy animals.
* Do not graze treated areas or feed crop refuse to livestock.
* Do not graze treated areas or use clippings from treated areas for feed or forage.
* Do not graze treated areas.
* For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
* Groundwater restriction.
* Keep out of lakes, streams, and ponds.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of DCPA. These estimates are derived from a variety of published and proprietary sources available to the Agency for 1988-1994. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

DCPA is registered and labeled for use on the following crops for which there is no reported usage: alfalfa, beans (succulent, snap) beets, cress (garden) kale, mustards, turnip, and yam. Although not registered uses, DCPA tolerances are being maintained for four additional crops which are sometimes grown in fields previously treated with DCPA. Those crops are: lettuce, soybeans, corn, and rutabagas. Table 1 below summarizes the use of DCPA by crop for the remaining registered uses.

Table 1: Typical Annual Usage and Percentage of Various U.S. Crops Treated with DCPA

Crop Name	Acres Grown /Harvested[a] (000)	Acres Treated[b] (000) (Range)		Percentage of Acres Treated[c] (Range)		Active Ingredient[c] (000 Lbs A.I.) (Range)		Percentage of Total A.I. (Range)	
BROCCOLI	110	55	83	50	61	230	300	14.29	20.91
BRUSSELS SPROUT	5	0	1	---	1	1	2	0.10	0.09
CABBAGE	91	18	23	18	24	30	50	2.38	2.73

Crop Name	Acres Grown /Harvested[a] (000)	Acres Treated[b] (000) (Range)		Percentage of Acres Treated[c] (Range)		Active Ingredient[c] (000 Lbs A.I.) (Range)		Percentage of Total A.I. (Range)	
CANTA-LOUPE	111	1	2	1	3	1	2	0.10	0.09
CAULI-FLOWER	55	14	36	26	36	50	100	4.76	4.55
COLLARDS	16	6	8	41	50	30	40	1.90	2.73
CUCUMBER	172	2	3	---	1	2	3	0.14	0.18
EGGPLANT	3.4	0	0	1	3	1	2	0.10	0.09
GREEN BEANS	306	3	6	---	1	1	2	0.10	0.09
GARLIC	26	1	1	1	2	3	4	0.19	0.27
HOT PEPPERS	51	8	10	16	24	25	30	1.43	2.27
HONEYDEW	26	0	1	1	2	1	2	0.10	0.09
ONIONS	157	55	79	38	63	300	750	35.71	27.27
PEPPERS (BELL)	68	1	1	1	2	1	3	0.14	0.09
POTATOES	1,379	14	28	---	1	2	3	0.14	0.18
RADISHES	30	0	2	1	2	2	3	0.14	0.18
SQUASH	69	3	7	5	10	25	30	1.43	2.27
STRAW-BERRIES	51	1	5	8	12	5	50	2.38	0.45
SWEET POTATOES	83.1	---	6	---	7				
TOMATOES	450	5	9	---	1	10	20	0.95	0.91
WATER-MELON	246	2	5	---	1	1	2	0.10	0.09
SEED CROPS	1,516	15	30	1	2	150	250	11.90	13.64
GOLF COURSES	1,445	29	43	2	3	150	300	14.29	13.64
SOD FARMS	152	8	15	5	10	75	150	7.14	6.82
TOTAL		0	0			1,100	2,100		

[a] Three years 1992-1994 or 1991-1993 average (with some 1992 data when available) is reported. Sources: USDA. Crop Production, 1994 Summary, January 1995; USDA. Vegetables 1994 Summary, January 1995; Department of Commerce. 1992 Census of Agriculture, Part 1, Volume 1, October 1994; EPA Proprietary Sources; Gianessi L. P. and Anderson J. E. (National Center for Food and Agricultural Policy) Pesticide Use in U.S. Crop Production, February 1995.

[b] Acres Treated is calculated by multiplying the Acres Grown by the Percentage of Acres Treated.

[c] Sources: EPA Proprietary Sources; Gianessi L. P. and Anderson J. E. (National Center for Food and Agricultural Policy) Pesticide Use in U.S. Crop Production, February 1995; State of California. Pesticide Use Report, Annual 1990; USDA. Agricultural Chemical Usage, 1993 Field Crop Summary, March 1994; USDA. Agricultural Chemical Usage, 1992 Field Crop Summary, March 1993; USDA. Agricultural Chemical Usage, Vegetables 1992 Summary, June 1993.

D. Data Requirements

Data requested in the June 1988 Registration Standard for DCPA include studies on product chemistry, ecological effects, environmental fate, and residue chemistry, toxicology, and occupational and residential exposure. These data were required to support the uses that were listed in the Registration Standard. Appendix B of this document includes all data requirements reviewed to support decisions in this reregistration document.

E. Regulatory History

DCPA was first registered under FIFRA in 1958 for use on turf grasses as an herbicide for the selective preemergence control of crabgrass and other assorted weeds. The DCPA Registration Standard ("EPA Guidance for Reregistration of Pesticide Products Containing DCPA as the Active Ingredient"), was issued in June, 1988. In the 1988 Registration Standard, the Agency listed the data required for continued registration of pesticide products that were manufactured with DCPA. Timeframes for submitting the required data to continue the registration of these products were set forth in that document. In addition, labeling amendments were required to bring all registered DCPA pesticide products into compliance with existing labeling policy of the Agency.

Today, there are 60 FIFRA Section 3 registrations and 6 FIFRA Section 24(c) registrations totalling 66 product registrations. There are presently two manufacturing use products from which all other products are formulated. ISK Biotech Corporation is the registrant of these manufacturing-use products - Dacthal 1.92F and 90% Dimethyl-T.

The DCPA technical products were subject to a June, 1987 Data Call-In Notice (DCI) requiring analysis for polyhalogenated dibenzo-p-dioxins/dibenzofurans (referred to as dioxin/furans). Data submitted by the registrant in response to the DCI reflected analysis of seven batches of technical DCPA for 15 dioxin/furans. To completely comply with the requirements of the 1987 DCI, ISK Biosciences must supply data reflecting analysis of duplicate samples spiked with each of the ^{13}C-labeled dioxin/furan standards at or below the EPA-required Level of Quantitation (LOQ) for the corresponding dioxin/furan analyte. The percent recoveries shall be 50-150% and relative percent differences (RPDs) shall be <20%. The registrant has indicated that two samples were sent for duplicate precision analysis in April of 1991. These data are considered confirmatory; no further dioxin analysis will be required to fulfill reregistration data requirements.

Additionally, the Agency's Environmental Chemistry Laboratory analyzed DCPA technical and end-use products for the presence of polyhalogenated dioxin/furans. One sample out of the 15 analyzed contained 2,3,7,8-TCDD at a level exceeding the Agency's specified Level of Quantitation (LOQ), 0.1 ppb. The registrant, ISK Biosciences, informed the Agency that the 75% FI sample which contained 2,3,7,8-TCDD had not been produced commercially in the plant, but had been formulated under laboratory conditions to fulfill the Agency's requirement for product samples. The registrant stated that the sample was not representative of the DCPA

products currently produced by ISK Biosciences.

DCPA formulations contain hexachlorobenzene (HCB) as an impurity. The Registration Standard required analytical data to determine residues of HCB in/on representative test crops. HCB data, submitted from field trials with representative commodities, indicated that no residues of HCB were present at greater than 1 ppb as the result of a 1x application of DCPA.

Because of TPA's potential to leach to groundwater, the Agency issued a Groundwater Advisory notice in 1992 which required all DCPA end-use products to bear the following statement:

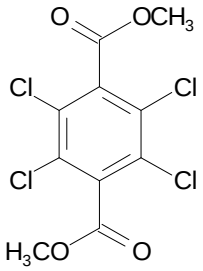
> Tetrachloroterephthalic acid, a breakdown product of Dacthal, is known to leach through soil as a result of agricultural and turf uses and has been found in groundwater which may be used for drinking water. Users are advised not to apply Dacthal to sand or loamy sand soils where the water table (groundwater) is close to the surface and where those soils are very permeable, i.e. well drained. Your local agricultural agencies can provide further information on the type of soil in your area and the location of groundwater used for drinking water.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Description of Chemical

DCPA (dimethyl tetrachloroterephthalate) is a pre-emergent herbicide used to control annual grasses and broadleaf weeds. The molecular structure of DCPA is illustrated below in figure A.



Other identifying characteristics and codes for the chemical are:

Empirical Formula: $C_{10}H_6Cl_4O_4$
Molecular Weight: 332

2. Identification of Active Ingredient

Technical DCPA is a colorless or white crystal with a melting point of 155° C and a bulk density of 0.75 g/cm^3. It is soluble in water at only 0.5 ppm at 25° C. Relative solubility of organic solvents is as follows: benzene>toluene>xylene>dioxane>acetone>carbon tetrachloride (25° C).

3. Manufacturing-Use Products

There are three DCPA manufacturing-use products (MPs) registered to ISK Biosciences Corporation (formerly Fermenta ASC Corporation): a 20.7% formulation intermediate (FI; EPA Reg. No. 50534-187), a 75% FI (EPA No. 50534-20), and a 90% FI (EPA Reg No. 50534-113). There is also a 98% minimum technical (T; EPA File Symbol No. 50534-ROA) which is currently in the initial registration process.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on DCPA is adequate for making reregistration eligibility decisions.

a. Acute Toxicity

Acute toxicity values and categories for DCPA are summarized in Table 2.

Table 2: Acute Toxicity Data[a]

TEST	RESULTS	CATEGORY
Oral LD50--rat	>5000 mg/kg	IV
Dermal LD50--rabbit	>2000 mg/kg	III
Inhalation LC50--rat	>4.48 mg/L	III
Eye irritation--rabbit[a]	mild irritation	III
Dermal irritation--rabbit[a]	mild irritation	IV
Dermal sensitization--guinea pig[a]	not sensitizing	--

[a] The dermal sensitization test was performed with a 90% technical material. All other acute toxicity tests were performed using a 98% and a 90% technical material. The reported values are the results from testing the 98% technical.

b. Subchronic Toxicity

In a 21-day dermal toxicity study, Charles River CD rats were dermally exposed to DCPA doses of 0, 100, 300, or 1000 mg/kg/day. No dermal irritation at the site of application was observed. No adverse effects were found; therefore, the NOEL was equal to or greater than 1000

mg/kg/day, the highest dose tested (GLN 82-2; MRID 41231803).

CD VAF/Plus Sprague Dawley rats were given 0, 10, 50, 100, 150, or 1000 mg/kg/day of DCPA in the diet for 90 days. The NOEL was 10 mg/kg/day. The LOEL was 50 mg/kg/day, based on increased liver weight and microscopic effects. The treatment-related effects were: increased weight and centrilobular hypertrophy in the liver; increased accumulation of foamy macrophages in the lung; increased weight, epithelial hyperplasia, and tubular hypertrophy of the kidney; and follicular hypertrophy of the thyroid. There were slight decreases in body weight and food consumption in high dose females only (GLN 82-1; MRID 41767901).

Male CD-1 mice were given doses of 0, 100, 199, 406, or 1235 mg/kg/day DCPA and females were given 0, 223, 517, 1049, or 2198 mg/kg/day DCPA in the diet for 90 days. There were no effects other than minimal histopathological effects on the liver. The NOEL was 406 mg/kg/day for males and 517 mg/kg/day for females. The LOEL for males was 1235 mg/kg/day and for females was 1049 mg/kg/day, based on the liver effects (GLN 82-1; MRID 41064801).

c. Chronic Toxicity and Carcinogenicity

Beagle dogs were given 0, 2.5, 25, or 250 mg/kg/day DCPA in the feed for two years. Adverse effects were not found. Therefore, the NOEL was equal to or greater than 250 mg/kg/day (GLN 83-1; MRID 00083584).

A chronic toxicity and carcinogenicity study was conducted with Sprague Dawley CD rats. The doses of DCPA given in the diet for two years were 0, 1,10, 50, 500 or 1000 mg/kg/day. The NOEL was 1 mg/kg/day. The LOEL was 10 mg/kg/day, with effects observed in the lungs, liver, and thyroid; decreases in thyroid hormone levels in both sexes; and effects in eyes in females. The specific effects were: (1) increased mortality in males at 1000 mg/kg/day (HDT) during the second year; (2) either decreased body weights or decreased body weight gains in both sexes at 1000 mg/kg/day, and in females at 500 mg/kg/day; (3) changes in hematology and clinical chemistry parameters indicative of liver and kidney toxicity at both 500 and 1000 mg/kg/day in both sexes; (4) treatment-related increases in thyroid, liver, and kidney weights in both sexes; (5) a dose-related increase in white foci in the lungs, which correlated with an increased incidence of foaming macrophages in both sexes at doses of 10 mg/kg/day and higher; (6) treatment-related exacerbation of chronic nephropathy in both sexes at 50 mg/kg/day and higher; (7) a dose-related increase in centrilobular hepatocytic swelling in both sexes at doses of 10 mg/kg/day and higher; (8) a dose-related increase in liver neoplasms in females; (9) an increase in follicular cell hyperplasia/hypertrophy at 10 mg/kg/day in males and at doses of 50 mg/kg/day and higher in both sexes; (10) decreased T_4 (thyroid hormone/thyroxine) values at 10 mg/kg/day in males, and at 50 mg/kg/day and higher in both sexes; and (11) a treatment-related increase in thyroid follicular cell neoplasms in both sexes (GLN 83-5; MRID 42731001).

In another combined chronic toxicity and carcinogenicity study, CD-1 mice were given DCPA in the diet for two years. The doses were 0, 12, 123, 435, or 930 mg/kg/day DCPA in the

diet for males and 0, 15, 150, 510, or 1141 mg/kg/day for females. The NOEL for systemic effects was 435 mg/kg/day in males; 510 mg/kg/day in females. The systemic LOEL was 930 mg/kg/day in males; 1141 mg/kg/day in females, based on liver effects. There were increased liver weights, increased SDH (sorbital dehydrogenase) and GPT (glutamic-pyruvic transaminase) activities, and increased incidence of hepatocyte enlargement or vacuolation in both sexes at the high dose levels; 930 and 1141 mg/kg/day for males and females, respectively. There was a significant increase in hepatocellular neoplasms in females at the high dose level of 1141 mg/kg/day. Corneal opacity was observed in this study (GLN 83-5; MRID 40958701).

Additionally, a supplementary rat chronic ophthalmology study was conducted to investigate the corneal opacity observed in the mouse study. There was no evidence of ocular toxicity observed in rats fed DCPA in the diet at levels up to 1000 mg/kg/day for two years (MRID 41750102).

d. Developmental Toxicity

A developmental toxicity study with Sprague Dawley rats used doses of 0, 500, 1000, or 2000 mg/kg/day given by gavage on gestation days 6-15. No adverse effects on the maternal rats or their offspring were observed. Therefore, the maternal and developmental toxicity NOELs were set at 2000 mg/kg/day, HDT (GLN 83-3; MRID 00160685).

Two studies were conducted with New Zealand white rabbits. In the first study, DCPA doses of 0, 500, 1000, or 1500 mg/kg/day were given by gavage on gestation days 6-19. There were maternal deaths and adverse clinical signs at all dose levels. In the second study, DCPA doses of 0, 125, 250, or 500 mg/kg/day were given by gavage on gestation days 7-19. None of these levels produced any maternal or developmental toxicity. The second study tested dose levels that overlapped those in the first study. Therefore, when considered together, the NOEL for maternal toxicity can be set at 250 mg/kg and the LOEL can be set at 500 mg/kg based on maternal deaths. The developmental toxicity NOEL can be set at 500 mg/kg. Although no developmental effects were observed at any of the higher dose levels, a higher NOEL cannot be set based on the limited number of litters at the higher dose levels. (The two studies together fulfill GLN 83-3; MRID 41054820, 41838301).

e. Reproductive Toxicity

In a two generation reproduction study, female Sprague Dawley rats were fed DCPA at doses of 0, 63, 319, or 1273 mg/kg/day while males received doses of 45, 233, or 952 mg/kg/day DCPA. (These doses were equivalent to 0, 1000, 5000, and 20,000 ppm food residue values, which are used for mammalian risk assessment in the Section III under Environmental Assessment.) No effects on reproductive performance in 2 generations with 2 litters per generation were seen. The maternal NOEL was 63 mg/kg/day. The maternal LOEL was 319 mg/kg/day, based on decreased body weight/body weight gain. The reproductive NOEL was 63 mg/kg/day. The LOEL was 319 mg/kg/day, based on decreased pup body weight. The paternal

NOEL was set at 233 mg/kg/day, and the LOEL was set at 952 mg/kg/day due to decreased body-weight gain. On day 0 of the F_{2b} litters, the diets for the low and mid-dose groups were changed to 18 and 47 mg/kg/day respectively to be able to set a NOEL for pup body weight. The offspring NOEL was set at 18 mg/kg/day (200 ppm), and the LOEL was 47 mg/kg/day (500 ppm) based on decreased body weight. (GLN 83-4; MRID 41750103, 41905201).

f. Mutagenicity

DCPA did not induce a mutagenic response in two independently performed mouse lymphoma forward mutation assays. The nonactivated concentration range was 7.5 to 100 μg/mL and the S9-activated range was 15 to 200 μg/mL (GLN 84-2(a) Category I; MRID 41054822).

In an *in vitro* cytogenetic assay, Chinese hamster ovary cells were exposed to DCPA at dose levels of 0, 30, 100, 300, or 1000 μg/mL for 4 hours both with and without S-9 activation. Cells were harvested at 12 and 18 hours. There were no indications of a clastogenic response as a result of exposure to test material at any dose level. (GLN 84-2(b) Category II; MRID 41054823).

DCPA was not genotoxic in two independently performed unscheduled DNA synthesis (UDS) assays in which the concentration ranged from 3 to 1000 μg/mL (GLN 84-2(b) Category III; MRID 41054824).

An *in vitro* assay for sister chromatid exchange (SCE) in Chinese hamster ovary cells was performed at dose levels of 0, 38, 75, 150, or 300 μg/mL both with and without S9-activation. There was no indication of a positive response; therefore, under the conditions of this assay the test material is negative (GLN 84-2(b) Category III; MRID 41054825).

g. Metabolism

In one study, a single oral dose of ^{14}C-DCPA at either 1 or 1000 mg/kg was given to Sprague-Dawley rats (5 rats/sex/dose level). The major metabolite of DCPA in the urine of both sexes at both dose levels was 4-carbomethoxy-2,3,5,6-tetrachlorobenzoic acid. No radiolabel was excreted in the urine as the parent compound, DCPA. (MRID 42155501)

There was a second study in which a single oral dose of ^{14}C-DCPA at either 1 or 1000 mg/kg was given to Sprague-Dawley rats. Bile was found to be a negligible excretory route for radiolabeled DCPA. At the low dose, 61% of the administered radiolabeled DCPA was excreted in the urine. The percent absorption (urine, blood, bile, cage rinse, and carcass) was 79% of the administered dose. At the high dose, 55 % of the administered radiolabel was excreted in the feces or was found in the GIT (gastro-intestinal tract). The percent absorption was 8% of the administered dose. (MRID 42155503)

There was a third study in which a single oral dose of ^{14}C-DCPA at either 1 or 1000

mg/kg was given to Sprague-Dawley rats (3 rats/sex/dose level) to determine the major route of excretion. Urine was the major route at the low dose, and feces was the major route at the high dose. Negligible amounts of radiolabel were found in the tissues examined at 48 hours following dosing. There were no significant differences observed between the sexes at either dose level. (MRID 42155502)

In a different study, nonradiolabeled DCPA was administered in single, daily oral doses to Crl:CD BR VAF/Plus rats (15 rats/sex/dose level) for 14 consecutive days at either the 1 or 1000 mg/kg/day dose level. Twenty four hours after the 14th dose, a single oral dose of ^{14}C-DCPA (1 or 1000 mg/kg) was administered to each rat. At the high dose level (both sexes), the majority of the administered ^{14}C-DCPA was unabsorbed and was eliminated in the feces, while at the low-dose level (both sexes) the majority of the administered ^{14}C-DCPA was absorbed and excreted in the urine. Radiolabel was found in all tissues examined, and the radiolabel concentration was higher in the high-dose rat tissue than in the same tissue at the low dose level. At 168 hours, radiolabel was still detectable in nearly all tissues at both dose levels and in both sexes. The elimination half-life of radiolabel was calculated to be 22-23 hours at the high dose and approximately 18 hours at the low dose. (MRID 42723201, 42723202)

In another study, Sprague-Dawley rats (5 rats/sex/dose level) were given single or multiple (14 days) oral doses of ^{14}C-DCPA (1 or 1000 mg/kg). The major metabolite of DCPA in the urine of both sexes at both dose levels following both single and multiple dosing was 4-carbomethoxy-2,3,5,6-tetrachlorobenzoic acid. A minor metabolite was tetrachloroterephthalic acid. No radiolabel was excreted in the urine as the parent compound, DCPA. (MRID 42723203) Together these studies fulfill GLN 85-1. (MRID 43052201)

h. Dermal Absorption

A study was conducted with male Sprague-Dawley rats using doses of 4.75, 47.5, 475.0 and 1000.0 ug/cm^2 of radiolabeled DCPA with a number of each dose group sacrificed at 0.5, 1.0, 2.0, 4.0, 10.0, and 24 hours. The area of the dermal application was washed to recover unabsorbed DCPA. The skin, blood, urine, feces, and carcass were analyzed for percent of total DCPA applied. At the 4.75 ug/cm^2 dosing level, for the group sacrificed at 10 hours, 14.9 % of the applied DCPA was absorbed. The percent absorption increased with duration of exposure and generally decreased with increasing dose. (MRID 42651502)

A complimentary study of radiolabeled HCB in DCPA with male Sprague-Dawley rats using dosing levels of 0.1%, 0.2%, and 0.3% (0.475, 0.950, and 1.425 ug/cm^2) was conducted. A number of each dose group was sacrificed at 0.5, 1.0, 2.0, 4.0, 10.0, and 24 hours. The area of the dermal application was washed to recover unabsorbed HCB. The skin, blood, urine, feces, and carcass were analyzed for percent of total HCB applied. At the 0.1% dosing level, for the group sacrificed at 10 hours, 26.46 % of the applied HCB was absorbed. The percentage of HCB that was removed during the washing procedure, as well as the percentage remaining in the skin at the application site decreased with duration of exposure. The percentage of HCB in the carcass

increased as the exposure duration increased. (MRID 42651501) These studies together fulfill GLN 85-2.

The Agency does not have dermal absorption data on dioxin/furans.

i. DCPA Reference Dose (RfD) and Cancer Potency Factor

Previously, the RfD for DCPA was determined to be 0.5 mg/kg/day based on a No Observed Effect Level (NOEL) of 50 mg/kg/day in a 1963 2-year rat study. DCPA's first RfD for DCPA was verified on February 18, 1987. However, as part of the re-registration process, newer information was submitted to the Agency, and it was decided to re-evaluate the RfD.

On 12/9/93 the Agency's Health Effects Division RfD Committee met and selected an RfD of 0.01 mg/kg body wt/day, based on a NOEL of 1.0 mg/kg/day in the chronic rat toxicity study (MRID 42731001, discussed in detail earlier). Effects were observed in lungs, liver, thyroid, and thyroid hormones in both sexes and the eyes in females at 10 mg/kg/day. An uncertainty factor of 100 was used to account for the inter-species extrapolation and intra-species variability. The current RfD was verified on February 17, 1994 by the Agency's Office of Research and Development, and entered into the Agency's Integrated Risk Information System (IRIS) in August 1994. The IRIS entry indicates that the principal study was well conducted receiving a high confidence level. The additional studies were considered to be of good quality and generally supportive of the principal study. Therefore, the DCPA database was given a high confidence rating which yields a logical conclusion of high confidence in the DCPA RfD.

The Carcinogenicity Peer Review Committee (CPRC) of the Office of Pesticide Programs discussed DCPA on 6/29/94 and 11/16/94. The CPRC classified DCPA as Group C, possible human carcinogen, based on evidence of increased incidence of thyroid tumors in both sexes of the rat (although only at an excessive dose in the female), and liver tumors in female rats and mice, at doses which were not excessive. It was recommended that a low dose extrapolation model be applied to the animal data for the quantification of human risk based on the combined liver tumors in the female rat liver.

DCPA's cancer potency factor was calculated using a multi-stage model (Tox_Risk Program, version 3.5). A 3/4's scaling factor is used to account for the body weight differences when extrapolating from rodent carcinogen bioassays to humans. There are several methodologies than can be used to produce good estimates of cancer potency in humans from rodent bioassays. EPA, the Food and Drug Administration, and the Consumer Product Safety Commission have all determined that the 3/4's scaling factor would be an appropriate default methodology. (Specific reasons for the selection and the use of the 3/4's scaling factor are specified in the June 5, 1992 Federal Register Notice.) The estimated Q_1^* $(mg/kg/day)^{-1}$ of DCPA is 1.49×10^{-3}.

The CPRC agreed that the manufacturing process impurities contained in DCPA may have

contributed to DCPA's tumor response. However, the CPRC also concluded that the tumors seen in these studies could not be attributed solely to the presence of either impurity HCB or 2,3,7,8-TCDD.

j. Hexachlorobenzene (HCB) as a DCPA Impurity

HCB is a recognized impurity in DCPA. The maximum level of HCB that is allowed in formulations of DCPA is 0.3 percent. Therefore, the risk assessments supporting this document assume that HCB is present at a level of 0.3 percent of DCPA in the food supply and in DCPA applied to a field.

The Agency has classified HCB as a B_2 (probable human) carcinogen, based on data sets which showed significant increases of tumor incidence in two species: hamsters and rats. In the IRIS database, the Q_1^* was 1.7 $(mg/kg/day)^{-1}$ calculated based on hepatocellular carcinomas in female Sprague-Dawley rats. However, since DCPA was calculated using the 3/4's scaling factor, the Q_1^* for HCB was modified by multiplying by 0.6 to account for the newer factor. The modified Q_1^* used in this risk assessment was 1.02 $(mg/kg/day)^{-1}$.

The RfD for HCB is 0.0008 mg/kg body wt/day based on a NOEL of 0.08 mg/kg/day in a 130 week feeding study in rats. (Effects observed were hepatic centrilobular basophilic chromogenesis.) An uncertainty factor of 100 was used to account for the inter-species extrapolation and intra-species variability.

The dermal absorption factor of HCB is 26.46% (see MRID 42651501 under Dermal Absorption). At this time no other toxicological endpoints of concern have been identified for HCB.

k. Polyhalogenated dibenzo-p-dioxins/dibenzofurans as DCPA Impurities

Polyhalogenated dibenzo-p-dioxins/dibenzofurans (dioxin/furans) are recognized impurities of DCPA. Of the dioxin/furans, only the 2,3,7,8-tetrachloro-dibenzo-para-dioxin (2,3,7,8-TCDD) congener has been assigned a quantified estimate of its carcinogenic potential. The Agency has classified 2,3,7,8-TCDD as a B_2 (probable human) carcinogen based on data sets which showed significant increases of tumor incidence in two species: Sprague-Dawley rats and B6C3F1 mice. The cancer potency factor Q_{1*} was calculated based on multiple tumor sites in the female Sprague-Dawley rats and is therefore estimated to be 1.56×10^5 $(mg/kg/day)^{-1}$. However, since DCPA was calculated using the 3/4's scaling factor, the Q_1^* for 2,3,7,8-TCDD was modified by multiplying by 0.6 to account for the newer factor. The modified Q_1^* used in this risk assessment was 1×10^5 $(mg/kg/day)^{-1}$.

Enough data exists, however, regarding the potency of the other congeners to estimate their relative potency in comparison to the 2,3,7,8-TCDD. Therefore, in evaluating the

toxicological significance of the dioxin/furan contamination, the Agency converts all of the congener detection values into one value which represents the equivalent 2,3,7,8-TCDD potency.

For example, if a product contained 10 ppb of a dioxin congener other than the 2,3,7,8-TCDD. If that congener is considered to be only 1/10 as potent as 2,3,7,8-TCDD, the Agency would use the equivalent of 1 ppb of 2,3,7,8-TCDD in its risk assessment.

DCPA's registrant submitted dioxin/furan detection values to the Agency from seven batch samples, as required in the 1987 DCI. During the first sampling, one of the dioxin/furan congeners was detected above the Agency specified Level of Quantitation (LOQ). The registrant subsequently altered their manufacturing process in an effort to reduce this contamination. (MRID 41241801)

Subsequent to this change, none of the dioxin/furan congeners were detected above Agency specified LOQs in the remaining six batch samples. The 2,3,7,8-TCDD equivalency of the dioxin/furans reported to the Agency is approximately 0.1 ppb, which would equal 0.00000001% of the DCPA formulations. The Agency used this contamination value (0.00000001%) to determine exposure values used in the risk assessments for DCPA's reregistration eligibility evaluation. The registrant must propose certified upper limits for all dioxin/furan congeners for which detection values were reported to the Agency.

The RfD for 2,3,7,8-TCDD is 0.000001 ug/kg/day based on a LOEL of 0.001 ug/kg/day from a three-generation feeding study in rats. (Effects at the lowest dose tested included dilated renal pelvises, decreased fetal weight, and changes in the gestational index). An uncertainty factor of 100 was used to account for the inter-species extrapolation and intra-species variability. An additional uncertainty factor of 10 was used to account for the lack of a NOEL. At this time, no other toxicological endpoints of concern have been identified for 2,3,7,8-TCDD.

l. Tetrachloroterephthalic Acid (TPA) as a DCPA Metabolite

Tetrachloroterephthalic Acid (TPA) is one of two DCPA animal metabolites. DCPA fed to lactating goats was metabolized into both TPA and monomethyl tetrachloroterephthalic acid (MTP). It is the TPA metabolite, however, that is found most frequently in the environment after DCPA use. Soil metabolism converts DCPA into TPA, which is known to leach through soil and pollute ground water. Therefore, the registrant submitted the following additional studies to specifically assess the toxicity of TPA.

Subchronic Toxicity

Disodium 2,3,5,6-tetrachloroterephthalic acid was given to Charles River CD rats in the diet for 13 weeks. There were 15 rats/sex/dose group using dose levels of 0, 2.5, 25, 50, or 500 mg/kg/day. There were no adverse effects in either sex at any dose level. The NOEL is greater

than or equal to 500 mg/kg/day, the highest dose tested. The LOEL cannot be determined. (GLN 82-1; MRID 00100773)

CD Sprague-Dawley rats (10/sex/dose group) were given 2,3,5,6-tetrachloroterephthalic acid via gavage for 30 days at dose levels of 0, 100, 500, or 2000 mg/kg/day. There were no apparent adverse effects observed at any dose level. The NOEL is greater than or equal to 2000 mg/kg/day, the highest dose tested. The LOEL cannot be determined. (MRID 00158011)

Developmental Toxicity

In a developmental toxicity study, 25 pregnant Charles River rats/dose group were dosed via gavage on gestation days 6 - 15 with TPA at dose levels of 0, 625, 1250, or 2500 mg/kg/day. The maternal toxicity NOEL was 1250 mg/kg/day. The maternal LOEL was set at 2500 mg/kg/day based on decreased body-weight gain and food consumption. There were no signs of developmental toxicity, therefore the developmental NOEL was set at 2500 mg/kg/day, the highest dose tested. A LOEL was not determined. (GLN 83-3(a); MRID 262303)

Mutagenicity

TPA did not induce a mutagenic response in the Ames assay or the HGPRT assay with or without metabolic activation. (GLN 84-2(a); MRID 262302) In the Sister Chromatid Exchange (SCE) assay, TPA did not induce a significant increase in the SCE frequency of Chinese Hamster Ovary cells, both with and without metabolic activation.

TPA did not induce an increase in unscheduled DNA synthesis. In an in vivo mouse micronucleus assay, TPA was negative for clastogenicity in females and at best equivocal in males. Based on the overall weight of evidence of no mutagenic response of this compound in other studies, as well as the lack of mutagenicity of the parent DCPA, further testing for mutagenicity is not warranted at this time.

2. Exposure Assessment

a. Dietary Exposure

Tolerances for residues of DCPA in or on raw agricultural commodities are currently expressed as the combined residues of DCPA and its metabolites monomethyl tetrachloroterephthalate (MTP) and tetrachloroterephthalic acid (TPA) calculated as DCPA. At present, no tolerances exist for residues of DCPA in animal commodities.

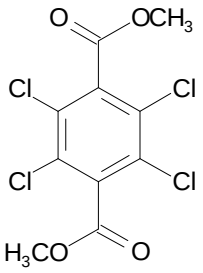
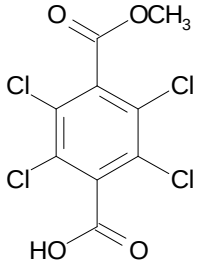
Although all the data requirements of the Reregistration Guidance have not been met at this time, the outstanding data are considered to be confirmatory to the reregistration eligibility decision. Sufficient data are available to conduct reasonable anticipated residue assessments.

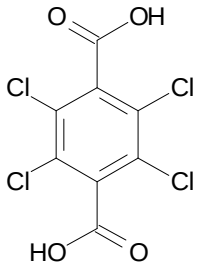
Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on acceptable studies on onions, turnips, and tobacco. The residues of concern in plants are DCPA, and its metabolites MTP and TPA which are the parent and metabolites that are currently regulated. (See Figure B below.) The proposed metabolism of DCPA in plants is via ester hydrolysis. Studies conducted with onion and turnip indicate that the impurity HCB is not metabolized appreciably in these plants.

Total radioactive residues (TRR) were 0.548 ppm in mature onion bulbs and 6.458 ppm in onion tops treated with ^{14}C-DCPA at 1x. DCPA and its metabolites, MTP and TPA, accounted for 66% and 79% of the TRR in onion tops and mature bulbs, respectively. TRR in mature turnip roots and tops were 4.732 and 2.015 ppm from 1x treatment with [^{14}C]DCPA. Combined residues of DCPA, MTP, and TPA accounted for 78-89% of the TRR in turnip roots and tops. In tobacco treated with ^{14}C-DCPA, TRR in whole plants were 21-23 ppm. DCPA, MTP, and TPA accounted for 91-98% of the radioactivity in tobacco.

Figure B: The Chemical Structure of DCPA and its Metabolites of Concern

Chemical name	Chemical structure
DCPA Dimethyl tetrachloroterephthalate	
MTP Monomethyl tetrachloroterephthalic acid	

Chemical name	Chemical structure
TPA Tetrachloroterephthalic acid	

Animal Metabolism

The nature of the residue in ruminants is adequately understood. DCPA, MTP, and TPA are the residues of concern. A lactating goat was dosed with ^{14}C-DCPA for 4 days. The daily dose was equivalent to 10 ppm in the diet, ~1x the theoretical maximum DCPA intake for dairy cattle and 2x the maximum beef cattle intake. Total radioactive residues (TRR) were less than or equal to 0.01 ppm in milk with 38.5% organosoluble (0.004 ppm). Milk residues were not further characterized. Residues in tissues were 0.0057 ppm in loin muscle, 0.0109 ppm in leg muscle, 0.0168 to 0.0179 ppm in fat, 0.0333 ppm in liver, and 0.1007 ppm in kidney. MTP was the predominant residue in kidney, liver, leg muscle, and fat, accounting for 80-98% of the TRR. The parent compound DCPA was detected only in fat at 10-15% of TRR. TPA was found only in omental fat at 5% of TRR. Until adequate cattle feeding studies are available, the data from this metabolism study will be used for estimating residues in meat and milk commodities.

The requirement for a poultry metabolism study has not been met, and remains in effect. Until these data are generated, the Agency will use the existing poultry feeding studies for exposure/risk assessment based on the assumption that the residues of concern in poultry tissues and eggs are the same as those delineated in meat and milk from the acceptable ruminant metabolism study.

Residue Analytical Methods - Plants and Animals

Three tolerance enforcement methods for plant commodities are published in the Pesticide Analytical Manual (PAM), Vol. II (Section 180.185), as Methods A, B, and C. Residue data submitted in response to the 6/88 Guidance Document were collected using GC/EC methods similar to the PAM, Vol. II methods. These methods are adequate for collection of DCPA, HCB, MTP, and TPA residue data from potatoes (including processed commodities), sweet potatoes, broccoli, celery, cucumbers, green and bulb onions, strawberries, sweet and bell peppers, cantaloupes, tomatoes (including processed commodities), summer squash, and processed commodities of beans and cottonseed. The limits of detection (LOD) are 0.01 ppm each for

DCPA, MTP, and TPA, and 0.0005 ppm for HCB. These methods are suitable candidates for validation procedures as enforcement methods for plant commodities.

Another GC/EC method, similar to those submitted for plants, is available for determining DCPA, MTP, and TPA in milk and beef fat. Recoveries of each compound using 12 samples each of milk and beef fat fortified at 0.01-5 ppm were acceptable. The LOD is 0.01 ppm. This method is suitable for Agency validation and inclusion in PAM, Vol. II pending successful independent laboratory validation. The registrant has indicated that independent laboratory validation of the method is underway. The registrant must submit independent laboratory validation data for enforcement method(s) for animal commodities and submit the method(s) for Agency validation and inclusion in PAM, Vol. II. Representative samples from adequate animal metabolism studies must be analyzed by preferred enforcement method(s) to ascertain their ability to adequately recover and quantify DCPA, MTP, and TPA.

DCPA *per se* is completely recovered using PAM, Vol. I Multiresidue Protocols D and E (PESTDATA, PAM, Vol. I, Appendix, 8/93). Data submitted by the registrant indicate that the TPA is not recovered by Protocols B and C. Multiresidue testing data on MTP are still required.

Storage Stability

The results of a storage stability study on tomato processed products demonstrated that residues of DCPA, MTP, and TPA are stable in these commodities during frozen storage for up to 3.5 years.

Adequate storage stability data on DCPA, MTP, TPA, and HCB residues are available for broccoli, peppers (sweet and bell), onions (green and bulb), radish (tops and roots), celery, succulent beans, and sweet potatoes. The available data from an ongoing 4-year storage stability study indicate that these compounds are generally stable for intervals of 12 to 24 months in frozen (-12 to -18 C) storage. The storage stability study on the above commodities encompassing storage intervals of up to 4 years (i.e., study completion) must be submitted.

Storage stability data supporting actual sample conditions and intervals of storage are required for all samples from residue studies used to support tolerances. Sample storage information is required to validate the residue studies.

These data are considered confirmatory to the existing evidence that residues of DCPA, MTP and TPA are stable in plant matrices during frozen storage.

Magnitude of the Residue in Plants

Provided that the required confirmatory storage stability data support studies reviewed for reregistration, all data requirements for the magnitude of DCPA and HCB residues in plants are adequate. Field trials have been performed representing the various conditions under which the

pesticide can be applied. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes have been conducted. Field trial data are required depicting residues of DCPA and its metabolites in/on cowpea forage hay. Alternatively, the registrants may restrict the use of DCPA on beans to varieties that are used for human consumption only. Because the Agency now considers cotton gin byproducts to be a feed commodity, data are required depicting residues of DCPA and its metabolites in/on cotton gin by-products. Once adequate data for the cowpea and cotton commodities have been submitted and evaluated, then suitable tolerances must be proposed.

Adequate HCB data were submitted from field trials with representative commodities from the following crop groups: leafy vegetables (celery), brassica leafy vegetables (broccoli), legume vegetables (beans), fruiting vegetables (tomatoes), small fruits and berries (strawberries), bulb vegetables (green onions), cucurbit vegetables (cucumbers, melons, and squash), and cottonseed. No residues of HCB were detected at $\geq$1 ppb (the required LOQ) as the result of a 1x application of DCPA; therefore, no additional HCB residue data are required.

Magnitude of the Residue in Processed Food/Feed

Processing studies have been conducted on beans, cottonseed, tomatoes, and potatoes. All data concerning the magnitude of the residue in processed food/feed commodities have been deemed adequate to determine the extent to which residues of DCPA concentrate in food/feed items upon processing of the raw agricultural commodity.

DCPA residues concentrate in wet (19x) and dry (35x) tomato pomace. The Agency no longer considers tomato pomace to be a significant animal feed. Therefore, no feed additive regulations are required.

DCPA residues also concentrate in succulent bean cannery waste (2x) and in dry potato peel (1.9x). The Agency no longer considers bean cannery waste a processed commodity; and presently uses only wet potato peel residue levels to set tolerances on potato waste. Therefore, no feed additive tolerances are necessary for beans and potatoes.

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

There are no established tolerances for DCPA residues in eggs, milk, animal fat, meat, and meat by-products. The maximum theoretical daily dietary intake of DCPA for cattle is approximately 10 ppm based on a dairy cattle diet consisting of 50% potato waste, 25% cottonseed, 15% bean seed, and 10% bean forage. In a 1963 cattle feeding study DCPA feeding levels of 200 and 20 ppm were used. At the 20 ppm feeding level, combined residues of DCPA, MTP, and TPA were nondetectable in milk and fat. Muscle, liver, and kidney were not analyzed. These existing cattle feeding studies are of limited usefulness because edible tissues were not analyzed. Furthermore, the data for milk and fat are inconsistent with the results of a recent goat metabolism study, indicating detectable DCPA residues in milk, fat, muscle, liver, and kidney from

a 10 ppm (1x) dosing level. The goat metabolism study indicates that tolerances are needed for DCPA and its metabolites in meat and milk. Therefore, a new cattle feeding study is needed to determine the appropriate tolerance levels. Until the new feeding studies are received, the data from the 1994 goat metabolism study will be used to estimate residues in meat and milk for purposes of a human dietary risk assessment.

Poultry feeding studies were conducted in 1973. Residues of DCPA, MTP and TPA were non-detectable in edible tissues from hens fed 4 ppm DCPA for 30 days. At the 10x feeding level (40 ppm) detectable combined residues were observed only in fat at 0.14 ppm. Combined residues in egg yolk from the 4 ppm feeding level were 0.07 ppm on day 21 of the study. At the 10x feeding level, 21-day egg yolk residues were 0.26 ppm. The existing data indicate that a tolerance for combined residues of DCPA, MTP, and TPA in eggs may be needed. Final judgment as to the adequacy of the existing hen feeding studies and the need for poultry tolerances will be determined after the requested poultry metabolism studies have been evaluated. In the interim, data from the existing poultry feeding studies will be used to estimate residues in poultry tissues and eggs for purposes of a human dietary risk assessment.

Confined/Field Rotational Crops

The confined rotational crop study is adequate. Carrots, lettuce, and green beans were grown in a greenhouse in soil treated 11 weeks previously with ^{14}C-DCPA. The identified ^{14}C-residues were DCPA, TPA, and MTP, with TPA being the predominant residue.

The limited field rotational crops studies used plant-back intervals (PBIs) of 29 to 365 days in soil that had been treated at 10.5 lbs a.i./acre (0.5x the maximum seasonal rate). Residues of DCPA, MTP, and TPA were detected in carrot roots and tops, corn fodder and silage, oat forage, and turnip tops planted at a 1 year PBI. These data indicated that inadvertent residue tolerance and label amendments imposing crop rotational restrictions for DCPA treated fields will be necessary. Any crop(s) without a registered use for which an inadvertent tolerance is desired will require field trial data to determine the appropriate tolerance level(s) for rotated crop commodities. The registrant must clarify their intentions as to the specific crop(s) to be allowed in rotation with the crops on the label(s) and the desired plant-back intervals.

Anticipated Residues

Table 3 lists the anticipated residues (ARs) for calculating carcinogenic and chronic, non-carcinogenic risk of DCPA and HCB for all raw agricultural commodities (RACs) in which DCPA tolerances have been established. The Dietary Risk Evaluation System (DRES) will incorporate these residue values, taking into account the percentage of the entire crop which is likely to be treated with DCPA. ARs were also calculated for animal commodities from uses of DCPA on RACs which are eventually fed to animals used for human consumption. The residues of concern in both plant and animal commodities are DCPA, its metabolites (MTP and TPA), and its contaminant, HCB. Residue data used to calculate anticipated residues for the RACs were

obtained from registrant field trials and processing studies, from monitoring data supplied by the U.S. Food and Drug Administration, and from survey data supplied by the U.S. Department of Agriculture.

Tolerances are presently established for corn, soybeans, rutabagas, and lettuce although there are no federally registered uses of DCPA on these crops. These tolerances are being retained to cover any inadvertent residues from rotation of crops to previously DCPA-treated fields. As previously stated, rotational crop studies indicate the need for inadvertent residue tolerances and label amendments imposing crop rotation restrictions for DCPA-treated fields. The established tolerances on corn, soybeans, rutabagas and lettuce will need to be reassessed.

Since the Agency lacks the needed data (from additional field rotational crop studies), ARs for corn, soybeans, and rutabagas were based on the established tolerances. Any inadvertent residues occurring on these crops should be considerably lower. For lettuce it was possible to refine the estimate of anticipated inadvertent residues by combining data from field trials and monitoring studies.

For calculating meat, milk, poultry and eggs, the livestock diet was assumed to contain the maximum levels of ARs of DCPA and HCB. Cottonseed commodities were chosen since it is the most likely of the livestock feeds to be used in a typical national livestock diet over an extended period of time. The transfer of DCPA to milk and livestock commodities was calculated using the total radioactive residues (TRRs) detected in a goat metabolism study. HCB transfer to meat, milk, poultry, and eggs was calculated using a transfer factor obtained from feeding studies of PCNB (pentachloronitrobenzene) contaminated with HCB. It was assumed that the transfer of HCB to animal tissues from feed would be independent of any other chemical(s) present in the feed.

Table 3: Anticipated Residues of DCPA, its Metabolites, and HCB from Use of DCPA on Food/Feed Crops[a]

Food Name	Residue Data Source		Anticipated Residues (ppm)	
	DCPA	HCB	DCPA, MTP & TPA	HCB
Strawberries	Field Trials	0.3% a.i.	0.22	0.00066
Horseradish	Field Trials	0.3% a.i.	0.81	0.00243
Paprika	Field Trials	0.3% a.i.	0.17	0.00051
Cantaloupes-unspecified	Field Trials	0.3% a.i.	0.25	0.00075
Cantaloupes-pulp				
Honeydew melons	Field Trials	0.3% a.i.	0.08	0.00024
Watermelon	Field Trials	0.3% a.i.	0.20	0.0006
Cucumbers	Field Trials	0.3% a.i.	0.08	0.00024
Squash-summer	Field Trials	0.3% a.i.	0.16	0.00048
Squash-winter	Field Trials	0.3% a.i.	0.16	0.00025
Eggplant	Field Trials	0.3% a.i.	0.11	0.00033
Peppers-sweet, garden	Field Trials	0.3% a.i.	0.17	0.00051

Food Name	Residue Data Source		Anticipated Residues (ppm)	
	DCPA	HCB	DCPA, MTP & TPA	HCB
Peppers-other	Field Trials	0.3% a.i.	0.17	0.00051
Chili peppers	Field Trials	0.3% a.i.	0.17	0.00051
Pimentos	Field Trials	0.3% a.i.	0.17	0.00051
Tomatoes-whole	Field Trials	0.3% a.i.	0.11	0.00033
Tomatoes-juice	Processing Study		0.11	0.00033
Tomatoes-puree	Processing Study		0.15	0.00045
Tomatoes-paste	Processing Study		0.396	0.00119
Tomatoes-catsup	Processing Study		0.12	0.00036
Broccoli	Field Trial	0.3% a.i.	0.10	0.0003
Brussels Sprouts	Field Trials	0.3% a.i.	0.04	0.00012
Cauliflower	Brussels Sprouts Data	Brussels Sprouts Data	0.04	0.00012
Cabbage-green/red	Field Trials	0.3% a.i.	0.35	0.00105
Cabbage-Chinese/celery, inc. Bok Choy				
Collards	Kale Data	0.3% a.i.	0.5	0.0015
Kale	Field Trials	0.3% a.i.	0.5	0.0015
Kohlrabi	Brussels Sprouts Data	Brussels Sprouts Data	0.04	0.00012
Lettuce-leafy varieties[a,b]	FDA Monitoring	PDP Survey	0.65	0.002
Lettuce-unspecified[a,b]	FDA Monitoring	PDP Survey	0.65	0.002
Mustard Greens[a]	Field Trials	FDA Monitoring	1	0.000625
Turnip-tops	Field Trials	0.3% a.i.	0.775	0.002325
Cress, Upland	Field Trials	0.3% a.i.	0.36	0.0011
Lettuce-head varieties[a,b]	FDA Monitoring	PDP Survey	0.65	0.002
Garlic	Onion Data	Onion Data	0.02	0.000063
Leeks	Field Trials	0.3% a.i.	0.57	0.00103
Onions-dry bulb (cipollini)	Field Trials	0.3% a.i.	0.02	0.000063
Onions-dehydrated or dried				
Potatoes-whole	Field Trials	0.3% a.i.	0.25	0.00075
Potatoes-unspecified				
Potatoes-peeled	Field Trials	0.3 % a.i.	0.25	0.00075
Potatoes-dry				
Potatoes-peel				
Radishes-roots	Field Trials	0.3% a.i.	0.07	0.00021
Radishes-tops	Field Trials	0.3% a.i.	9.12	0.027

Food Name	Residue Data Source		Anticipated Residues (ppm)	
	DCPA	HCB	DCPA, MTP & TPA	HCB
Rutabagas-roots[b]	Tolerance	0.3% Tolerance	2	0.006
Shallots	Field Trials	0.3% a.i.	0.57	0.00103
Sweet potatoes (including Yams)	Field Trials	0.3% a.i.	0.64	0.00192
Turnip-roots	Field Trials	0.3% a.i.	0.275	0.000825
Corn, pop[b]	Tolerance	0.3% Tolerance	0.05	0.00015
Corn, sweet[b]				
Corn, grain-endosperm[b]				
Corn, grain-bran[b]				
Corn, sugar[b]				
Corn, grain-oil[b]				
Beans-succulent, lima	Field Trials	0.3% a.i.	0.26	0.00078
Beans-succulent, green				
Beans-succulent, other				
Beans-succulent, yellow, wax				
Beans-succulent, broadbeans (immat. seed)				
Beans-dry	Field Trials	0.3% a.i.	0.09	0.00027
Mung Beans (sprouts)				
Black-eyed Peas dry	Field Trials	0.3% a.i.	0.36	0.00108
Onions-green	Field Trials	0.3% a.i.	0.57	0.00103
Cottonseed-oil Cottonseed-meal	Field Trial	0.3% a.i.	0.02	0.00006
Soybeans-mature, seeds dry[b]	Tolerance	0.3% Tolerance	2	0.006
Soybeans-oil[b]				
Soybeans-unspecified[b]				
Soybeans-flour, full fat[b]				
Soybeans-flour, low fat[b]				
Soybeans-flour, defatted[b]				
Milk-non-fat solids	Goat Metabolism Study	Cattle Feeding Study	0.0000006	0.0000001
Milk-fat solids				
Milk sugar (lactose)				
Beef, Goat, Sheep, Pork - meat byproducts	Goat Metabolism Study	Cattle Feeding Study	0.0000011 [c]	0.0000068 [c]
Beef, Goat, Sheep, Pork - (organ meats) - other			0.0000017	0.0000003
Beef- dried			0.0000006	0.0000005
Beef,Goat,Sheep,Pork(boneless) -fat			0.0000011	0.0000068
Beef, Goat, Sheep, Pork (organ meats) - kidney			0.0000057	0.0000003

Food Name	Residue Data Source		Anticipated Residues (ppm)	
	DCPA	HCB	DCPA, MTP & TPA	HCB
Beef, Goat, Sheep, Pork (organ meats) - liver			0.0000017	0.0000003
Beef, Goat, Sheep, Pork (boneless)- lean (w/o removable fat)			0.0000006	0.0000005
Turkey, Other Poultry, Chicken - byproducts	Poultry Feeding Study	Poultry Feeding Study	0.0000230 [c]	0.0000084 [c]
Turkey, Other Poultry, Chicken - giblets (liver)			0.0000009	0.0000028
Turkey, Chicken - flesh (w/o skin, w/o bones)			0.0000009	0.0000002
Turkey, Other Poultry, Chicken -flesh (+skin,w/o bones)			0.0000230 [c]	0.0000084 [c]
Turkey-unspecified			0.0000230 [c]	0.0000084 [c]
Eggs-whole (36.55 yolk)			0.0000011	0.0000001
Eggs-white only			0.0000009	0.0000000
Eggs-yolk only			0.0000138	0.0000028

[a] The residue values for these crops are based on FDA monitoring or USDA survey data, and were not adjusted for % crop treated in the DRES analysis.

[b] There are no established uses on this crop; however, the registrant has expressed an interest in retaining a tolerance to cover potential residues from rotation of this crop into fields that have been previously treated with DCPA. The tolerance on this crop, and anticipated residues, will be reassessed in conjunction with review of rotational crop studies and registrant proposals for inadvertent residue tolerance and rotational crop restrictions on DCPA labels.

[c] The anticipated residue on this food is assumed to be the same as for fat.

b. Drinking Water Exposure

The available information is inadequate to assess exposure to DCPA and its metabolites on a national level. However, sufficient information is available on local detections of DCPA and its metabolites which can be used to extrapolate the following conclusions/generalizations. Note that HCB and 2,3,7,8-TCDD were not considered in the drinking water assessment. Sufficient information on their detections was not available.

Ground Water

National Survey of Pesticides in Drinking Water Wells

The Agency's National Survey of Pesticides in Drinking Water Wells (NPS) detected a DCPA metabolite, TPA, in the ground water in 25 states. TPA was the most frequently detected pesticide residue (49 detections in 1347 wells). The limit of detection (LOD) for TPA in the NPS

was 0.10 ug/L. The highest concentration of detected TPA was 7.20 ug/L. DCPA was not detected in the NPS; the LOD for DCPA was 0.06 ug/L.

State Studies

Ground water monitoring studies for pesticides have been conducted in a number of states and regions. Several of these monitoring studies have also detected DCPA and/or its metabolites in ground water.

The occurrence of DCPA residues have been confirmed in groundwater in Suffolk County, New York, by pesticide sampling programs conducted by the Suffolk County Department of Health Services. Water samples were analyzed for DCPA, its metabolites TPA and MTP, and the manufacturing impurity HCB. DCPA degradates were detected in 56 of 213 samples (26%) analyzed from shallow private and public water supply wells. HCB was not detected in any samples. It should be noted that only the number of samples, including resampling, were given and not the actual number of wells. Therefore, the number of wells for this report was assumed to be equal to the number of samples. The average concentration of the positive samples was 109 ug/L with the highest concentration detected being 1039 ug/L. The limit of detection (LOD) for the Suffolk County sampling program is 0.3 ug/L.

This information was used to perform an exposure assessment of groundwater in Suffolk County. Using the average concentration of the detected samples (109 ug/L) and one-half of the LOD (0.15 ug/L) for the non-detected samples, an average of all 213 samples can be calculated, which is 28.768 ug/L.

Registrant Studies

As required by the Agency, the registrant is currently performing two small-scale groundwater monitoring studies to determine the potential for DCPA residues to leach to groundwater from current uses. Both studies (onions in California and turf in New York) began in 1992. The Agency received preliminary data in support of the registrant's request to terminate the studies. To date, the studies have been performed over a time-period of 17 months in New York, and 22 months in California. Since these time periods are greater than a year, the Agency used these data in assessing drinking water risk in this RED. However, the delivery date for the final report is July 1996. At that time the Agency will revise its drinking water risk assessment.

The ground water was analyzed for DCPA, TPA, and MTP. More data points were collected in the New York study. The LOD was 0.1 ug/L; therefore, one-half of the LOD (0.05 ug/L) was used for non-detects. When analyses were performed in duplicate, the two results were averaged to obtain a single result. The data did not indicate which wells were in a cluster or the screening depth. Therefore, the average concentrations for DCPA, for MTP, and for TPA were calculated for each well. These averages were summed to obtain the total residues in each well without regard for depth.

At the New York site, a total of 29.4 lbs a.i./acre was applied in three applications. The data are from nine wells (three clusters with three wells each). This information can be used to perform an exposure assessment of groundwater at the turf site in New York. The average of the sums of DCPA, TPA, and MTP over the 17 months was 50.36 ug/L.

At the California site, a total of 18.2 lbs a.i./acre was applied in two applications. However, the results of analyses from only eight wells were reported, although it was stated that cluster wells were also used. This information can be used to perform an exposure assessment of groundwater at the onion site in California. The average of the sums of DCPA, TPA, and MTP over the 22 months was 12.75 ug/L.

Surface Water

The available data on concentrations of DCPA in surface waters is limited. The U.S. Geological Survey collected samples from two creeks in Colorado from April, 1993 to April, 1994. Samples were collected once a month from October through March, and two or more times per month during other months. The reported LODs for DCPA varied from 0.002 to 0.005 ug/L. One-half of the LOD was used for non-detects (varying 0.001 to 0.0025 ug/L.)

One of the creeks, Lonetree Creek, drained an agricultural watershed. The time-weighted mean for DCPA concentration was 5.95 ug/L. The second creek, Cherry Creek, drained an urban watershed. The time-weighted mean for DCPA concentration was 0.0078 ug/L.

Exposure Estimates

For drinking water, exposure is calculated using the following formula:

exposure = (ppb DCPA and/or metabolites in the water consumed) $(10^{-6})(22.6)$

Water consumption is defined as all water obtained from the household tap that is consumed either directly as a beverage or is used to prepare foods (mixing water with a can of soup) and beverages (diluting frozen juice concentrate). Two generally accepted default values for water consumption are 2 liters (28.57 g/kg/day based on a 70 kg adult male) or 1.5 liters (21.42 g/kg day based on a 70 kg adult male). The 22.6 g/kg/day used in this calculation was derived using water consumption values obtained from USDA's 1977-1978 Nationwide Food Consumption Survey. It should be noted that the individuals participating in the survey self-reported their body weights which were then used in calculating the 22.6 value.

The other assumption used is that water from the same source containing the same contaminant level is consumed throughout a 70-year lifetime. The second of these assumptions is extremely conservative, since most of the U.S. population moves at some time during their life and does not live in the same area, drinking from the same water source for a 70-year lifetime. It

could be considered as either an over-estimation or an under-estimation of risk depending on the contaminant levels in the other sources of drinking water.

Groundwater

State Studies (Suffolk County, NY)

Exposure = (28.768) (10-6) (22.6)

Registrant Studies

New York turf

Exposure = (50.36) (10-6) (22.6)

California onions

Exposure = (12.75) (10-6) (22.6)

Surface Water

Lonetree Creek

Exposure = (5.95) (10-6) (22.6)

Cherry Creek

Exposure = (0.0078) (10-6) (22.6)

c. Occupational and Residential Exposure

Use Patterns

DCPA is applied with tractor mounted boom sprayers, tractor drawn granular spreaders, shaker cans, residential push-type and whirly-bird spreaders, and by aerial application.

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are met, AND (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete.

DCPA contains small amounts of several contaminants, HCB and dioxin/furans (represented as 2,3,7,8-TCDD). The Registration Standard required foliar dissipation data

(turfgrass) for both HCB and 2,3,7,8-TCDD. A foliar dissipation study was submitted for HCB, but not for 2,3,7,8-TCDD, with the registrant stating that 2,3,7,8-TCDD data could not be provided due to the unavailability of analytical methodology to detect the theoretical levels of 2,3,7,8-TCDD. The residues of 2,3,7,8-TCDD which would theoretically be present as a result of an application of DCPA at the label rate of 10.5 lbs a.i./acre was estimated as 5.3×10^{-13} g/ft^2 or 5.74×10^{-10} ug/cm^2. The Agency agreed that this residue level was much lower than 1991 analytical methods could detect; therefore, assays for 2,3,7,8-TCDD were not subsequently required.

Both occupational and residential exposures to DCPA and its contaminant HCB are estimated in the following assessment. However, exposure to 2,3,7,8-TCDD is not included. "Worst case" exposure values for 2,3,7,8-TCDD were calculated using application rates and the percentage of contamination only, since there are no foliar dissipation or dermal absorption data on 2,3,7,8-TCDD. These exposure values (shown in the risk assessment section) were used to produce rough estimates of risk.

Mixer/Loader/Applicator (M/L/A) exposure monitoring studies were not required in the June, 1988 Registration Standard. However, a subsequent Data-Call-In (dated 9/25/92), did include requirements for M/L/A exposure monitoring studies to support the application of DCPA granulars to turf and DCPA wettable powders to various crops and turf. Protocols were submitted and reviewed for the M/L/A studies. At that time, the Agency determined that these studies were no longer required based on the availability of surrogate data in the Pesticide Handlers Exposure Database (PHED) Version 1.1 which was used in this assessment to estimate M/L/A exposures resulting from registered uses of DCPA. However, based on this exposure assessment which used PHED surrogate data, confirmatory data are now required to address the Agency's concerns for two of the exposure scenarios.

Mixer/Loader/Applicator Exposure Scenarios

Based on the use-patterns and potential exposures previously described, ten major exposure scenarios were identified for DCPA: (1) mixing/loading the liquid flowable formulation, (1a) mixing/loading the wettable powder formulations, (2) mixing and loading granulars for ground applications, (3a) aerial application of liquid formulation, (3b) aerial application of granulars, (4) applying the liquid and wettable powders with groundboom equipment, (5) applying with a granular spreader cultivator mounted, (6a) flagger exposure to liquids, (6b) flagger exposure to granulars, (7) applying with a shaker can, (8) applying with a backpack, (9) mixing/loading and applying with a residential push-type spreader, and (10) mixing/loading and applying with a whirly-bird spreader. Table 4 summarizes the parameters specific to each exposure scenario, including a description of the actual clothing and equipment worn by all persons being monitored in the exposure studies. Each exposure assessment in Table 5, DCPA Exposure Values, or Table 6, HCB Exposure Values, is based on workers wearing long pants, long-sleeve shirts, and no gloves, with the exception of the exposure assessment for

mixing/loading liquids, wettable powder formulations, shaker cans, and backbacks (scenarios I, Ia, VII, and VIII), which includes wearing gloves in addition to long pants and long-sleeve shirts.

Table 4: Exposure Scenarios

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario[a]	Equipment	Daily Max Treated[b] (acres)	Comments[c]
Mixer/Loader Exposure					
Liquids (I)	PHED V1.1	Long pants, long sleeves, chemical resistant gloves	Open mixing for groundboom and aerial applications	80 acres groundboom, and 350 acres aerial	Acceptable grades; Dermal = 59 to 122 replicates; Inhalation = 85 replicates; High confidence in dermal and inhalation data.
Wettable Powder (Ia)	PHED V1.1	Long pants, long sleeves, chemical resistant gloves	Wettable powder packaged in open bags for groundboom and aerial applications	80 acres groundboom, and 350 acres aerial	Dermal and inhalation grades A,B,C; Dermal = 22 to 45 replicates; Inhalation = 44 replicates; Medium confidence in dermal and inhalation data
Granular (II)	PHED V1.1	Long pants, long sleeves, no gloves	Open mixing for cultivated spreader and aerial applications	80 acres spreader, and 350 acres aerial	All grades for dermal; Acceptable grades for inhalation; Dermal = 10 to 78 replicates Inhalation = 58 replicates; Low confidence in dermal data and high confidence for inhalation data
Applicator Exposure					
Aerial (liquids) (IIIa)	PHED V1.1	Long pants, long sleeves, no gloves	Open cockpit	350 acres	Dermal grades A, B, C; inhalation all grades; Dermal = 1 to 17 replicates; Inhalation = 17 replicates; Low confidence in dermal and inhalation data
Aerial (granulars) (IIIb)	PHED V1.1	Long pants, long sleeves, no gloves	Open cockpit	350 acres	Dermal and inhalation all grades; Dermal = 4 to 13 replicates; inhalation = 13 replicates; Low confidence in dermal and inhalation data
Groundboom (IV)	PHED V1.1	Long pants, long sleeves, no gloves	Open Cab	80 acres	Acceptable grades; Dermal = 23 to 33 replicates; Inhalation = 22 replicates; High confidence in dermal and inhalation data
Granular Spreader Cultivator Mounted (V)	PHED V1.1	Long pants, long sleeves, no gloves	Cultivator mounted or pull-behind; Ag or Turf; closed cab	80 acres	Acceptable grades; Dermal = 24 to 25 replicates; Inhalation = 25 replicates; High confidence in dermal and inhalation data
Flagger Exposure					
Liquids (VIa)	PHED V1.1	Long pants, long sleeves, no gloves	Unknown	350 acres	Acceptable grades; Dermal = 16 to 18 replicates; Inhalation = 18 replicates; High confidence in dermal and inhalation data
Granulars (VIb)	PHED V1.1	Long pants, long sleeves, no gloves	Unknown	350 acres	Dermal and inhalation all grades; Dermal = 4 to 20 replicates; inhalation = 4 replicates; Low confidence in dermal and inhalation data
Mixer/Loader/Applicator Exposure					
Shaker Can (VII)	PHED V1.1	Long pants, long sleeves, chemical resistant gloves	Granulars dispersed by hand (worst case surrogate)	1,000ft^2 residential, 5,000ft^2 commercial	Dermal and inhalation grades A, B, C; Dermal = 15 to 16 replicates; inhalation = 16 replicates; Medium confidence in dermal and inhalation data
Backpack (VIII)	PHED V1.1	Long pants, long sleeves, chemical resistant gloves	Backpack sprayer	1 acre residential, 5 acres commercial	Dermal grades A, B, C; acceptable inhalation grades; Dermal = 9 to 11 reps.; inhalation = 11 replicates; Low confidence in dermal and inhalation data

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario[a]	Equipment	Daily Max Treated[b] (acres)	Comments[c]
Residential Push-type Spreader (IX)	PHED V1.1	Long pants, long sleeves, no gloves	Rotary spreader	1 acre residential, 5 acres commercial	Dermal grade C; inhalation grade B; Dermal = 15 (no head data) replicates; Inhalation = 15 replicates; Medium confidence in dermal data and high confidence for inhalation data
Whirly-bird spreader (X)	PHED V1.1	Long pants, long sleeves, no gloves	Belly grinder	1 acre	Dermal grades = 9A and 36C; Inhalation grades = acceptable; Dermal = 23 to 45 replicates; Inhalation = 40 replicates; Medium confidence in data

[a] Clothing scenario represents actual, not simulated, exposure data.

[b] The value represents the maximum area or the maximum volume of spray solution which can be used in an 8 hour work day to complete treatments for each exposure scenario of concern.

[c] These grades are based on Quality Assurance/Quality Control data provided as part of the exposure studies. "Acceptable grades" for dermal and inhalation studies are A and B as defined in Subdivision U Guidelines. All grades that do not meet the guidelines are listed separately. A replicate refers to data acquired during one complete work cycle. High confidence in data indicates that there were at least 15 replicates of Grades A and B data. Medium confidence in data indicates that there were at least 15 replicates, but that some of the data did not meet the criteria for Grades A and B data. Low confidence in data indicates that there were less than 15 replicates of data.

Table 5: DCPA Occupational and Residential Exposure Values

Exposure Scenario (Scen. #)	Dermal Exposure[a1] (mg/lb ai)	Absorbed Dermal Exposure[a2] (mg/lb ai)	Inhalation Exposure[b] (mg/lb ai)	Total Absorbed Exposure (mg/lb ai)	Label Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres)	Daily Dose[e] (mg/kg/day)	LADD[f] (mg/kg/day)	
								Private Appl.[g]	Commercial Appl.[h]
Mixer/Loader Exposure									
Liquids (I)	0.04	0.0060	0.0012	0.0072	10	80	0.082	0.00011	0.0011
						350	0.36	NA	0.0049
Wettable Powder (Ia)	0.2	0.030	0.0434	0.073	10	80	0.83	0.0011	0.011
						350	3.65	NA	0.05
Granulars (II)	0.01	0.0015	0.0017	0.0032	10	80	0.037	0.000051	0.00051
						350	0.16	NA	0.0022
Applicator Exposure									
Aerial (liquids) (IIIa)	0.05	0.00745	0.0003	0.0078	10	350	0.39	NA	0.0053
Aerial (granulars) (IIIb)	0.002	0.00030	0.0013	0.0016	10	350	0.08	NA	0.0011
Groundboom (IV)	0.01	0.0015	0.0007	0.0022	10	80	0.025	0.00003	0.0003
Granular Spreader Cultivator Mounted (V)	0.002	0.00030	0.0001	0.00040	10	80	0.0046	6.3×10^{-6}	6.3×10^{-5}
Flagger Exposure									
Liquids (VIa)	0.01	0.0015	0.0003	0.0018	10	350	0.09	NA	0.0012
Granulars (VIb)	0.003	0.00045	0.0001	0.00055	10	350	0.028	NA	0.00038
Mixer/Loader/Applicator Exposure									
Shaker Can (VII)	71.3	10.6	0.468	11.1	10	1,000ft^2	0.036	0.00005	5×10^{-4}
						5,000ft^2	0.18	0.00025	0.0025
Backpack (VIII)	2.5	0.37	0.03	0.40	10	1, 5[i]	0.057, 0.29[i]	0.00008	0.004

Exposure Scenario (Scen. #)	Dermal Exposure[a1] (mg/lb ai)	Absorbed Dermal Exposure[a2] (mg/lb ai)	Inhalation Exposure[b] (mg/lb ai)	Total Absorbed Exposure (mg/lb ai)	Label Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres)	Daily Dose[e] (mg/kg/day)	LADD[f] (mg/kg/day)	
								Private Appl.[g]	Commercial Appl.[h]
Residential Push-type Spreader (IX)	2.9	0.43	0.0063	0.44	10	1, 5[i]	0.063, 0.31[i]	0.00009	0.0042
Whirly-bird Spreader (X)	10.4	1.55	0.0618	1.61	10	1	0.23	0.00032	NA

[a1] Dermal unit exposures are reported as the best fit mean to simulate workers wearing long pants, long-sleeve shirts, and no gloves except for mixer/loaders/liquid/wettable powder and shaker can and backpack applicators. The liquid and wettable powder mixer/loaders and shaker can and backpack applicators simulate workers wearing long pants, long sleeve shirts, and chemical resistant gloves. The best fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. Protection factors were not used to calculate dermal unit exposure values because sufficient data are available for PPE in these scenarios.

[a2] Dermal exposure was multiplied by the dermal absorption factor (which for DCPA is 14.9%) to obtain an exposure consistent with the amount of DCPA absorbed, not the amount of DCPA in contact with the skin.

[b] Inhalation Exposure Values are reported as geometric means (lognormal distributions). No adjustment has been made to simulate workers wearing dust/mist respirators.

[c] Dacthal W75 Label, EPA Reg # 50534-1; Dacthal Flowable Herbicide Label, EPA Reg # 50534-10; Dacthal G-2.5 Label, EPA Reg # 50534-17; Dacthal G-5 Label, EPA Reg # 50534-3. The 10 lb ai/acre application rate represents the high rate that is used on clay loams having 3-5% organic matter. The rate of 15 lb ai/acre was not used in the assessment since this rate is for turfgrass. The 15 lb rate requires 40 to 100 gallons of water per acre for grass which is unlikely for aerial applications.

[d] Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.

[e] Daily Dose (mg/kg/day) = $\frac{\text{Total Absorbed Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/cycle) * Max. Treated}}{\text{70 kg}}$

[f] Lifetime Average Daily Dose (LADD) (mg/kg/day) = Daily Dose (mg/kg/day) * (Work Days Per Yr/365 Days Per Year) * (35 Yrs/70 Yrs).

[g] Private applicator is defined as a short term exposed individual (i.e., one day).

[h] Commercial applicator is defined as an intermediately exposed individual (i.e. 10 days).

[i] Homeowner treats 1 acre; commercial home-lawn applicator can treat 5 acres/day.

Table 6: HCB Occupational and Residential Exposure Values

Exposure Scenario (Scen. #)	Dermal Exposure[a1] (mg/lb ai)	Absorbed Dermal Exposure[a2] (mg/lb ai)	Inhalation Exposure[b] (mg/lb ai)	Total Absorbed Exposure (mg/lb ai)	Label Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres)	Daily Dose[e] (mg/kg/day)	LADD[f] (mg/kg/day)	
								Private Appl.[g]	Commercial Appl.[h]
Mixer/Loader Exposure									
Liquids (I)	0.04	0.011	0.0012	0.012	0.03	80	0.00041	5.6×10^{-7}	5.6×10^{-6}
						350	0.0018	NA	2.5×10^{-5}
Wettable Powder (Ia)	0.2	0.053	0.0434	0.096	0.03	80	0.0033	4.5×10^{-6}	4.5×10^{-5}
						350	0.014	NA	1.9×10^{-4}
Granulars (II)	0.01	0.0026	0.0017	0.0043	0.03	80	0.00015	2.1×10^{-7}	2.1×10^{-6}
						350	0.00065	NA	8.9×10^{-6}
Applicator Exposure									
Aerial (liquids) (IIIa)	0.05	0.013	0.0003	0.013	0.03	350	0.0020	NA	2.7×10^{-5}
Aerial (granulars) (IIIb)	0.002	0.00053	0.0013	0.0018	0.03	350	0.00027	NA	3.7×10^{-6}
Groundboom (IV)	0.01	0.0026	0.0007	0.0033	0.03	80	0.00011	1.5×10^{-7}	1.5×10^{-6}
Granular Spreader Cultivator Mounted (V)	0.002	0.00053	0.0001	0.00063	0.03	80	2.2×10^{-5}	3.0×10^{-8}	3.0×10^{-7}
Flagger Exposure									
Liquids (VIa)	0.01	0.0026	0.0003	0.0029	0.03	350	0.00044	NA	6.0×10^{-6}
Granulars (VIb)	0.003	0.00079	0.0001	0.00089	0.03	350	0.00013	NA	1.8×10^{-6}
Mixer/Loader/Applicator Exposure									
Shaker Can (VII)	71.3	18.9	0.468	19.4	0.03	$1{,}000 ft^2$	0.00019	2.6×10^{-7}	2.6×10^{-5}
						$5{,}000 ft^2$	0.00096	1.4×10^{-6}	1.4×10^{-5}
Backpack (VIII)	2.5	0.66	0.03	0.69	0.03	1, 5[i]	0.00030, 0.0015[i]	4.1×10^{-7}	2.1×10^{-5}
Residential Push-type Spreader (IX)	2.9	0.77	0.0063	0.78	0.03	1, 5[i]	0.00033, 0.0017[i]	4.5×10^{-7}	2.3×10^{-5}
Whirly-bird Spreader (X)	10.4	2.75	0.0618	2.81	0.03	1	0.0012	1.6×10^{-6}	NA

[a1] Dermal unit exposures are reported as the best fit mean to simulate workers wearing long pants, long-sleeve shirts, and no gloves except for mixer/loaders/liquids/wettable powder and shaker can and backpack applicators. The liquid and wettable powder mixer/loaders and shaker can and backpack applicators simulate workers wearing long pants, long sleeve shirts, and chemical resistant gloves. The best fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. Protection factors were not used to calculate dermal unit exposure values because sufficient data are available for PPE in these scenarios.

[a2] Dermal exposure was multiplied by the dermal absorption factor (which for HCB is 26.46%) to obtain an exposure consistent with the amount of HCB absorbed, not the amount of HCB in contact with the skin.

[b] Inhalation Exposure Values are reported as geometric means (lognormal distributions). No adjustment has been made to simulate workers wearing dust/mist respirators.

[c] The label application rate for HCB is 0.3 percent of the label application rate of DCPA which is taken from the Dacthal W75 Label, EPA Reg # 50534-1; Dacthal Flowable Herbicide Label, EPA Reg # 50534-10; Dacthal G-2.5 Label, EPA Reg # 50534-17; Dacthal G-5 Label, EPA Reg # 50534-3. The 10 lb ai/acre application rate represents the high rate that is used on clay loams having 3-5% organic matter. The rate of 15 lb ai/acre was not used in the assessment since this rate is for turfgrass. The 15 lb rate requires 40 to 100 gallons of water per acre for grass which is unlikely for aerial applications.

[d] Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.

[e] Daily Dose (mg/kg/day) = $\frac{\text{Total Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/cycle)} * \text{Max. Treated}}{70\ \text{kg}}$

[f] Lifetime Average Daily Dose (LADD) (mg/kg/day) = Daily Dose (mg/kg/day) * (Work Days Per Yr/365 Days Per Year) * (35 Yrs/70 Yrs)

[g] Private applicator is defined as a short term exposed individual (i.e., one day)

[h] Commercial applicator is defined as an intermediate exposed individual (i.e. 10 days)

[i] Homeowner treats 1 acre; commercial home-lawn applicator can treat 5 acres/day.

Post-application Exposure

There is a potential for exposure to persons entering a DCPA treated area after application is complete. One concern is potential post-application exposure arising from re-entering a treated agricultural crop area. Based on label use information for application of DCPA to agricultural crops (considering methods and timing of applications), the agricultural use site with the highest potential for post-application worker exposure is cucumbers. Foliar dissipation data for DCPA and HCB on cucumbers and the corresponding worker exposure levels during cucumber harvesting are summarized in Table 7 below. These calculations incorporated the following assumptions: an 8 hour work day; 30 days exposure each year for a total of 35 years over a 70 year lifetime; average body weight is 70 kg.

Table 7: Foliar Dislodgeable Residues (FDR) of DCPA and HCB on Cucumbers and Corresponding Worker Reentry Exposure During Cucumber Harvesting

DAT[a]	FDR (μg/cm^2)[b]		LADD (mg/kg/day)[c]	
	DCPA	HCB	DCPA	HCB
0	17.4	0.025	0.82	0.0012
1	15.0	0.018	0.70	0.0009
2	12.9	0.013	0.61	0.0006
3	11.1	0.010	0.52	0.0005
4	9.5	0.007	0.45	0.0003
5	8.2	0.005	0.38	0.0002
6	7.0	0.004	0.33	0.0002

[a] DAT = Days After Treatment

[b] FDR values were calculated using a regression analysis of dissipation data (MRID 41750105)

[c] Lifetime Average Daily Dose (LADD) was calculated using the following equation:

[FDR (μg/cm^2) x (10000 cm^2/hr) x (1 mg/1000 μg) x (1/70 Kg) x (8 hrs/day) x (30 days harvesting/365 days per year) x (35 years harvesting/70 year lifetime)]

where 10,000 cm^2/hour is a transfer coefficient for citrus harvesters excerpted from Zweig, Leffingwell, Popendorf, 1985.

Another concern is potential post-application exposure arising from re-entering turf areas following application of DCPA (e.g., residential lawns and recreational areas).

Table 8 (Foliar Dislodgeable Residues of DCPA) and Table 9 (Foliar Dislodgeable Residues of HCB) summarize the residue dissipation data on turf and the corresponding exposure levels for children (ages 2 - 12) playing on treated lawns. The data necessary to assess a toddler's (age 1 -2) exposure are not available.

Table 8: Foliar (turf) Dislodgeable Residues (FDR) of DCPA, Total (Dermal and Oral) DCPA Exposure to Children Following Application of Dacthal W-75 to Turfgrass

Sampling Interval (hr/days post-treatment)	Irrigated*		Nonirrigated	
	FDR (ug/cm^2)	Total DCPA Exposure to Children (mg/kg/day)[a,b,c]	FDR (ug/cm^2)	Total DCPA Exposure to Children (mg/kg/day)[a,b,c]
1 HAT	4.15	2.35	3.64	2.06
2 HAT	1.67	0.89	4.26	2.41
6 HAT	1.48	0.84	4.60	2.60
1 DAT	1.29	0.73	5.56	3.14
24 hour TWA[d]	**1.46**	**0.82**	**5.27**	**2.98**
2 DAT	1.33	0.75	4.83	2.73
3 DAT	1.20	0.68	2.16	1.22
7 DAT	0.79	0.45	3.35	1.89
14 DAT	0.67	0.38	2.22	1.26
14 Day TWA[e]	**0.85**	**0.48**	**2.94**	**1.66**
Average Annual[f]		**0.018**		**0.064**

HAT = Hours After Treatment DAT = Days After Treatment TWA = Time Weighted Average

* An irrigated lawn was watered 1 hour after the application of DCPA with 1/2 inch of water.

[a] Total exposures were calculated by adding the results of the equations listed in footnotes b and c below.

[b] Dermal + oral exposure for children (ages 2 - 6) was calculated using: [(FDR µg/cm^2) x (0.0314 m^2/kg/day) x (10,000 cm^2/1 m^2)/1,000 μg/mg] + [(FDR µg/cm^2 x 321.5 cm^2)/17 kg/day/1,000 μg/mg].

[c] Dermal + oral exposure for children (ages 7 - 12) was calculated using: [(FDR µg/cm^2) x (0.0221 m^2/kg/day) x (10,000 cm^2/1 m^2)/1,000 μg/mg] + [(FDR µg/cm^2 x 361.5 cm^2)/31 kg/day/1,000 μg/mg].

[d] The 24 hour TWA was calculated using:
sum (FDR µg/cm^2 1 HAT x 1 hr, FDR µg/cm^2 2 HAT x 1 hr, FDR µg/cm^2 6 HAT x 4 hrs, FDR µg/cm^2 1 DAT x 18 hrs)/24 hrs.

[e] The 14 day TWA was calculated using:
sum (FDR µg/cm^2 24 hr TWA x 1 day, FDR 2 DAT x 1 day, FDR 3 DAT x 1 day, FDR 7 DAT x 4 days, FDR 14 DAT x 7 days)/14 days.

[f] The Average Annual was calculated using:
(14 Day TWA x 14 days)/365 days/year.

Table 9: Foliar (turf) Dislodgeable Residues (FDR) of HCB, Total (Dermal and Oral) HCB Exposure to children Following Application of Dacthal W-75 to Turfgrass

Sampling Interval (hr/days post-treatment)	Irrigated*		Nonirrigated	
	FDR (ug/cm^2)	Total HCB Exposure to Children (mg/kg/day)[a,b,c]	FDR (ug/cm^2)	Total HCB Exposure to Children (mg/kg/day)[a,b,c]
1 HAT	0.0035	2.0×10^{-3}	0.0091	5.2×10^{-3}
2 HAT	0.0014	8×10^{-4}	0.0024	1.4×10^{-3}
6 HAT	0.0013	7.3×10^{-4}	0.0033	1.9×10^{-3}
1 DAT	0.0004	2.2×10^{-4}	0.0028	1.6×10^{-3}
24 hour TWA[d]	**0.0007**	**4.1×10^{-4}**	**0.0031**	**1.8×10^{-3}**
2 DAT	0.0042	2.4×10^{-3}	0.0185	1.0×10^{-2}
3 DAT	0.0009	5.1×10^{-4}	0.0044	2.5×10^{-3}
7 DAT	0.0004	2.2×10^{-4}	0.0024	1.4×10^{-3}
14 DAT	0.0000	0	0.0006	3.4×10^{-4}
14 Day TWA[e]	**0.0005**	**3.0×10^{-4}**	**0.0028**	**1.6×10^{-3}**
Average Annual[f]	**0.0000**	**1.0×10^{-5}**	**0.0001**	**7.0×10^{-5}**

HAT = Hours After Treatment DAT = Days After Treatment TWA = Time Weighted Average

* An irrigated lawn was watered 1 hour after the application of DCPA with 1/2 inch of water.

[a] Total exposures were calculated by adding the results of the equations listed in footnotes b and c below.

[b] Dermal + oral exposure for children (ages 2 - 6) was calculated using:
[(FDR µg/cm^2) x (0.0314 m^2/kg/day) x (10,000 cm^2/1 m^2)/1,000 μg/mg] + [(FDR µg/cm^2 x 321.5 cm^2)/17 kg/day/1,000 μg/mg].

[c] Dermal + oral exposure for children (ages 7 - 12) was calculated using:
[(FDR µg/cm^2) x (0.0221 m^2/kg/day) x (10,000 cm^2/1 m^2)/1,000 μg/mg] + [(FDR µg/cm^2 x 361.5 cm^2)/31 kg/day/1,000 μg/mg].

[d] The 24 hour TWA was calculated using: sum (FDR µg/cm^2 1 HAT x 1 hr, FDR µg/cm^2 2 HAT x 1 hr, FDR µg/cm^2 6 HAT x 4 hrs,
FDR µg/cm^2 1 DAT x 18 hrs)/24 hrs.

[e] The 14 day TWA was calculated using: sum (FDR µg/cm^2 24 hr TWA x 1 day, FDR 2 DAT x 1 day, FDR 3 DAT x 1 day, FDR 7 DAT x 4 days, FDR 14 DAT x 7 days)/14 days.

[f] The Average Annual was calculated using: (14 Day TWA x 14 days)/365 days/year.

3. Risk Assessment

a. Dietary Assessment

(1) Acute Dietary Risk

An acute (one day) dietary risk assessment was not required. The NOELs in the studies appropriate for selecting this endpoint were too high to be of concern; therefore, an appropriate toxicological endpoint of concern was not identified.

(2) Chronic Dietary Risk

To calculate chronic dietary risk, the RfDs (0.01 mg/kg/day for DCPA, 0.0008 mg/kg/day for HCB, and 0.000001 ug/kg/day for 2,3,7,8-TCDD) are used. It was assumed that DCPA (including the impurities HCB and TCDD) is uniformly distributed in the commodity supply, however, it was not assumed that the entire commodity nationwide was treated with DCPA. Percent crop treated (%CT) information was obtained from a variety of published and proprietary sources for 1988 - 1994. This information was presented previously in Table 1.

Currently, there are no registrations for use on lettuce, soybeans, corn, and rutabagas; however, these four DCPA tolerances are being retained to cover any inadvertent residues from rotation of crops in previously DCPA-treated fields. Percent crop treated for soybeans, rutabagas, corn, sweet corn, and lettuce were estimated. This was done by estimating the approximate number of acres that are treated with DCPA in a year (excluding seed crops, golf courses, and sod farms) which is 440,000 acres. It was then assumed that each of these 440,000 acres was rotated to soybeans. Since over 61 million acres of soybeans are grown each year, the resulting %CT is less than 1% (440,000/61,000,000). If all 440,000 DCPA treated acres are rotated to sweet corn, then the %CT is 59% 440,000/798,000 total sweet corn acreage). For corn grain, 1% was used since over 78 million acres of corn are grown each year. For rutabagas, 100% CT was used since the acres grown is less than 440,000. For lettuce, 100% CT as stated in footnote A of Table 3 was used.

The Agency was able to establish that there are no reported uses of DCPA for all dry beans and peas. Therefore, a default value of 1% was used. One hundred percent CT was assumed if data were not available.

Two chronic dietary risk assessments (for DCPA and HCB) were performed. The first analysis can be considered a worst case analysis. To calculate a Theoretical Maximum Residue Contribution (TMRC), tolerance level residues (as specified in Table 30: Tolerance Reassessment Summary) were used for DCPA. There are no tolerances for HCB; therefore, "tolerance level" residues for HCB were calculated by multiplying the DCPA tolerance by 0.3%.

A pending tolerance for parsley (4 ppm) was included since monitoring data indicate that DCPA is being found on parsley. Currently, there are not any registered uses for lettuce, soybeans, corn and rutabagas; however, these four DCPA tolerances are being retained to cover any inadvertent residues from rotation of crops in previously DCPA-treated fields. There are no tolerances for DCPA in meat, milk, poultry, or eggs; however, metabolism and feeding studies indicate the probable need. Residue levels were estimated for meat, milk, poultry, or eggs using total radioactive residues from a goat metabolism study and a poultry feeding study. These estimated residues (see Table 3: Anticipated Residues) are the best information available at this time.

"Worst Case" Chronic Dietary Exposure from **DCPA**

The TMRC was calculated for the U.S. population and 22 subgroups.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.007446	74
Non-nursing Infants (< 1 yr)	0.010580	106
Children (1-6 yr)	0.012878	129
Children (7-12 yr)	0.010361	104

All other subgroups were less than 100% of the RfD.

"Worst Case" Chronic Dietary Exposure from **HCB** as an Impurity in DCPA

The TMRC was calculated for the U.S. population and 22 subgroups.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.000024	3
Non-Nursing Infants (< 1 yr)	0.000037	5
Children (1-6)	0.000041	5

All other subgroups were less than 5% of the RfD.

In a second analysis, "More Realistic Case" Chronic Dietary Exposure, the anticipated residues in Table 3 were used in the calculation. This is considered to be a more realistic scenario since the residue data were obtained from field trials and surveys. As previously discussed, ARs could not be calculated for corn, soybeans, and rutabagas and are therefore included at tolerance level. Parsley also is included at the proposed tolerance level because monitoring data have indicated the presence of DCPA residues on parsley in the food supply.

"More Realistic Case" Chronic Dietary Exposure from **DCPA**

The Anticipated Residue Contribution (ARC) was calculated for the U.S. population and 22 subgroups.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.000233	2
Non-Hispanic blacks	0.000305	3

All other subgroups were less than 3% of the RfD.

"More Realistic Case" Chronic Dietary Exposure from **HCB** as an Impurity of DCPA

The ARC was calculated for the U.S. population and 22 subgroups.

Subgroup	Exposure(mg/kg/day)	%Reference Dose
U.S. population	<0.0000007	0.09
Non-Hispanic Others	<0.000001	0.1

All other subgroups were less than 1% of the RfD.

Thus, in the more realistic scenario in which anticipated residues and percent crop treated refinements are used in estimating chronic dietary risk, the % Reference Dose for both DCPA and its impurity HCB are less than 100 for the U.S. population and all subgroups.

Neither DCPA nor its impurity HCB pose a significant chronic dietary risk for uses that are currently registered or for uses such as meat, milk, poultry, or eggs which may need to be established.

"Worst Case" Chronic Dietary Exposure from **2,3,7,8-TCDD** as an Impurity in DCPA

A chronic dietary risk for TCDD was calculated for the general population of the U.S. only. To estimate exposure, the TMRC (Theoretical Maximum Residue Contribution) of 0.007446 mg/kg/day for exposure to DCPA in the diet was used. Exposure to 2,3,7,8-TCDD in the diet can be estimated by multiplying DCPA exposure by the percent of 2,3,7,8-TCDD in the formulation.

$(0.007446)(0.0000000001) = 7.446 \times 10^{-13}$ mg/kg/day

Using an RfD of 0.000001 ug/kg/day (0.000000001 mg/kg/day), the percent RfD can be estimated as 0.07%.

(3) Carcinogenic Dietary Risk

Carcinogenic Risk from DCPA

The upper bound carcinogenic risk from food uses of DCPA for the general U.S. population was estimated using anticipated residues and the following equation:

$$\text{Upper Bound Cancer Risk} = \text{Dietary Exposure (ARC)} \times Q_1^*$$

Based on a Q_1^* of 0.00149 $(\text{mg/kg/day})^{-1}$, the upper bound carcinogenic risk was estimated to be 3.5×10^{-7}.

For reasons previously stated, soybeans, corn, rutabagas, lettuce, parsley, meat, milk, poultry, and eggs were included in this estimate of carcinogenic risk. The contributions to the risk from these commodities are soybeans (1×10^{-8}), corn (1.1×10^{-8}), rutabagas (8×10^{-9}), lettuce (2.2×10^{-7}), parsley (2.2×10^{-8}), and meat, milk, poultry, and eggs (3×10^{-11}).

Carcinogenic Risk from HCB as an Impurity in DCPA

The upper bound carcinogenic risk from food uses of HCB for the general U.S. population was estimated using the following equation:

$$\text{HCB Upper Bound Cancer Risk} = \text{Dietary Exposure (ARC)} \times Q_1^*$$

Based on a Q_1^* of 1.02 $(\text{mg/kg/day})^{-1}$, the upper bound cancer risk was estimated to be 7×10^{-7}.

As with the DCPA risk assessment, soybeans, corn, rutabagas, lettuce, parsley, meat, milk, poultry, and eggs were included in this estimate of carcinogenic risk. HCB does not pose a significant risk of excess life time carcinogenic risk to the overall U.S. population with an upper bound estimate of 7×10^{-7}. In this risk assessment the estimate of upper bound carcinogenic risk from HCB could be considered to be an over-estimate of actual risk. This is due to the assumption that residues of HCB are present at the certified upper limit, 0.3%, in all DCPA formulations.

Carcinogenic Risk for 2,3,7,8-TCDD as an Impurity in DCPA

To estimate exposure, the TMRC of 0.007446 mg/kg/day for exposure to DCPA in the diet was used. Exposure to 2,3,7,8-TCDD in the diet can be estimated by multiplying DCPA exposure by the percent of 2,3,7,8-TCDD in the formulation.

$(0.007446)(0.0000000001) = 7.446 \times 10^{-13}$ mg/kg/day

Carcinogenic risk can be estimated by multiplying the 2,3,7,8-TCDD exposure by its cancer potency factor.

$(7.446 \times 10^{-13})(1 \times 10^{5}) = 7 \times 10^{-8}$

b. Drinking Water Assessment

(1) Chronic Drinking Water Risk

Drinking water chronic risk was calculated using the following formula:

Risk = % RfD = [Exposure/RfD](100) where:

the RfD for DCPA (0.01 mg/kg/day) is used for DCPA, TPA, and MTP. A complete database exists only for DCPA. Without a complete database for each metabolite, Agency policy is to use a default assumption that each metabolite is no more or less toxic than the parent; and, as previously stated

exposure = (ppb DCPA and/or metabolites in the water consumed) $(10^{-6})(22.6)$

Groundwater

State Studies (Suffolk County, NY)

%RfD = $[(28.768)\ (10^{-6})\ (22.6)/(0.01)](100)$
= 6.5%

Registrant Studies

New York turf

%RfD = $[(50.36)\ (10^{-6})\ (22.6)/(0.01)](100)$
= 11%

California onions

%RfD = $[(12.75)\ (10^{-6})\ (22.6)/(0.01)](100)$
= 3%

Surface Water

Lonetree Creek

%RfD = $[(5.95)\ (10^{-6})\ (22.6)/(0.01)](100)$
= 1%

Cherry Creek

Risk = $[(0.0078)\ (10^{-6})\ (22.6)/(0.01)](100)$
= 0.002%

The highest %RfD was 11% at the New York turf site. Even if this drinking water risk were to be combined with the chronic dietary risk, the total %RfD would be much less than 100.

(2) Carcinogenic Drinking Water Risk

Carcinogenic risk for drinking water was calculated using the following formula.

Risk = Exposure x Q_1^* where:

- the Q_1^* for DCPA, 0.00149 $(mg/kg/day)^{-1}$ is used for DCPA, TPA, and MTP. A complete database exists only for DCPA. Without a complete database for each metabolite, Agency policy is to use a default assumption that each metabolite is no more or less carcinogenic than the parent; and as previously stated

- exposure = (ppb DCPA and/or metabolites in the water consumed) $(10^{-6})(22.6)$

Groundwater

State Studies (Suffolk County, NY)

Risk = $(28.768)(10^{-6})(22.6)(0.00149)$
= 9.7×10^{-7}

Registrant Studies

New York turf

Risk = $(50.36)(10^{-6})(22.6)(0.00149)$
= 1.7×10^{-6}

California onions

Risk = $(12.75)(10^{-6})(22.6)(0.00149)$
= 4.3×10^{-7}

Surface Water

Lonetree Creek

Risk = $(5.95)(10^{-6})(22.6)(0.00149)$
= 2×10^{-7}

Cherry Creek

Risk = $(0.0078)(10^{-6})(22.6)(0.00149)$
= 2.6×10^{-10}

Generally, the information available to the Agency does not identify a population consuming drinking water equal to or greater than 50 ug/L (DCPA and metabolites) for a period of 70 years. It should be noted that the highest concentration of detected TPA in the NPS was 7.20 ug/L, and there were no detections of DCPA.

Consumption of drinking water obtained from groundwater at the New York turf site may be a worst case scenario. If drinking water were to be obtained solely from this source (containing DCPA and its metabolites at 50 ug/L) then the carcinogenic risk would be 1.7×10^{-6}. The Agency will be refining this risk estimate, since it has been based on preliminary information and could change based on final groundwater data due to the Agency in the summer of 1996.

The information available to the Agency indicates that the NOELs for TPA would be higher than those of DCPA for similar studies. However, adequate information to estimate a health advisory level for TPA is not available. As previously stated, a complete database exists only for DCPA, and it was necessary for the Agency to default to the DCPA database for the TPA (and MTP) metabolites.

c. Occupational and Residential Assessment

(1) Short Term and Intermediate Term Risk

A short term (1 - 7 days) occupational or residential risk assessment was not required because the NOEL for the 21 day dermal study is greater than 1000 mg/kg/day. Additionally, no appropriate toxicological endpoint of concern was identified.

An intermediate term (1 week to several months) occupational or residential risk assessment was not required. The NOELs in the studies appropriate for selecting this endpoint were too high to be of concern; therefore, an appropriate toxicological endpoint of concern was not identified.

(2) Carcinogenic Risk

Using the exposures presented in Table 8, the carcinogenic risk after exposure to foliar dislodgeable residues of DCPA following an application of Dacthal W-75 to turfgrass was calculated using the following formula:

> Risk = [[Average annual exposure (mg/kg/day)] [play exposure interval (10 yrs)/average lifetime (70 yrs)]] x [Q_1^*(0.00149 (mg/kg/day)$^{-1}$)] x [dermal absorption factor (0.149)].

For irrigated lawns the average annual risk estimate for children playing on a treated lawn is 5.6×10^{-7}. For non-irrigated lawns the average annual risk for children playing on a treated lawn is 2.0×10^{-6}.

A similar formula was used to calculate the carcinogenic risk after exposure (Table 9) to foliar dislodgeable residues of HCB following an application of Dacthal W-75 to turfgrass:

> Risk = [[Average annual exposure (mg/kg/day)] [play exposure interval (10 yrs)/average lifetime (70 yrs)]] x [Q_1^*(1.02 mg/kg/day)$^{-1}$)] x [dermal absorption factor (0.2646)].

For irrigated lawns the average annual risk from HCB as an impurity of DCPA for children playing on a treated lawn is 3.9×10^{-7}. For non-irrigated lawns the average annual risk for toddlers and children playing on a treated lawn is 2.7×10^{-6}.

As previously stated, the Agency does not have the foliar residue data to calculate exposure to 2,3,7,8-TCDD following an application of Dacthal W-75 to turfgrass. However, a rough estimation of the risk for children ages 2-12 playing on non-irrigated turf at 1 hour after treatment was 3.9×10^{-7}.

The carcinogenic risk for the previously identified occupational and residential scenarios are given in Table 10 for DCPA and in Table 11 for HCB. The highest estimated risk for a commercial applicator is for the wettable powder scenario. For the commercial mixer/loader (assuming 350 acres) the risk for DCPA was estimated to be 7.5×10^{-5} and for HCB (in DCPA) to be 1.9×10^{-4}.

These risks could be mitigated by the use of a dust mist respirator with a TC-21C filter. The application of an 80% protection factor for the inhalation exposure component of treating 350 acres yields an LADD (mg/kg/day) of 0.027 for DCPA and 1.3×10^{-4} for HCB. The corresponding carcinogenic risk would be 4.0×10^{-5} for DCPA and 1.3×10^{-4} for HCB.

The scenario with the highest risk for a private applicator for exposure to DCPA is also the wettable powder scenario (assuming 80 acres are treated). For DCPA the risk is 1.6×10^{-6}. The scenarios with the highest risk for a private applicator for exposure to HCB are the wettable powder scenario (assuming 80 acres treated), the shaker can scenario (5000 ft^2), and the whirly-bird scenario with corresponding risk estimates of 4.6×10^{-6}, 1.4×10^{-6}, and 1.6×10^{-6}. The Agency is requiring additional handler studies for these scenarios.

Risk for several of the M/L/A scenarios for exposure to TCDD was estimated using an application rate of 10^{-9}, which is the DCPA label application rate of 10 multiplied by the TCDD exposure values of 0.00000001%. The risk for the whirly-bird scenario was 2×10^{-8} and for the wettable powder scenario, commercial applicator (300 acres) was 1.6×10^{-6}. It should be emphasized that these can be considered as overestimates due to the lack of a dermal absorption factor and the use of 0.00000001% of the DCPA formulation.

Foliar dissipation data for DCPA and HCB on cucumbers and corresponding worker exposure and risk during cucumber harvesting are summarized in Table 12. The highest risk for

exposure to DCPA is 1.8×10^{-4} and for exposure to HCB (in DCPA) is 3.2×10^{-4} both at zero days after treatment. The risk values decrease as the days after treatment increase. The exposure and risk levels in 12 were calculated based on very conservative assumptions regarding transfer of foliar dislodgeable residues (FDRs) to fieldworkers during harvesting and the number of days of exposure per year at each FDR level (i.e., 30 days of exposure per year at each FDR level).

The Agency also lacks the FDR data to calculate TCDD exposure during cucumber harvesting. However, a rough estimation for zero days after treatment is 8×10^{-6}, which should be considered as an overestimation since a very conservative transfer factor was used and no dermal absorption factor was available.

Table 10: DCPA Occupational and Residential Carcinogenic Risk Values (based upon exposure values from Table 5)

Exposure Scenario (Scen. #)	Risk[a]	
	Private Appl.[b]	Commercial Appl.[c]
Mixer/Loader Risk		
Liquids (I)	80A: 1.6×10^{-7}	80A: 1.6×10^{-6}
		350A: 7.3×10^{-6}
Wettable Powder (Ia)	80A: 1.6×10^{-6}	80A: 1.6×10^{-5}
		350A: 7.5×10^{-5}
Granulars (II)	80A: 7.6×10^{-8}	80A: 7.6×10^{-7}
		350A: 3.3×10^{-6}
Applicator Risk		
Aerial (liquids) (IIIa)	NA	7.9×10^{-6}
Aerial (granulars) (IIIb)	NA	1.6×10^{-6}
Groundboom (IV)	4.5×10^{-8}	4.5×10^{-7}
Granular Spreader Cultivator Mounted (V)	9.4×10^{-9}	9.4×10^{-8}
Flagger Risk		
Liquids (VIa)	NA	1.8×10^{-6}
Granulars(VIb)	NA	5.7×10^{-7}
Mixer/Loader/Applicator Risk		
Shaker Can (VII) 1000 ft^2	7.3×10^{-8}	7.3×10^{-7}
Shaker Can (VII) 5000 ft^2	3.7×10^{-7}	3.7×10^{-6}
Backpack (VIII)	1.2×10^{-7}	6.0×10^{-6}
Residential Push-type Spreader (IX)	1.3×10^{-7}	6.3×10^{-6}
Whirly-bird Spreader (X)	4.8×10^{-7}	NA

[a] Risk = [LADD (mg/kg/day)] * [Q_1^* of 0.00149 $(mg/kg/day)^{-1}$]

[b] Private applicator is defined as a short term exposed individual (i.e., one day).

[c] Commercial applicator is defined as an intermediate exposed individual (i.e. 10 days).

Table 11: HCB Occupational and Residential Carcinogenic Risk Values (based upon exposure values from Table 6)

Exposure Scenario (Scen. #)	Risk[a] Private Appl.[b]	Commercial Appl.[c]
Mixer/Loader Risk		
Liquids (I)	80A: 5.7×10^{-7}	80A: 5.7×10^{-6}
		350A: 2.6×10^{-5}
Wettable Powder (Ia)	80A: 4.6×10^{-6}	80A: 4.6×10^{-5}
		350A: 1.9×10^{-4}
Granulars (II)	80A: 2.1×10^{-7}	80A: 2.1×10^{-6}
		350A: 9.1×10^{-6}
Applicator Risk		
Aerial (liquids) (IIIa)	NA	2.8×10^{-5}
Aerial (granulars) (IIIb)	NA	3.8×10^{-6}
Groundboom (IV)	1.5×10^{-7}	1.5×10^{-6}
Granular Spreader Cultivator Mounted (V)	3.1×10^{-8}	3.1×10^{-7}
Flagger Risk		
Liquids (VIa)	NA	6.1×10^{-6}
Granulars (VIb)	NA	1.8×10^{-6}
Mixer/Loader/Applicator Risk		
Shaker Can (VII) 1000 ft^2	2.6×10^{-7}	2.6×10^{-5}
Shaker Can (VII) 5000 ft^2	1.4×10^{-6}	1.4×10^{-5}
Backpack (VIII)	4.2×10^{-7}	2.1×10^{-5}
Residential Push-type Spreader (IX)	4.6×10^{-7}	2.3×10^{-5}
Whirly-bird Spreader (X)	1.6×10^{-6}	NA

[a] Risk = LADD (mg/kg/day)] * [Q_1^* of 1.02 $(mg/kg/day)^{-1}$]

[b] Private applicator is defined as a short term exposed individual (i.e., one day)

[c] Commercial applicator is defined as an intermediate exposed individual (i.e. 10 days)

Table 12: Foliar Dislodgeable Residues (FDR) of DCPA and HCB on Cucumbers and the Worker Reentry Exposure and Risk During Cucumber Harvesting Corresponding

DAT	FDR ($\mu g/cm^2$)[a]		LADD (mg/kg/day)[b]		Risk Levels[c]	
	DCPA	HCB	DCPA	HCB	DCPA	HCB
0	17.4	0.025	0.82	0.0012	1.8×10^{-4}	3.2×10^{-4}
1	15.0	0.018	0.70	0.0009	1.6×10^{-4}	2.3×10^{-4}
2	12.9	0.013	0.61	0.0006	1.3×10^{-4}	1.6×10^{-4}
3	11.1	0.010	0.52	0.0005	1.2×10^{-4}	1.3×10^{-4}
4	9.5	0.007	0.45	0.0003	9.9×10^{-5}	8.9×10^{-5}
5	8.2	0.005	0.38	0.0002	8.5×10^{-5}	6.3×10^{-5}
6	7.0	0.004	0.33	0.0002	7.3×10^{-5}	5.1×10^{-5}

DAT = Days After Treatment
The calculations use the following assumptions: 8 hour work day, 30 days exposure each year for a total of 35 years over a 70 year lifetime, average body weight of 70 kg

[a] FDR values were calculated using a regression analysis of dissipation data (MRID 417501-05)

[b] Lifetime Average Daily Dose (LADD) was calculated using the following equation:
[FDR ($\mu g/cm^2$) x (10000 cm^2/hr) x (1 mg/1000 μg) x (1/70 Kg) x (8 hrs/day) x (30 days harvesting/365 days per year) x
(35 years harvesting/70 year lifetime)]
where 10,000 cm^2/hour is a transfer coefficient for citrus harvesters excerpted from Zweig, Leffingwell, Popendorf, 1985.

[c] Risks for DCPA and HCB were calculated using the following equation:
[LADD (mg/kg/day) x $Q1^*$ $(mg/kg/day)^{-1}$ x (Dermal Absorption Factor)
The Q_1^* value for DCPA is 0.00149 $(mg/kg/day)^{-1}$ and for HCB is 1.02 $(mg/kg/day)^{-1}$.
The dermal absorption factor for DCPA is 0.149 and for HCB is 0.2646

Additional Occupational/Residential Exposure Studies

Handler Studies

The Agency does not have handler exposure studies for three of the occupational scenarios for which DCPA is used. The Agency used surrogate data from the Pesticide Handler's Exposure Database to estimate a handler's exposure to DCPA and HCB in these scenarios. Resulting risk estimates are in the 10^{-4} to 10^{-6} range, with a great amount of uncertainty associated with those values. Therefore, the registrant is being required to submit handler exposure studies for three scenarios to confirm that these uses are eligible for reregistration. The three scenarios are listed below.

- loading/applying granular formulations using whirly-bird spreader equipment,
- mixing/loading wettable powder formulations to support aerial applications, and
- loading/applying granular formulations using a shaker can.

A dermal exposure study (Guideline 231) and an inhalation exposure study (Guideline 232) are being required for each of these scenarios. These studies should be conducted concurrently; i.e., dermal and inhalation samples should be collected from the same handler and at the same site during each trial for both DCPA and HCB exposure. Requirements for such studies are addressed in subdivision U of the Pesticide Assessment Guidelines.

Post-Application Studies

The registrant must submit post-application exposure studies as confirmatory data for reregistration. Requirements for such post-application exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. Post-application/reentry exposure studies are required as confirmatory data to determine definitive REIs for crop/use sites on which DCPA is registered for use. The REIs established in this document will be adjusted accordingly upon submission of the additional data. Studies are required for:

- **Low crops (such as cucumber)**
- **Residential sites (turfgrass)**

Requirements for post-application/reentry exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. The required data include:

*****133-3	Post-application Dermal Passive Dosimetry Exposure
*****133-4	Post-application Inhalation Passive Dosimetry Exposure

*****Guidelines 133-3 and 133-4 may be reserved at this time pending completion of the databases on agricultural and residential postapplication/reentry exposure currently being developed by the Agricultural Reentry Task Force and Outdoor Residential Exposure Task Force, **provided** the registrant is a member of both Task Forces.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to assess the hazard of DCPA to nontarget terrestrial organisms, although the guideline requirements for avian reproduction are not fulfilled; and plant seedling emergence, germination and vegetative vigor are only partially fulfilled (i.e., the risk assessment was completed with supplemental data).

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of DCPA to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

Table 13: Avian Acute Oral Toxicity

Avian Acute Oral Toxicity Findings					
Species	**% A.I.**	**LD_{50} mg/kg)**	**MRID No**	**Toxicity Category**	**Fulfills Guideline Requirement**
Northern Bobwhite	100	>2,250	41155705	practically nontoxic	yes

Table 14: Avian Subacute Oral Dietary Toxicity

Avian Subacute Dietary Toxicity Findings					
Species	**% A.I.**	**LC_{50} (ppm)**	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Northern Bobwhite	100	>5,620	41155706	practically nontoxic	yes
Mallard	100	>5,000	41155707	practically nontoxic	yes

[1] This study is classified as supplemental.

These results indicate that DCPA is practically nontoxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled. (MRID 411557705, 41155706, and 41155707)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. DCPA is persistent enough to result in chronic exposure to birds.

However, no data were available on the effect of DCPA on reproduction of the quail and mallard duck. Therefore, the Agency requires that an avian reproduction study be conducted in order to quantify the chronic risks of DCPA use to avian species. The guideline requirements for avian reproduction testing are not satisfied.

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, a rat acute oral LD_{50} is used as a small mammal surrogate to estimate toxicity to mammals. This LD_{50} is reported below.

Table 15: Mammalian Acute Oral Toxicity

Mammalian Acute Oral Toxicity Findings					
Species	**% A.I.**	**LD_{50} (mg/kg)**	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Rat (small mammal surrogate)	90	>5,000	41054808	practically nontoxic	Yes

The available mammalian data indicate that DCPA is practically nontoxic to small mammals on an acute oral basis. (MRID 41054808)

(4) Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure.

Table 16: Nontarget Insect Acute Toxicity

Nontarget Insect Acute Contact Toxicity Findings					
Species	**% A.I.**	**LD_{50} μg a.i./bee**	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Honey Bee	99.6	>230	00009181	practically nontoxic	Yes

There is sufficient information to characterize DCPA as practically nontoxic to bees. The guideline requirement is fulfilled. (MRID 00009181)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study must use a coldwater species (preferably the rainbow trout), and the other must use a warmwater species (preferably the bluegill sunfish).

Table 17: Freshwater Fish Acute Toxicity

Freshwater Fish Acute Toxicity Findings					
Species	**% A.I.**	**LC_{50} (ppm)**	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Rainbow trout	2.5	>180	00107142	practically nontoxic	No[1]
	75	30	40227001	slightly toxic	Yes
	75	>6.6	41054826		Yes
Bluegill sunfish	75	>320	00045822	practically nontoxic	No[1]
	75	>120	40227002	practically nontoxic	Yes
	96.7	>96.7	41054827	slightly toxic	Yes

[1] This study is classified as supplemental.

The results of the 96-hour acute toxicity studies indicate that DCPA is probably no more than slightly toxic to fish. The guideline requirements are fulfilled. (MRID 41054827, 00107142, 40227001, 00045822, 40227002 and 41054826)

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Table 18: Freshwater Invertebrate Toxicity

Freshwater Invertebrate Toxicity Findings					
Species	**% A.I.**	**LC_{50}** (ppm)	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Daphnia magna	tech.	>100	40098001	practically nontoxic	Yes
	75	138	40226901	practically nontoxic	Yes
	75	27	078701 40098001 40098001	slightly toxic	Yes
	75	30	40098001	slightly toxic	Yes
	75	47		slightly toxic	Yes
Chironomus plumous	tech.	>100	40098001	practically nontoxic	Yes
	75	138	40098001	practically nontoxic	Yes
Gammarus pseudolimnaeus	tech.	138	40098001	practically nontoxic	No[1]
	75	138	40098001	practically nontoxic	No[1]

[1] This study is classified as supplemental.

There is sufficient information to characterize DCPA as slightly toxic to practically nontoxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID 40098001, 40226901)

This study is classified as supplemental.

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The terrestrial uses of DCPA may result in exposure to the estuarine environment.

The requirements under this category include a 96-hour LC_{50}/EC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

Table 19: Estuarine/Marine Acute Toxicity

Estuarine/Marine Acute Toxicity Findings					
Species	**% A.I.**	**EC/LC_{50} (ppm)**	**MRID No.**	**Toxicity Category**	**Fulfills Guideline Requirement**
Eastern oyster shell deposition	tech.	0.62	40098001	highly toxic	Yes
Brown Shrimp	tech.	>1.0	40098001	moderately toxic	Partial[1]
Sheepshead minnow	tech.	>1.0	40098001	moderately toxic	Partial[1]

[1] These studies are classified as supplemental because no LC_{50} was obtained. However, they provide sufficient information to show that the LC_{50} for these species is greater than 1 ppm, which approximates maximum solubility.

There is sufficient information to characterize DCPA as moderately to highly toxic to nontarget estuarine and marine organisms. The guideline requirement is fulfilled. (MRID 078701)

c. Toxicity to Plants

(1) Terrestrial

Currently, terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides which have terrestrial non-residential outdoor use patterns and appear to move off-site of application through volatilization (vapor pressure 2.5 x 10^{-6} torr at 25 C) or drift (aerial or irrigation); and/or which may have endangered or threatened plant species associated with the site of application. The above conditions apply for DCPA (refer to Section IV.C.3, Endangered Species).

Tier II toxicity data on the technical/TEP material for the most sensitive species is listed below:

Table 20: Nontarget Terrestrial Plant Toxicity

Nontarget Terrestrial Plant Toxicity Findings		
Test and Species	**% A.I.**	**EC_{25}**
Seedling emergence and germination (tomato)	tech.	>7.5 lbs ai/acre
Vegetative vigor (soybean)	tech.	>7.5 lbs ai/acre

The studies submitted for seedling emergence and germination and vegetative vigor have been classified as supplemental. The Agency did not use these data for risk assessment purposes since tolerant species were used. Further, the Agency is requiring that additional nontarget testing not be conducted **with these same species**. See Data Requirements section of DCPA RED for discussion.

The guideline requirements are not fulfilled. (MRID 41564901, 41440101)

(2) Aquatic

Currently, aquatic plant testing is required for any herbicide which has outdoor non-residential terrestrial uses that may move off-site of application by runoff (solubility >10 ppm in water), by drift (aerial or irrigation), or is applied directly to aquatic use sites (except residential) as in the case of DCPA. The following species must be tested: *Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae,* and a freshwater diatom.

Tier II toxicity data on the technical/TEP material is listed below:

Table 21: Nontarget Aquatic Plant Toxicity

Nontarget Aquatic Plant Toxicity Findings		
Species	**% A.I.**	**EC_{50}** (ppm)
Navicula pelliculosa (Freshwater diatom)	98.4	>11.0
Lemna gibba	98.4	>11.0
Selenastrum capricornutum	98.0	>12.38
Skeletonema costatum	98.4	>11.0
Anabaena flos-aquae	98.4	>11.0

The guideline requirements are fulfilled. (MRID 41155714, 42836102, 42882401, 42836103, 4236101, and 41054829)

2. Environmental Fate

a. Environmental Fate Assessment

The Agency has sufficient data to define the environmental fate of DCPA. Biodegradation is the primary dissipation process for DCPA. Under laboratory conditions, the half-life is approximately 15-30 days, but longer half-lives have been reported in the field. Parent DCPA is not especially persistent or mobile. Tetrachloroterephthalic acid (TPA or di-acid) is the only significant DCPA metabolite, with monomethyl tetrachloroterephthalic acid (mono-acid) as a minor metabolite. TPA is unusually mobile and persistent in the field. Data suggest that TPA will leach to groundwater wherever DCPA is used, regardless of soil properties.

Volatilization from soil is also a major dissipation route for parent DCPA. Volatilization appears to be the source of DCPA residues on crops to which it has not been applied. The maximum distance that DCPA may move following volatilization is not known, but drift has been reported in the published literature. Under warm conditions in fields with high soil moisture levels, volatilization may be the major dissipation route for DCPA. More typically, volatilization

probably accounts for 20-40 percent of DCPA loss. For TPA, leaching is the major dissipation route.

TPA does not appear to be phytotoxic, as weed control occurs rapidly after application of DCPA and control declines with the decline of parent DCPA concentration in the soil.

Concentrations of DCPA reported in fish exposed to DCPA through volatility drift alone (38 ppb) raise concerns about exposure of endangered freshwater mollusks to DCPA. Substantial amounts of DCPA could be available for runoff for several weeks post-application. Most DCPA runoff will generally occur in the form of adsorption to eroding soil as opposed to dissolution in runoff water. DCPA could be somewhat persistent in many surface waters, particularly those with low microbiological activities and long hydrological residence times.

TPA appears to be substantially more persistent than parent DCPA and exhibits low soil/water partitioning. Therefore, substantial quantities of TPA should be available for runoff for a longer period than the parent DCPA.

TPA is extremely mobile and can leach to ground water under many different conditions. Although contrary to the environmental chemistry and environmental fate data which indicate that parent DCPA would not be very mobile, it appears that under certain conditions both the DCPA parent and the mono-acid can also find their way into the ground water. The persistence of TPA in ground water is not known.

The lifetime Health Advisory for DCPA in drinking water is currently established at 4000 µg/L (ppb). DCPA and/or TPA have been reported in four percent of ground water (206 wells of 4917) in ground water monitoring studies conducted in 24 states. Concentrations of TPA ranged from trace levels to 1477 ppb. The maximum parent DCPA concentration reported is 7.7 ppb. Concentrations of DCPA residues have all been below the current lifetime Health Advisory.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis. DCPA was stable in water for 36 days at pH 5, 7, and 9. (MRID 00114648)

Photolysis in water. DCPA was stable to photolysis in unbuffered water. After the equivalent of 191 12-hour exposure days, less than 10 percent of the parent DCPA had photolyzed. (MRID 41508607)

Photolysis on soil. DCPA was stable to photolysis on soil. In an early study, DCPA was stable under a sunlamp having "297 nm in wavelength." After 38.5 days equivalent of radiation on a glass bead surface, 95.7 percent of the applied was present as parent DCPA. With the same sunlamp and DCPA on silica gel in the presence of a photosensitizer (unnamed), 90.8 percent remained as DCPA after the equivalent of 168 days of exposure. The primary photoproduct was monomethyl tetrachloroterephthalic (MTP or mono-acid) at 5.2 percent. No photodegradation

occurred under black light and fluorescent light, shown to be similar to natural sunlight in the range of wavelengths where DCPA absorbs light. (MRID 41508608, accession number 093786)

Aerobic soil metabolism. DCPA will undergo microbial degradation and is enhanced by warmer temperatures and increased soil water content. Parent half-life was estimated at 18-37 days. After 197 days, virtually all of the parent DCPA had been converted into TPA, although small amounts of monomethyl tetrachloroterephthalic acid (MTP) were also identified. DCPA did not degrade in steam-sterilized soil. Wettasinghe and Tinsley (1993) confirmed these results, with a half-life of 16.6 days at 25 C and 12.6 percent water content. Decreasing the temperature to 5 C and the water constant to 9.6 percent decreased the rate of degradation, giving a half-life of 289 days (Walker 1978, cited by Wettasinghe and Tinsley). Choi et. al. (1988, cited by Wettasinghe and Tinsley) confirmed these observations, reporting a half-life of parent DCPA at 11-16 days at medium soil moisture and 25 C. For the DCPA degradates, the mono-acid had a half-life of 2.8 ± 0.1 days. However, TPA was very persistent. There was virtually no degradation of TPA during a 300 day study. (MRID 00114649, 41648801)

Anaerobic soil metabolism. Anaerobic soil conditions slowed DCPA degradation only slightly, with estimated half-lives of 37-59 days. TPA was also the final degradate under anaerobic conditions. (MRID 00114651, 41648802).

(2) Mobility

Leaching/adsorption/desorption. Although not fully acceptable, the study of parent DCPA strongly suggests that DCPA is not mobile. In an unaged column leaching study, the sand portion of the soil may have been removed by sieving through too fine a mesh, resulting in a finer soil fraction and making the parent compound appear less mobile. For the degradates of DCPA, both TPA and MTP are highly mobile in all soils. (MRID 41648803, 41648804, 41648805, 42262602)

Aged column leaching. DCPA residues were shown to leach through soil, with the leachate containing primarily TPA. In this early study, soil columns were prepared with 2 g of treated soil aged 30 days placed atop a 12 inch column. The columns were leached with 1/2 inch of water a day for 45 days. In two sandy loams, one pH 5.9 and the other pH 8.0, DCPA residues were shown to leach. The residue found in the leachate was overwhelmingly TPA. Leaching was much more extensive in the high pH soil: 85.2 percent of the applied was found in the leachate. (MRID 00114650)

Lab and field volatility. Based on a relatively low Henry's constant (2.2×10^{-6} atm-m^3/mol) and moderately to relatively high soil/water partitioning, DCPA does not appear to have a high volatilization potential from soil. Nevertheless, several published studies have shown that parent DCPA is volatile, especially from moist or wet soil.

Nash and Gish (1989) suggested that DCPA volatilization may be adsorption and diffusion controlled, which would explain the poor predictability of volatilization from vapor pressure. At a temperature of 35 C, volatility accounts for the majority of the applied DCPA.

Majewski et.al. (1991) suggested that in the early phase after application, volatilization is the primary dissipation route for DCPA. They measured a total DCPA loss of between 1.27 and 1.59 kg per hectare out of 7 kg per hectare applied. They also found that DCPA volatilization flux was very dependent upon the soil surface moisture content. High fluxes occurred immediately following irrigation. Approximately 36 to 52 percent of the total measured DCPA loss from soil was accounted for by volatilization and 26 percent by breakdown in soil during the 21 days of air sampling.

Ross et. al. (1990) estimated that 10 percent of the DCPA applied was lost to the atmosphere within 21 days of application. This group investigated DCPA volatility because DCPA residues have been found repeatedly on a variety of produce samples to which it had not been applied in California. They concluded that these detections may have been due to DCPA volatilization and drift. Volatilization accounted for 29 percent of the DCPA lost from soil in this study. Although DCPA moved off target both as a gas and on particles, 62 to 93 percent of the atmospheric residues were in the vapor phase when the field was wet. Field moisture in this case may have reduced the number of airborne dust particles as well as promoted DCPA volatilization.

(3) Accumulation

Fish bioaccumulation. DCPA bioaccumulates significantly in bluegill sunfish with bioconcentration factors (BCFs) of 1894, 777, and 2574 in whole fish, edible tissue, and viscera, respectively. Depuration appears to be complete after 14 days. Little metabolism or degradation of DCPA occurs in fish tissues, although there is a detectable amount of demethylation. (MRID 41155716, 41197602)

(4) Terrestrial Field Dissipation

Gilroy, CA: Bareground plots of loam soil were treated up to three times with DCPA (75% WP), at 7.0-10.5 lbs. a.i. per application. DCPA was detected to 18-inches, the maximum sampling depth, in all of the plots, while the mono-acid was not detected below 6 inches in any plot. However, TPA was detected as deep as 60 inches 552 days after the single treatment and up to 96 inches 552 days after the double treatment. TPA was found at 0.03 ppm at the 72 inch depth 552 days after the triple treatment. (MRID 41508609)

This study was rejected for the large variation of DCPA concentrations with time. DCPA did not degrade steadily with time, but increased and decreased erratically until a significant reduction in concentration was noted in all experiments after about 185 days. The study author calculated a half-life of 35 days for all plots based on DCPA residues in the upper 18 inches of soil, but the erratic decline curves meant that half-life determinations were not statistically significant. The study author suggested that detections of parent DCPA below the surface layer were most likely due to sample contamination with surface soil. The study was considered supplemental.

Greenfield, CA: Bareground plots of sandy loam soil were treated up to three times with DCPA (75% WP), at 7.0-10.5 lbs. a.i. per application. DCPA was detected to 18-inches, the maximum sampling depth, in all of the plots, while the mono-acid was not detected below 6

inches in any plot. TPA was detected at 48 inches. In the plot treated three times, parent DCPA was again detected in the 15-18 inch layer. The mono-acid was not found below 6 inches, while TPA was found at 18 inches (the lowest layer sampled).

This study was rejected for the large variation of DCPA concentrations with time. DCPA did not degrade steadily with time, but increased and decreased erratically until a significant reduction in concentration was noted in all experiments between about 60 and about 120 days. The study author calculated half-lives of 44 days for the single application plot, 86 days for the double application plot, and 126 days for the triple application plot, but the erratic decline curves meant that half-life determinations were not statistically significant. The study author suggested that detections of parent DCPA below the surface layer were most likely due to sample contamination with surface soil. The study was considered supplemental. The data requirement is not satisfied. (MRID 41508609, 41508610)

(5) Spray Drift

Droplet size spectrum (Guideline 201-1) and drift field evaluation (Guideline 202-1) data are required for DCPA, as the 75 percent wettable powder formulation may be applied by aircraft. Since the registrant, ISK Biosciences, is a member of the Spray Drift Task Force, the Agency will not require droplet size spectrum or drift field evaluation data at this time. The registrant may satisfy these data requirements through the Spray Drift Task Force unless required by the Agency in advance of the Task Force's final report.

(6) Water Resources

(a) Ground Water

Detections of parent DCPA have been reported. This is contrary to the environmental chemistry and environmental fate data of parent DCPA which indicate that parent DCPA would not be mobile. TPA (the di-acid metabolite of DCPA) is extremely mobile and can leach to ground water under many different conditions. Although the persistence of TPA in ground water is not known, indications are that TPA is quite persistent. The mono-acid can also find its way into the ground water. However, TPA is the major degradate found in ground water.

The lifetime Health Advisory for parent DCPA in drinking water is currently established at 4000 µg/L (ppb). DCPA or TPA and the mono-acid degradate have been detected in ground water in 24 states. Concentrations of DCPA degradates ranged from trace levels to 1477 ppb. The maximum parent DCPA concentration reported is 7.7 ppb. Concentrations of DCPA residues have all been below the current lifetime Health Advisory.

National Survey of Pesticides in Drinking Water Wells (NPS): The Agency initiated the National Survey of Pesticides in Drinking Water Wells (NPS) to determine the frequency of community water systems (CWS) and rural drinking water wells (RDW) nationwide were contaminated by pesticides and nitrate-nitrogen (USEPA, 1990). DCPA and TPA were included in the suite of pesticides analyzed in the NPS. Parent DCPA was not detected in the NPS. However, TPA was the most commonly detected pesticide residue by the NPS. There were 31

CWS (5.5 percent of CWS 564 wells) and 18 RDW (2.3 percent of the 783 RDW wells) wells with detections (49 or 3.7 percent of 1347 wells) of TPA in twenty-two states. States with confirmed detections were AK, CA, CO, CT, IA, IL, IN, MA, MI, MN, MO, NH, NJ, NM, NY, OH, PA, RI, SD, VA, and WI. Maximum values of TPA were 7.2 ppb in CWS wells and 2.4 ppb in RDW wells. The median of the detectable values were 0.34 ppb and 0.38 ppb for the CWS and RDW wells, respectively.

State Studies. Approximately 157 wells (4.4 percent) of 3570 wells sampled in the various state ground-water monitoring studies (excluding registrants prospective studies) have detected parent DCPA residues. The 157 wells were located in seven (CA, IA, MA, NY, OR, WA, and WI) states.

Of the 3570 wells mentioned above, only parent DCPA was analyzed for in 2229 of the wells. For the remaining 1341 wells, analysis included both parent DCPA and TPA. For these wells, TPA was detected in 11.3 percent of the wells. The highest TPA value reported was 1039 ppb, which occurred in Suffolk County, New York. Suffolk County is highly vulnerable to ground water contamination as the frequency of detections for other pesticides is also quite high. Reported average and median DCPA residue concentrations for the New York data were 109 ppb and 13.2 ppb, respectively. The highest reported TPA value in Oregon was 986 ppb (Cox, 1991). The average TPA concentration reported for three wells in Wisconsin was 256 ppb. Generally, the maximum reported values were 15 ppb or less.

Both Suffolk County, New York, and Treasure Valley in Malheur County, Oregon, may represent examples of "hotspots." More than half (116 wells out of 206) of the wells with confirmed DCPA detections occurred in these two areas. The California Department of Food and Agriculture conducted a seven county study which may also be considered a hot spot, as 18 wells of 60 were confirmed to be contaminated with DCPA residues, with an additional 33 wells having unconfirmed detections.

Registrant studies. The registrant is currently conducting two small-scale ground water monitoring studies: on onions in California and on turf in New York. Although only a portion of data have been collected and analyzed to date, the ground water monitoring results are informative. As expected, TPA was detected most frequently and in the highest concentrations; however, both DCPA and the monoacid were detected in higher than expected frequency, although much lower concentrations. DCPA parent was detected in 16 and 26 percent of the wells in New York and California, respectively; the mono-acid was detected in 12 and 29 percent of the wells in New York and California, respectively. Preferential flow and transport mechanisms may have contributed to presence of these residues in ground water.

Other Observations and Concerns. Environmental fate data indicate that DCPA degradation is slower under cooler conditions compared to warmer conditions. This factor may at least partially explain the greater frequency of detections in New York and Oregon (cool) in comparison to California (warm) conditions. Seventeen states with DCPA residue detections could be classified as states with cooler temperatures (AK, CT, IA, IL, IN, MA, MI, MN, NH, NJ, NY, OH, OR, PA, RI, SD, and WI). States considered "warm" states with detections were California, Colorado, and New Mexico. Irrigation also is potentially a factor affecting the degree

of leaching in California, Colorado, and New Mexico, and should not be ruled out in the other states. Other environmental factors which can influence the transport of chemicals to ground water are the amount, intensity, frequency, and temporal distribution of precipitation.

Summary. The state and NPS studies found DCPA or TPA in 4.2 percent (excluding repeated samples) of the 4917 wells sampled and analyzed for either DCPA or TPA. TPA was found in 7.6 percent of the 2688 wells sampled and analyzed for that metabolite, and parent DCPA was detected in 0.12 percent. DCPA and its metabolites were detected in a total of twenty-four states. Parent DCPA residues were detected in the New York, Iowa, and Washington state studies, but no residues were found in those states where sampling was done for the NPS.

The maximum values of DCPA reported by all studies were less than the LHA of 4000 ppb. The maximum value found of TPA in the NPS was 7.2 ppb. DCPA was not found. Maximum TPA residue values reported (in ppb) by state are: California, 15 (326 for registrant sponsored study); Iowa, 0.03; Massachusetts, 1.07; New York, 1039 (1477 for registrant sponsored study); Oregon, 986; and Washington, 1.1.

(b) Surface Water

Substantial amounts of DCPA could be available for runoff for several weeks post-application (aerobic soil metabolism half-lives of 18-37 days). The intermediate soil/water partitioning of DCPA (Freundlich K_{ads} values of 5.5, 32.1, 9.4, and 70.3; SCS database K_{oc} of 5000) indicates that DCPA runoff will occur via both dissolution in runoff water and adsorption to eroding soil. The resistance of DCPA to abiotic hydrolysis and to direct photolysis in water coupled with only a moderate susceptibility to aerobic biodegradation and a lower susceptibility to anaerobic biodegradation (anaerobic metabolism half-life 37-59 days) indicates that DCPA will be somewhat persistent in many surface waters, particularly those with low microbiological activities and long hydrological residence times. Although the magnitude of its Henry's constant (2.2×10^{-6} atm-m^3/mol) is sufficient to indicate some moderate susceptibility to volatilization from water, it does not appear to be high enough for volatilization to rapidly remove DCPA from surface waters. The intermediate soil/water partitioning of DCPA indicates that it will be both dissolved in the water column and adsorbed to suspended and bottom sediment. However, concentrations should be greater on suspended and bottom sediment than in the water column.

The primary degradate of DCPA is tetrachloroterephthlate acid (TPA). TPA appears to be substantially more persistent than dacthal and exhibits low soil/water partitioning. Therefore, substantial quantities of TPA should be available for runoff for a longer period than the parent DCPA. Unlike DCPA, most TPA runoff should be in the form of dissolution in runoff water. TPA should also persist longer in most surface waters than DCPA, and unlike DCPA, exist primarily dissolved in the water column.

According to the pre-1988 listings in STORET, DCPA was detected in 386 of 1995 surface water samples at a 85th percentile of detections of 0.39 ug/L, and a maximum concentration of 8.5 ug/L.

The available data on concentrations of DCPA in surface waters is limited. Although most detections have been below 1 ug/L, concentrations of 30, 40, and 100 ug/L were reported in a stream draining a small agricultural watershed in Colorado.

The USGS (Kimbrough and Litke 1995) collected samples from Cherry Creek at Denver, CO and from Lonetree Creek at Greely, CO from April 1993 through April 1994. Samples were collected once a month from October through March, and two or more times per month during other months. Reported method detection limits for DCPA varied from 0.002 to 0.005 ug/L. In Cherry Creek which drains a primarily urban watershed, DCPA was detected in 14 of 25 samples at concentrations ranging from 0.004 to 0.029 ug/L. Five of the samples had DCPA concentrations $\geq$ 0.020 ug/L. In Lonetree Creek which drains a primarily agricultural watershed, DCPA was detected in 21 of 25 samples at concentrations ranging from 0.002 to 100 ug/L. Eight of the samples had DCPA concentrations $\geq$ 1ug/L (30, 1.9, 2.4, 40, 8.9, 6.0, 2.6, and 100 ug/L). The highest concentrations were in samples collected in May 1993 and in April 1994.

The USGS (MacCoy, Crepeau, and Kuivila 1995) collected samples daily from the San Joaquin River at Vernalis, and three times per week from the Sacramento River at Sacramento from October 1992 through September 1993. Samples collected two days in a row from the San Joaquin River were combined for analysis unless they were collected during runoff events. Samples were collected close to the center of the rivers with depth integrating samplers. The samples were filtered through 0.7 u filters and analyzed by GC/mass spectrometry. The reported method detection limits for DCPA were 0.063 ug/L and 0.044 ug/L for the San Joaquin and Sacramento River samples, respectively. DCPA was not detected in any of the Sacramento River water samples. DCPA was not analyzed for in samples collected from the San Joaquin River from October 1992 through mid-January 1993. In 176 samples collected from mid-January 1993 through September 1993 that were analyzed for DCPA, the compound was detected in 42 samples, but only 2 of the detections were above the reported method detection limit of 0.063 ug/L (0.091 ug/L and 0.181 ug/L).

The state of Kansas (Robbins 1987) reported DCPA detections in their surface waters. Over a period of 13 years from 1973 to 1986, DCPA was detected in 21 samples at concentrations ranging from 0.03 to 5.6 ug/L with a mean detected concentration of 0.49 ug/L. The Kansas river and stream sampling network includes up to 110 sampling stations, but no information was provided on the number of samples collected, where the samples were collected, the sampling intervals or the detection limit.

Washington State (Davis 1993) reported DCPA concentrations ranging from 0.006 to 12.1 ug/L in samples collected from various surface waters in 1992 and 1993. The four concentrations $\geq$ 1 ug/L (1.24, 2.2, 3.9 and 12.1 ug/L) were all in samples collected from agricultural watersheds east of the Cascades. No information was provided on the number of samples collected, the sampling intervals or the detection limit.

DCPA is not currently regulated under the Safe Drinking Water Act (SDWA). Therefore, no MCL has been established for it, and water supply systems are not required to sample and analyze for it. However, it has high 1-10 day drinking water HAs (80,000 ug/L), a high lifetime drinking water HA (4000 ug/L), and an intermediate soil/water partitioning that should make the

primary treatment process employed by most water supply systems somewhat effective in removing it. Consequently, DCPA does not appear to pose a direct substantial risk to surface source drinking water. Although the low soil/water partitioning of the TPA degradate should make its removal by primary methods ineffective, no drinking water HAs have been established for TPA.

3. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms.

There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, e.g. the LC_{50}.

The **acute** effect levels typically are:

- EC_{25} for terrestrial plants;
- EC_{50} for aquatic plants and invertebrates;
- LC_{50} for fish and birds; and
- LD_{50} for birds and mammals.

The **chronic** test results are:

- NOEL (No Observable Effect Level) for avian and mammal reproduction studies; and
- NOEL or MATC (Maximum Allowable Toxicant Concentration), which is the geometric mean of the NOEL and the LOEL (Lowest Observable Effect Level) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented below along with the corresponding LOCs.

Table 22: Levels of Concern (LOCs)

Levels of Concern (LOC) and Associated Risk Presumption[1]		
SPECIES	**LOC**	**PRESUMPTION**
Mammals, Birds		
If the		
acute RQ	>0.5	High acute risk
acute RQ	>0.2	Risk that may be mitigated through restricted use
acute RQ	>0.1	Endangered species may be affected acutely
chronic RQ	>1	Chronic risk, endangered species may be affected chronically,
Fish, Aquatic Invertebrates		
If the		
acute RQ	>0.5	High acute risk
acute RQ	>0.1	Risk that may be mitigated through restricted use
acute RQ	>0.05	Endangered species may be affected acutely
chronic RQ	>1	Chronic risk, endangered species may be affected chronically
Plants		
If the		
RQ	>1	High risk
RQ	>1	Endangered plants may be affected

[1] Currently, no separate criteria for restricted use or chronic effects for plants exist.

Table 23: Established Levels of Concern (LOCs)

Established Levels of Concern (LOCs)			
Risk Endpoint/Scenario	**Quotient**	**Non-Endangered LOC**	**Endangered LOC**
Mammalian acute	EEC/LC_{50}	0.5	0.1
Mammalian chronic	EEC/LEL*	1.0	1.0
Avian acute	EEC/LC_{50}	0.5	0.1
Avian chronic	EEC/LEL*	1.0	1.0
Aquatic acute	EEC/LC_{50}	0.5	0.05
Aquatic chronic	EEC/LEL*	1.0	1.0
Non-target insects	Not Quantified	N/A	N/A
Non-target plants	EEC/EC_{25} or EC_{50}	1.0	1.0

* LEL= Lowest Effect Level. The LEL is a theoretical level which is a value somewhere between the NOEL and the LOEL.

a. Nontarget Terrestrial Animals

(1) Birds

Acute Risks to Birds

Definitive LC_{50} values are not available for birds. The available data indicate the LC_{50} is greater than 5,620 ppm. It is not considered useful to calculate risk quotients using a "greater than" value, since the resulting quotient is not an indication of likely acute effects. The maximum concentration on food items from the maximum application rate (15 lb a.i./acre for turf) would probably not exceed 3,600 ppm. This is significantly less than the dietary concentration that did not kill any birds. Therefore, it may be reasonable to conclude that DCPA represents minimal acute risk to birds including endangered species.

However, there is uncertainty in this conclusion, since the standard risk assessment procedure used by the Agency is to apply a safety factor to the avian LC_{50} values to determine potential risk. These safety factors are applied to accommodate possible greater sensitivity of birds other than those tested and to protect a greater portion of the bird population than 50 percent.

As stated above, the estimated residues on short grass for turf use are approximately 3,600 ppm. These residues potentially exceed the LOC of 0.5 (3,600 ppm/>5,620 ppm = 0.6) for avian acute risk **if** the LC_{50} is indeed close to 5,620 ppm. Normally, when such exposure exceeds an LOC of 0.5, a conclusion of high risk to birds is made. When exposure exceeds an LOC of 0.2, a restricted use classification is warranted. If exposure exceeds 0.1, effects to endangered birds are presumed. However, the LC_{50} is greater than 5,620 ppm. Therefore, it cannot be presumed that the LOC has in fact been exceeded, as the Agency does not know what the true LC_{50} value is.

To address this question, the registrant must conduct a special dietary study with mallard ducks at higher test levels. If that test shows the LC_{50} is substantially greater than 5,000 ppm, (e.g., at least greater than 18,000 ppm), it would be possible to conclude with a very high degree of certainty that use rates up to 15 lb a.i./acre do not represent an acute risk to birds, including endangered species.

Chronic Risks to Birds

Long-term exposure to birds is possible since DCPA is persistent. Such exposure is possible not only from turf treatment, but also on other use sites. Even though the application is to bare ground, residual seeds, and other food items may be contaminated and provide a food source for some birds. The Agency cannot provide a risk assessment for **chronic** affects to birds because of lack of chronic data on birds. The Agency requires an avian reproduction study for mallard duck and bobwhite quail so that chronic effects to birds can be assessed.

(2) Mammals

Small mammal risk is addressed using acute oral LD_{50} values converted to estimate a LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

$$LC_{50} = \frac{LD_{50} \text{ x body weight (g)}}{\text{food consumed per day (g)}}$$

Table 24: Small Mammal Food Consumption

Small Mammal Food Consumption in PPMs (Based on an LD_{50} = >5,000 mg/kg)				
Small Mammal	**Body Weight in Grams**	**% of Weight Eaten Per Day**	**Food Consumed Per Day in Grams**	**Estimated LC_{50} Per Day (ppm)**
Meadow vole	46 gms	61 %	28.1 gms	>8,185
Adult field mouse	13 gms	16 %	2.1 gms	>30,952
Least shrew	5 gms	110 %	5.5 gms	>4545

The above table is based on information contained in Principles of Mammalogy by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

Acute Risks to Mammals

The estimated LC_{50} is then compared to the residues listed above to calculate a risk quotient (EEC/LC_{50}). The table below indicates the risk quotients for application of DCPA at the highest application rate of 15 lb a.i./A on **turf**.

Table 25: Mammalian Dietary Risk Quotients on Turf

Mammalian Dietary Risk Quotients on Turf (based on Dietary RQ = EEC/Lowest LC_{50})			
Mammal Type	**Food Item**	**Residues (ppm)**	**Risk Quotient**
Meadow vole consuming range grasses	short grasses	3600	<.43
	leafy crops	1875	<.23
Adult field mouse consuming seeds	short grass	3600	<.12
	seeds	180	<.006
Least shrew consuming forage and insects	small insects	870	<0.19

The table below indicates the risk quotients for application of DCPA at the application rate of 10.5 lb a.i./A on **vegetables and cotton**.

Table 26: Mammalian Dietary Risk Quotients on Vegetables and Cotton

Mammalian Dietary Risk Quotients on Vegetables and Cotton (based on Dietary RQ = EEC/Lowest LC_{50})			
Mammal Type	**Food Item**	**Residues (ppm)**	**Risk Quotient**
Meadow vole consuming range grasses	short grasses	2520	<.31
	leafy crops	1313	<.16
Adult field mouse consuming seeds	short grass	2520	<.08
	seeds	126	<.004
Least shrew consuming forage and insects	small insects	609	<0.13

The LOC for high **acute** risk (0.5) to mammals has not been exceeded. Residues on short grass when divided by the meadow vole LC_{50} do result in a risk quotient which exceeds the LOC (0.2) for restricted use. Also, endangered mammals exposed to areas treated with DCPA may be affected (RQ for endangered species LOC of 0.1).

Chronic Risks to Mammals

The table below indicates the **Chronic** risk quotients for application of DCPA at various application rates. For purposes of establishing chronic risk, the two-generation reproduction study on rats was used, with a NOEL of 1,000 ppm/day. The LOEL for this study was 5,000 ppm/day, resulting in weight loss and an increase in stillborn births. (MRIDs 41905201, 41750103)

Table 27: Mammalian Chronic Risk Quotients

Mammalian Chronic Risk Quotients (based on Dietary RQ = EEC/1,000 ppm NOEL)				
Use Rate lb a.i./A(Crop)	**Food Item**	**Residues**	**Risk Quotient**	**LOC**
15 (on turf)	short grass	3600	3.6	1
10.5 (on vegs & cotton)	leafy crops	1313	1.3	1
10.5 (on vegs & cotton)	short grass	2520	2.5	1
9 (on strawberry)	leafy crops	1125	1.1	1

For ground application to vegetables, cotton, and strawberries, the risk quotients in the above table may be misleading, overstating the potential risks. This is because for these crops, the treated area is usually free of vegetation before DCPA is applied. Alternatively, if the crop is present during treatment, the spray is directed past the foliage to treat only the bare ground. Therefore, minimal chronic risk to mammals is concluded for these crops.

Aerial application (cotton and vegetables) would result in treatment of crop foliage of cotton and vegetables. However, the maximum level of residues (about 780 ppm) does not exceed the NOEL for mammals.

For turf, on the other hand, both aerial and ground treatment is applied to newly emerged grass or established turf. So, using maximum residues on typical food items for mammals, the risk quotients exceed the chronic LOC.

Other factors are considered when determining the extent of risk and the certainty that chronic effects will occur. Uncertainty stems both from using laboratory toxicity test results, and from limitations in estimating actual exposure.

1. The study, from which the chronic NOEL was derived was a 2-generation rat reproduction study. It is not known at what duration of exposure at 5000 ppm would be required to result in the observed effects. Relatively short exposure to some chemicals has been known to cause delayed effects.

2. There is a large gap between the NOEL (1000 ppm) and the LOEL (5000 ppm). It is not known at what concentration between those test levels adverse effects may actually occur. The estimated residues exceed the NOEL, but do not exceed the LOEL.

3. It is assumed that other mammals would have different sensitivities than the representative test organism (laboratory rat). It is not known if wild mammals would be more or less sensitive. If they are more sensitive, even the lower residue levels may result in sublethal or reproductive risk.

4. It is not known how long the residues will last on mammalian food items. It is unlikely they will last the full 2 or so months that the rat 2-generation study lasted, especially at levels exceeding the NOEL.

5. Not all vegetation would contain residue levels exceeding the NOEL. In turf, where the predominant vegetation type is short grass, risk from consumption of maximum or typical residues exceed the LOC for chronic risk. Therefore, mammals grazing on treated turf would have a high probability of ingesting food items with residues exceeding the NOEL of 1000 ppm. However, in other crop areas, where application is to bare ground, the potential for exposure is minimal.

There seems to be moderate probability that chronic effects to mammals will occur. It is not clear how significant this risk is ecologically. It is possible that endangered mammals may be affected from turf use.

(3) Insects

For beneficial insects, it appears that there will be minimum adverse effects (LD_{50} >230 ug/bee) since it is practically nontoxic to bees.

b. Nontarget Aquatic Animals

Below are Estimated Environmental Concentrations from a 10 hectare watershed basin runoff into an hectare pond 6 feet deep after one application. The **exposures are in ppb** and are derived from a computer program (GENEEC) using Koc values, aerobic soil metabolism half-life, and solubility and use rates.

For calculating the risk quotient (RQ), the exposure (EEC) will be divided by the toxicity values of the organisms (fish LC_{50}=30 ppm, aquatic invertebrates LC_{50}=27 ppm and estuarine species LC_{50}=0.62 ppm). Since the invertebrates and freshwater fish share a similar LC_{50} value, the toxicity value in the RQ formula will be LC_{50} = 27 ppm. The RQ is derived from EEC/LC_{50}. Below is a table of risk quotients and risk criteria for DCPA:

Table 28: Application Rate with EEC and Risk Quotient for Aquatic Organisms (including endangered species)

Use Sites	Maximum Application Rate (lb ai/A)	Method of Application	EEC (ppb)	RQ[1] Freshwater Fish & Invertebrates	RQ[1] Estuarine Species
Strawberries	9.0	ground	33	<0.05	0.052
		aerial	45	<0.05	0.07
Broccoli, Cabbage, Cauliflower, Kale, Field Beans, Mung Beans, Snap Beans, Cowpeas, Garlic, Horseradish, Onions, Potatoes, Sweet Potatoes, Yams, Radish, Tomato, Eggplant, Pepper, Cotton, Watermelon, Cantaloupe, Cucumber, Squash, Newly Seeded Turf	10.5	ground	38	<0.05	0.06
		aerial	53	<0.05	0.08
Established Turf	15.0	ground	55	<0.05	0.09
		aerial	76	<0.05	0.12

[1] High acute risk RQ ≥ 0.5, Restricted use RQ ≥ 0.1, Endangered Species RQ≥ 0.05.

(1) Freshwater Fish and Invertebrates

Application of DCPA will not result in risk that exceeds any of the LOCs for freshwater fish or invertebrates. There are no data available to assess the risks to freshwater mollusks. Therefore, in the absence of data and because the mollusk was the most sensitive aquatic species, it may be appropriate to use the results from testing with estuarine species to assess risk to freshwater mollusks. LOCs for restricted use were exceeded for estuarine mollusks by the turf use when applied aerially. LOCs for endangered mollusk species were exceeded for all use scenarios.

(2) Estuarine Species

Application of DCPA will not result in risk that exceeds any of the LOCs for estuarine species. LOCs for restricted use were exceeded for estuarine mollusks by the turf use when applied aerially. LOCs for endangered mollusk species were exceeded for all use scenarios.

c. Nontarget Plants

(1) Terrestrial and Semi-aquatic

Nontarget terrestrial plants inhabit non-aquatic areas. Nontarget "semi-aquatic" plants are plants that usually inhabit low-lying wet areas that may or may not be dry in certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. The terrestrial and "semi-aquatic" plants are exposed to pesticides from runoff, drift or volatilization.

With the available data, given the fact that little or no effect was seen at the 9 lb ai/acre application rate, LOCs would not be exceeded for terrestrial plants. Since there is little confidence that the test data reflect the potential toxicity of DCPA to terrestrial plants, numerical estimates of risk will not be made. Calculating exposure and calculating risk quotients based on what is considered misleading data would yield equally misleading risk conclusions.

It is recommended that additional (Guideline 123-1 a & b) vegetative vigor and seedling emergence studies (tier II) be done with sensitive species.

(2) Aquatic

Runoff exposure is from preliminary EEC (GENEEC). Spray drift is assumed to be 5 percent of the application rate.

The risk assessment made for aquatic vascular plants is from the surrogate duckweed *Lemna gibba*. Algae and diatom risk assessment are useful indicators to determine impact to food sources of aquatic organisms. The EC_{50} values are similar for algae, diatoms and *Lemna gibba*. Therefore, the RQ will reflect all aquatic species from the toxicity value of EC_{50}= 11 ppm.

Table 29: Application Rate & EECs & Risk Quotients for Nontarget Aquatic Plant Species (including endangered species)

Use Site	Maximum Application Rate (lb ai/A)	Method of Application	Estimated Environmental Concentration (ppb)	Risk Quotient* for Aquatic Plants (EEC/EC_{50})
strawberries	9	ground	33	<1
		aerial	45	<1
broccoli, cabbage, cauliflower, kale, collards, field bean, cowpeas, snap bean, mung bean, horseradish, onion, potato, radish, sweet potato, yams, cotton, tomato, eggplant, pepper, cucumber, squash, watermelon, cantaloupe, newly seeded turf	10.5	ground	38	<1
		aerial	53	<1
established turf	15	ground	55	<1
		aerial	76	<1

* Endangered and non-endangered plants species have the same LOC which is 1.0.

From the available data, minimal adverse impact is expected for aquatic plants from the labeled uses of DCPA.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing DCPA. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing DCPA under the conditions specified in the RED. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of DCPA, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of DCPA and to determine that DCPA can be used without resulting in unreasonable adverse effects to humans and the environment, if used according to the labels as amended by this RED. The Agency therefore finds that all products containing DCPA as the active ingredient are eligible for reregistration under the conditions specified in this RED. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of DCPA are eligible for reregistration under the conditions specified in this RED, it should be understood that the Agency may take additional appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing DCPA, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient DCPA, the Agency has sufficient information on the health effects of DCPA and on its potential for causing adverse effects in fish and wildlife and the environment.

The Agency concludes that products containing DCPA for all non-turf uses are eligible for reregistration. The Agency has determined that such DCPA products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency is unable to make an eligibility decision regarding the use of DCPA on turf at this time. The Agency has identified several risks of regulatory concern associated with DCPA's turf use. These risks include carcinogenic risk (from DCPA and its impurities) to children playing on lawns post-treatment, carcinogenic risk posed through contaminated drinking water, chronic risks to wild mammalian species (including endangered species), and acute risks to estuarine and freshwater mollusks. The Agency will conduct a risk-benefits assessment before determining whether DCPA's use on turf is eligible for reregistration. The Agency will also refine some of the risk estimates, as a final report regarding leaching of DCPA and its metabolites to groundwater will be submitted to the Agency during the summer of 1996.

The Agency will announce the eligibility decision for the turf use through a Federal Register Notice, as an amendment to this document.

C. Regulatory Position

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

1. Tolerance Discussion

a. HCB and dioxin/furans

Although DCPA end-use formulations may contain minute amounts of HCB and dioxin/furans as impurities, tolerances for contaminants are not established on food commodities. The Food and Drug Administration (FDA) and the U.S. Department of Agriculture routinely monitors the food supply. Unacceptable levels of such contaminants would be identified by the FDA and affected crops would be removed from the market. However, the FDA monitoring program to date has not found any crops treated with DCPA to show residues of HCB.

b. DCPA Tolerance Reassessment

Tolerances are currently established for DCPA in or on beans, peas, cantaloupes, corn, cottonseed, cress, cucumbers, eggplant, garlic, honeydew melons, horseradish, lettuce, onions (green and dry bulbs), peppers, pimentos, potatoes, rutabagas, soybeans, squash (summer and winter), strawberries, sweet potato, tomatoes, turnips, *Brassica* (cole), watermelon, yams, and radish.

Tolerances Listed Under 40 CFR §180.185(a):

The tolerances listed in 40 CFR §180.185(a) are for combined residues of DCPA and its metabolites monomethyl tetrachloroterephthalic acid (MTP) and tetrachloroterephthalic acid

(TPA). A summary of the DCPA tolerance reassessment and modifications in commodity definitions are presented in Table 30.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.185(a) for the following commodities: beans which include black-eyed peas (succulent and dried), cantaloupes, cottonseed, cress, cucumbers, eggplant, garlic, honeydew melons, horseradish, onions, peppers, pimentos, potatoes, squash (summer and winter), strawberries, sweet potatoes, yams, tomatoes, turnips, brassica leafy vegetables, and watermelons.

ISK Biosciences Corp. is not supporting uses of DCPA on lettuce, soybeans, corn and rutabagas. EPA will reassess the existing tolerances for residues in/on these crops on completion of the review of the confined/field rotational crop studies. However, preliminary examination of these studies indicates the need for inadvertent residue tolerance on crops rotated to DCPA-treated fields.

Tolerances Listed Under 40 CFR §180.185(b)

The tolerances listed in 40 CFR §180.185(b) are for a regional registration as defined in 40 CFR §180.1(n) for the combined residues of DCPA and its metabolites MTP and TPA in/on radish roots and tops. Sufficient data are available to ascertain the adequacy of these established tolerances.

The tolerance for cress (upland) listed under 40 CFR §180.185(a) was established for a regional registration and should therefore be listed under 40 CFR §180.185(b).

New Tolerances Required Under 40 CFR §180.185:

The updated Livestock Feeds Table (9/95) indicates that data depicting residues of DCPA and its metabolites in or on cotton gin byproducts (gin trash), cowpea forage, and hay are required. The registrant must propose tolerances for these commodities once adequate data have been submitted and evaluated. In lieu of tolerances on cowpea commodities, the registrant may restrict the use of DCPA on beans to those varieties that are used for human consumption only.

Tolerances for animal commodities have not been established. The available ruminant metabolism and poultry feeding studies indicate that tolerances may be needed. The need for tolerances for animal commodities will be determined following review of the required data on poultry metabolism and ruminant feeding studies.

New Tolerances Proposed Under 40 CFR §180.185(b):

A tolerance for parsley at four ppm, with a regional registration for California only, has been proposed for the combined residues of DCPA and its metabolites MTP and TPA. The petitioner has been required to submit residue data for DCPA residues in/on parsley flakes processed from DCPA-treated parsley.

Table 30: Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR 180.185(a):			
Beans, field dry Beans, mung, dry Beans, snap, succulent Peas, southern, black-eyed	2	2	A single tolerance for residues in/on beans (dried and succulent) is appropriate/*Beans, dried and succulent*
Cantaloupes	1	1	---
Corn, field (forage and fodder) Corn, sweet (forage and fodder) Corn, pop (forage and fodder)	0.4	TBD	No registered uses exist. Tolerances will be reassessed in conjunction with review of field rotational crop studies.
Corn, sweet (K+CWHR) Corn, grain (including field and pop)	0.05		
Cottonseed	0.2	0.2	*Cotton, undelinted seed*
Cress, upland	1	1	Tolerance should be appropriately listed under 40 CFR §180.185(b).
Cucumbers	1	1	---
Eggplant	1	1	---
Garlic	1	1	---
Honeydew melons	1	1	---
Horseradish	2	2	---
Lettuce	2	TBD	No registered uses exist. Tolerances will be reassessed in conjunction with review of field rotational crop studies.
Onions (green and dry bulbs)	1	1	---
Peppers	2	2	---
Pimentos	2	Revoke	The *peppers* tolerance applies to pimentos. A separate pimentos tolerance is not necessary.
Potatoes	2	2	---
Rutabagas	2	TBD	No registered uses exist. Tolerances will be reassessed in conjunction with review of field rotational crop studies.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Soybeans	2	TBD	No registered uses exist. Tolerances will be reassessed in conjunction with review of field rotational crop studies.
Squash (summer and winter)	1	1	---
Strawberries	2	2	---
Sweet potato	2	2	---
Tomatoes	1	1	---
Turnips, greens	5	5	*Turnip, tops*
Turnip, root	2	2	---
Vegetables, leafy, *Brassica* (cole)	5	5	---
Watermelon	1	1	---
Yams	2	2	---
Tolerances listed under 40 CFR 180.185(b):			
Radish, root	2	2	---
Radish, tops	15	15	---
New Tolerances Required under 40 CFR 180.185:			
Cowpea, forage	None	TBD	Data are required.
Cowpea, hay	None	TBD	Data are required.
Cotton gin, byproducts	None	TBD	Data are required.
New Tolerances Proposed under 40 CFR 180.185(b)			
Parsley	None	TBD	A 4 ppm tolerance with regional registration has been proposed (PP#0E3883). Additional data are required.

Codex Harmonization

No maximum residue limits (MRLs) for DCPA have been established by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

2. Tolerance Revocations and Import Tolerances

During the Agency's reregistration process, the registrant decided not to support the use of DCPA on lettuce, soybeans, corn, and rutabagas. The use of DCPA on these four crops has been voluntarily cancelled. Normally, once a pesticide use is no longer registered in the U.S., the related pesticide residue tolerance is no longer needed. It is the Agency's policy to propose revocation of a tolerance following the deletion of a related food use from a registration, or

following the cancellation of a related food-use registration. The Agency has the responsibility under FFDCA to revoke a tolerance on the grounds that the Agency cannot conclude that the tolerance is protective of public health.

However, in the case of DCPA, the Agency is not seeking revocation of these tolerances, as it normally would under the above policy. The registrant is supporting rotational crop tolerances for these four commodities, thereby allowing DCPA residues which result from use on registered crops previously grown in the same field. The reassessed tolerances will be determined once field rotational crop residue data has been submitted to the Agency and reviewed. Subsequently, the tolerances of DCPA on these four commodities may be significantly reduced.

The Agency recognizes, however, that interested parties may want to retain a tolerance which is higher than the rotational crop tolerance (yet to be determined) in the absence of a U.S. registration, to allow legal importation of treated food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, the Agency requires the same product chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. In addition, the Agency requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that the Agency requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance.

Parties interested in supporting an existing DCPA tolerance as an import tolerance should ensure that all of the data noted above are available to the Agency, so that the Agency may determine whether maintenance of the tolerance would be protective of the public health.

3. Regulation of DCPA Impurities

The Agency requires pesticide registrants to establish a certified upper limit for each "impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product" (40 CFR part 158.175). These certified limits, once accepted by the Agency, become legally binding levels representing the maximum allowable contamination of associated DCPA formulations. The Agency has identified HCB and all of the 15 dioxin/furan congeners for which DCPA was analyzed as being of toxicological significance.

There is an existing certified upper limit for HCB of 0.3% and a preliminary certified upper limit for the 2,3,7,8-TCDD congener. However, the registrant must propose certified upper limits for each of the remaining dioxin/furans for which a positive detection was reported to the Agency.

4. Dietary Risk

Acute dietary risk assessments were not necessary since there were no acute toxicological endpoints of concern for DCPA or its impurities. Chronic and carcinogenic dietary risk was

assessed, however, due to exposure to DCPA, HCB, and dioxin/furans. Chronic risk estimates for the U.S. population and all subgroups were well below 100% of the RfD for DCPA, HCB, and dioxin/furans. Based on these estimates, the Agency concludes that DCPA use does not pose a significant chronic dietary risk.

Carcinogenic risk estimates for exposure to DCPA, HCB, and dioxin/furans through food were 3.5×10^{-7}, 7×10^{-7}, and 7×10^{-8}, respectively. All of these risk estimates are within the range (zero to 1×10^{-6}) generally considered to be negligible by the Agency. Thus, the Agency concludes that DCPA use does not pose a significant excess lifetime cancer risk.

5. Drinking Water Risk

Risk due to exposure to DCPA and its metabolites which have been detected in ground and surface water was assessed. The Agency is concerned that the public may be exposed to DCPA and its metabolites through drinking water. Since there is no Maximum Contaminant Level (MCL) established for DCPA or its metabolites, there is no enforceable federal regulatory oversight of DCPA and its metabolites in public drinking water systems. Therefore, the Agency assumed that the public may be exposed to the contamination levels found in ground and surface water.

The Agency's Office of Water has established a Health Advisory (HA) for DCPA at 4000 ppb. Although not enforceable, a HA benchmarks the concentration of DCPA in drinking water that is not expected to cause any adverse non-carcinogenic effects over a lifetime with a margin of safety. The current HA was calculated using an RfD of 0.5 mg/kg/day based on a 1963 two year rat study. Newer studies reviewed in this document have led to the RfD being lowered to 0.01 mg/kg/day.

If a new HA were to be calculated with the revised RfD of 0.01 mg/kg/day, the HA would likely decrease to 70 ppb. The Agency calculated this lowered HA estimate based on the following formula, which uses default assumptions for body weight, amount of water consumed, and the relative source contribution for DCPA exposure.

$$\frac{\text{RfD}(70\text{ kg})(0.2\text{ RSC})}{(2\text{ L/day})} = 70\text{ ug/l (ppb)}$$

The information regarding the reevaluation of DCPA's RfD will be forwarded to the Office of Water for HA recalculation as resources permit.

The Agency assessed both chronic (non-cancer) and carcinogenic risk due to exposure to DCPA and its metabolites through contaminated ground and surface water. The Agency used annual contamination averages from five geographic regions as potential drinking water exposure values. The highest annual average was 50 ppb in New York from a turf study. Although this represents approximately 71% of the HA, it only corresponds to 11% of RfD. Even if part of this

population were exposed to the maximum 3% of the RfD from other dietary sources, the chronic dietary risk would still be considered minimal.

Individual excess lifetime cancer risk from the New York turf site was 1.7×10^{-6}. The next highest risk estimate is based on data from Suffolk County, New York. The risk estimate from that site is 9.7×10^{-7}. DCPA's registrant has voluntarily withdrawn from selling the product in Suffolk, New York. Exposure values from all other sites resulted in risks below the Agency's cancer benchmark of 1×10^{-6}.

Based on these estimates, the Agency concludes that DCPA and its metabolites do not currently pose a significant cancer or chronic non-cancer risk from *non-turf* uses to the overall U.S. population from exposure through contaminated drinking water.

6. Contamination of Water Resources and Mitigation Measures

One of DCPA's metabolites, TPA, is known to leach to groundwater. TPA has been a frequently detected pesticide residue in groundwater studies. The Agency is continuing to require all DCPA products to bear a groundwater advisory statement.

In addition, the registrant has voluntarily agreed to limit the manufacture of DCPA technical grade active ingredient for use within the U.S. to current production levels. This will help to ensure that contamination rates do not significantly increase in the future. Since DCPA is produced intermittently, the production limit will be set at the average of the last three production campaigns, allowing for a 5% variance. The Agency will enforce this production cap through review of manufacture data which the registrant is required to submit under FIFRA, Section 7. The registrant will produce no more than the agreed upon limit every 3 calendar years, beginning in January, 1997.

The registrant has also voluntarily agreed to drop the fall turf application from their labels in order to reduce the usage of DPCA. This will lower the maximum application rate on turf from 15 lbs. active ingredient/Acre to 12 lbs. active ingredient/Acre. There are additional groundwater data due to the Agency in the summer of 1996. Once those data are reviewed, the Agency will reassess potential drinking water risk and evaluate the need for additional groundwater protection measures.

Through the reregistration process, the Agency has also identified concerns for the contamination of surface water by DCPA. Consequently, the Agency is requiring all DCPA products to bear a surface water advisory statement as well. Refer to Section V of this document for the language of the groundwater and surface water advisories.

7. Occupational Risk

Risk assessments were performed to assess the individual excess lifetime cancer risk from DCPA and HCB resulting from occupational exposure to DCPA. The Agency will not generally

allow non-dietary risks to exceed 10^{-4}, except in cases where EPA has determined that benefits exceed the risks.

The highest risk for both commercial applicators and private applicators (farm owners) is associated with the use of the wettable powder formulation. For the commercial applicator, the risk for DCPA was estimated to be 7.5×10^{-5} and for HCB (in DCPA) to be 1.9×10^{-4}. The Agency is requiring mixer/loader/applicators using DCPA wettable powders to wear a dust-mist respirator fitted with a TC-21 filter to mitigate these risks. Wearing a dust-mist respirator reduces the risks to 4.0×10^{-5} and 1.3×10^{-4} for DCPA and HCB, respectively.

For the private applicator, the risk for DCPA was estimated to be 1.6×10^{-6} and for HCB (in DCPA) to be 4.6×10^{-6}. The Agency concludes DCPA does not pose a significant individual excess lifetime cancer risk for occupational (commercial and private) applicators.

Risk from exposure to DCPA and HCB through worker reentry into a cucumber field was assessed. Harvesting cucumbers one day after application resulted in risk estimates of 1.8×10^{-4} for DCPA and 3.2×10^{-4} for HCB. Longer reentry periods only minimally reduced risk estimates. However, the Agency believes that the worker exposures are overestimates. These scenarios were based solely on a foliar dissipation study, not on dermal exposure studies. DCPA's registrant is a member of a task force which will address dermal exposure for hand labor tasks required by various crops, such as cucumber harvesting. The risk assessment will be refined when the task force submits it dermal exposure data.

Only rough estimates of risk for occupational exposure to dioxin/furans were calculated, since there are no foliar dissipation or dermal absorption data for dioxin/furans. The Registration Standard required foliar dissipation data for both HCB and dioxin/furans. However, the registrant asserted that the dioxin/furan data could not be provided due to the unavailability of analytical methodology to detect the expected levels of dioxin/furans. The Agency agreed that the theoretical residue level was lower than 1991 analytical methods could detect.

The wettable powder scenario produced the highest dioxin/furan risk for mixer/loader/applicators with a 1.6×10^{-6} estimate. Workers entering the cucumber harvesting field at zero days after treatment were estimated to be exposed to a 8×10^{-6} risk. Both of these risk estimates should be considered as overestimates since conservative assumptions were made in estimating these exposures.

8. Residential Risk

Risks to children playing on a treated lawn were assessed for exposure to DCPA and HCB. These risks were estimated by assuming a child would be exposed to a DCPA product applied to their lawn once a year. The exposure is assumed to be present for 14 continuous days following treatment. The scenario presumed a child might play outdoors several times a day and not receive a bath until 10 hours after the first play period. It was further assumed that children

between the ages of 2 and 6 weigh 17 kilograms and weigh 31 kilograms between the ages of 6 and 12.

The resulting risks from DCPA and HCB to children playing on an irrigated lawn are 5.6 x 10^{-7} and 3.9 x 10^{-7}, respectively. The risks from DCPA and HCB to children playing on non-irrigated lawns are 2.0 x 10^{-6} and 2.7 x 10^{-6}, respectively. Based in part on these estimates, the Agency has decided to assess the benefits from turf use before making an eligibility decision. However, to reduce risks to children in the interim period, the Agency is requiring DCPA labels to recommend residential lawns be watered after DCPA product use and that reentry not occur until the grass has dried.

The rough estimation of risk from dioxin/furans to children playing on non-irrigated lawn one hour after treatment is 3.9 x 10^{-7}. Again, dioxin/furan risk values could be overestimated since neither foliar dissipation or dermal absorption data are available for dioxin/furans.

9. Ecological Effects (Non-Endangered Species)

Current risk estimates indicate minimal acute risks to birds from DCPA use. However, there is uncertainty regarding the actual LC_{50} values available for birds. To address this concern, the Agency is requiring a dietary study using mallard ducks. In addition, long-term exposure to birds is possible; yet there are no data on DCPA to assess chronic effects to birds. Consequently, the Agency is requiring avian reproduction studies using the mallard duck and bobwhite quail so that chronic effects to birds can be assessed.

Levels of Concern (LOCs) regarding chronic effects to mammals are exceeded for all four use scenarios. In the three crop scenarios, the risk is overstated because DCPA is applied as a pre-emergent herbicide, when the land is free of vegetation. If the crop has emerged, DCPA sprays would be directed past the foliage to treat the bare ground. Therefore, the Agency does not expect to see substantial mammalian exposure to DCPA through grazing on or near cropland.

The remaining use for which the mammalian chronic LOC is exceeded is turf. The restricted use LOC for freshwater and estuarine mollusks is also exceeded by the turf use, aerial application. In the interim period while the Agency assesses benefits from the turf use, spray drift advisory language is being required which may mitigate the risk to mollusk species.

Numerical estimates of risk were not calculated for terrestrial and semi-aquatic nontarget plant species. Since little or no effect was seen at 9 lbs a.i./acre application rate in the toxicity study, LOCs are not likely to be exceeded. Since it is unlikely that a herbicide would not affect plant species, the Agency is requiring additional testing of sensitive species in the areas of vegetative vigor and seedling emergence. Minimal adverse impact is expected for aquatic plants from DCPA use.

10. Endangered Species

The Agency has concerns about the exposure of threatened and endangered mammal and mollusk species to DCPA as discussed above in the Section III. Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use limitations 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 existing or 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.

11. Spray Drift

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on DCPA product labels/labeling as specified in Section V of this document. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift. Actions taken to reduce spray drift will help to mitigate contamination of surface water, reduce risk to estuarine species, and reduce harm to nontarget crops and plants.

12. Labeling Rationale

THE WORKER PROTECTION STANDARD (WPS)

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 label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within the scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

Current registered uses of DCPA include uses within the scope as well as some uses outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Those that are outside the scope of the WPS include:

- on plants grown for other than commercial or research purposes, which may include homeowner uses; and

- on plants 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. (However, pesticides used on sod farms **are** covered by the WPS).

Compliance with the WPS

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

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products 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, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by any person.

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

Current labels for end-use products containing DCPA do not include engineering control requirements for mixers, loaders, or applicators, such as closed mixing systems or closed tractor cabs.

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

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- # In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
- # These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
- # The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for DCPA. For handlers, the exposure/risk assessments assumed that chemical-resistant gloves were worn in the following handler scenarios: (1) mixers/loaders using liquid formulations, (2) mixers/loaders using wettable powder formulations, (3) mixer/loader/applicators applying by shaker can, and (4) mixers/loaders/applicators applying by backpack sprayer. Therefore, chemical-resistant gloves will be required for occupational handlers in these scenarios.

EPA notes that the only data available for assessing exposure for cultivator mounted granular spreaders (scenario V) were studies in which the applicator was inside an enclosed cab. The risk levels for this exposure scenario are quite low (9.4×10^{-9} for DCPA and 3.1×10^{-8} for HCB for private applicators; and 9.4×10^{-8} for DCPA and 3.1×10^{-7} for HCB for commercial applicators); therefore, enclosed tractor cabs will not be required for application of DCPA by cultivator mounted granular spreaders.

WPS and NonWPS Uses:

Since potential handler exposure is similar for WPS and nonWPS uses, there is only one set of active-ingredient-based minimum (baseline) PPE requirements for occupational uses of DCPA (specified in Section V). These requirements must be followed in the labeling of all DCPA end-use products intended primarily for occupational use.

Homeowner-Use Products

EPA is not establishing minimum (baseline) handler PPE for DCPA end-use products that are intended primarily for homeowner uses, because the Agency has determined that the frequency, duration, and degree of exposure by such users do not warrant such risk mitigation measures.

Entry Restrictions

Occupational-Use Products (WPS Uses)

Current registered uses of DCPA include uses within the scope, as well as uses outside the scope of the Worker Protection Standard for Agricultural Pesticides (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 REIs established by the Agency prior to the promulgation of the WPS: (1) product-specific REIs established on the basis of adequate data, and (2) interim REIs that are longer than those that would be established under the WPS.

For occupational end-use products containing DCPA as an active ingredient, a 12-hour restricted-entry interval will be established for each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The basis for this recommendation is that DCPA is categorized as toxicity category IV for acute dermal toxicity, category IV for acute oral toxicity, category III for acute inhalation toxicity, category III for eye irritation potential, and category IV for dermal irritation and the results of the post-application risk assessment for agricultural crops indicates that regulatory action beyond the 12-hour REI is not warranted. However, since DCPA and HCB are both quantifiable carcinogens, DCPA is not a candidate for reducing the REI from 12 hours to 4 hours.

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 is 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 determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since DCPA is classified as category IV for skin irritation potential and IV for acute dermal toxicity, and EPA has determined that no regulatory action must be taken due to the acute effects or other adverse effects of DCPA, the PPE for dermal protection required for early entry is the minimum early-entry PPE permitted under the WPS: coveralls, chemical-resistant gloves, socks, and shoes. Since DCPA is classified as toxicity category III for eye irritation potential, no protective eyewear is required.

WPS Notification Statement:

Under the WPS, the labels of some pesticide products must require employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The reregistration process also may decide that a product requires this type of "double notification."

EPA has determined that double notification is not required for DCPA end-use products.

Occupational-Use Products (NonWPS Uses)

Since EPA has concerns about immediate post-application exposures to persons after nonWPS occupational uses of DCPA, it is establishing entry restrictions for all nonWPS occupational uses of DCPA end-use products. For specific requirements, refer to Section V of this document.

Homeowner-Use Products

Since EPA has concerns about immediate post-application exposures to persons after homeowner applications of DCPA, it is establishing entry restrictions for all homeowner uses of DCPA end-use products. For specific requirements, refer to Section V of this document.

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing DCPA. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of DCPA for the above eligible uses has been reviewed and determined to be substantially complete. However, confirmatory data are required in the areas of residue chemistry, ecological effects, and occupational exposure, as listed below. The Data Call-In Notice in the Appendices outlines the specific data requirements and the time frames for submission of the data.

Guideline	Study
133-3	Post-application dermal passive dosimetry exposure
133-4	Post-application inhalation passive dosimetry exposure
231	Dermal exposure study
232	Inhalation exposure study
171-4(b)	Poultry Metabolism
171-4(e)	Storage Stability
171-4(j)	Cattle Feeding study
171-4(j)	Poultry Feeding study (on reserve pending review of poultry metabolism study)
71-4(a)	Avian Reproduction - Quail
71-4(b)	Avian Reproduction - Mallard duck
123-1(a)	Seedling emergence
123-1(b)	Vegetative vigor (using sensitive species)

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 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.

2. Labeling Requirements for End-Use Products

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain DCPA, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain DCPA, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use (WPS and nonWPS)

Minimum (Baseline) PPE/Engineering Control Requirements

EPA is establishing minimum (baseline) PPE for some occupational uses of DCPA. These minimum (baseline) PPE are listed below. PPE for all formulations not listed below will be based on the toxicity of the end-use products as assessed during product reregistration.

For liquid concentrate formulations:
Mixers and loaders must wear:
--Long-sleeve shirt and long pants,
--Socks plus shoes,
--Chemical-resistant gloves*.

For wettable powder formulations:
Mixers, loaders, and applicators must wear:
--Long-sleeve shirt and long pants,
--Socks plus shoes,
--Chemical-resistant gloves*.
--a dust mist respirator with a TC-21C filter

For applications using a shaker can or backpack sprayer:
Applicators must wear:
--Long-sleeve shirt and long pants,
--Socks plus shoes,
--Chemical-resistant gloves*.

* For the glove statement, use the statement established for DCPA through the instructions in Supplement Three of PR Notice 93-7.

Determining PPE Requirements for End-use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment 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 requirements 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.

Products Intended Primarily for Homeowner Use

Minimum (baseline) PPE Requirements

EPA is not establishing active-ingredient-based minimum (baseline) handler PPE for DCPA end-use products that are intended primarily for homeowner use.

Determining PPE Requirements for End-Use Product Labels

Any necessary PPE for each DCPA end-use product intended primarily for homeowner use will be established on the basis of the end-use product's acute toxicity category.

Placement in Labeling

The personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

Entry Restrictions

For **sole-active-ingredient** end-use products that contain DCPA, the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain DCPA, the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. 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 on all DCPA end-use products.

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:

-- coveralls,
-- chemical-resistant gloves, and
-- shoes plus 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:

The Agency is establishing the following entry restrictions for nonWPS occupational uses of DCPA end-use products:

For liquid applications:

"Do not enter or allow others to enter the treated area until sprays have dried."

For granular applications:

"Do not enter or allow others to enter the treated area until dusts have settled. If soil incorporation is required following the application, do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete. If the incorporation is accomplished by watering-in, do not enter or allow others to enter the treated area until the surface is dry following the watering-in."

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 restrictions in that box.

If no WPS uses are on the label -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Products Intended Primarily for Homeowner Use

Entry restrictions: The Agency is establishing the following entry restrictions for all homeowner uses of DCPA end-use products:

Entry Restrictions for Home Use Products

For liquid and granular formulations:

"This product must be watered in following application. Do not allow persons or pets to enter the treated area until the grass is dry following watering-in."

Placement in labeling: Place the appropriate entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Other Labeling Requirements for End-Use Products

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing DCPA that are intended primarily for occupational use:

Application Restrictions:

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

User Safety Requirements:

{Registrants: select this if coveralls are required for pesticide handlers on the end-use product label:}

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

{Registrants: select this always:}

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

User Safety Recommendations:

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."

Engineering Controls:

"When handlers use closed systems, or enclosed cabs or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the

handler PPE requirements may be reduced or modified as specified in the WPS."

Soil Incorporation Statement:

Registrants must add the following statement to their labeling in the "Agricultural Use Requirements" box immediately following the restricted entry interval:

"Exception: if the product is soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

Products Intended Primarily for Home Use

Application Restrictions

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

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."

{Registrants: select this only if gloves and/or protective eyewear are required for homeowner users:}

- "Users should remove protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. Keep and wash protective clothing and equipment separately from other laundry."

ADDITIONAL LABELING REQUIREMENTS

The use directions for DCPA on beans prohibit grazing in treated areas and the feeding of treated plant material or refuse to livestock. Under current Agency policy, label restrictions prohibiting the feeding of bean forage and straw/hay to livestock are inappropriate. The registrant must delete restrictions prohibiting the feeding of bean forage and hay/straw to livestock from all labels. However, the registrant may restrict the uses of DCPA on beans to those varieties that are used for human consumption only.

When end-use product DCIs are developed (e.g., at issuance of the RED), EPA should require that all end-use product labels (e.g., multiple active ingredient labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

3. Groundwater Advisory

All DCPA end-use products must continue to bear the following groundwater advisory:

Tetrachloroterephthalic acid, a breakdown product of Dacthal, is known to leach through soil as a result of agricultural and turf uses and has been found in groundwater which may be used for drinking water. Users are advised not to apply Dacthal to sand or loamy sand soils where the water table (groundwater) is close to the surface and where those soils are very permeable, i.e. well drained. Your local agricultural agencies can provide further information on the type of soil in your area and the location of groundwater used for drinking water.

a. Surface Water Advisory

All DCPA end-use products must bear the following surface water advisory:

DCPA can contaminate surface water through spray drift. Under some conditions, DCPA may also have a high potential to contaminate surface water through runoff (via both dissolution in runoff water and adsorption to eroding soil) for several weeks post-application. Users are advised not to apply Dacthal to poorly draining or wet soils with readily visible sloping towards adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow groundwater, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and highly erodible soils.

b. Spray Drift Labeling

The following language must be placed on each label for products which can be applied aerially:

> Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.
>
> The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer-most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

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

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

INFORMATION ON DROPLET SIZE

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

CONTROLLING DROPLET SIZE

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

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

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

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

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

BOOM LENGTH

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

APPLICATION HEIGHT

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

SWATH ADJUSTMENT

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

WIND

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

TEMPERATURE AND HUMIDITY

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

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes

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

SENSITIVE AREAS

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

C. Tolerance Revocation and Import Tolerances

The use of DCPA on pimentos is being voluntarily canceled as part of the Agency's reregistration eligibility decision regarding this pesticide. It is the Agency's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration. As a result, any parties interested in supporting the tolerance/regulation for import purposes in the absence of a registered U.S. use should notify the Agency as soon as possible.

In responding, the Agency will provide detailed information on the outstanding data requirements for these tolerances and/or regulations. The Agency will consider commitments made to generate data to support such tolerances/regulations and the timeliness of data submissions in its assessment of whether the tolerances/regulations should be retained. Persons interested in establishing a new tolerance for import purposes only, or retaining a current tolerance for import purposes following cancellation of the related use, must submit a petition, along with the appropriate supporting data.

D. Existing Stocks

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

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

VI. APPENDICES

APPENDIX A - Table of Use Patterns Subject to Reregistration

Appendix A is 169 pages long and is not being included in this RED. Copies of Appendix A are available upon request per the instructions in Appendix E.

GUIDE TO APPENDIX B

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

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	DATA GAP
61-2A	Start. Mat. & Mnfg. Process	ALL	00156951, 40958804, 41054801, 41241801, DATA GAP
61-2B	Formation of Impurities	ALL	00156951, 40958808
62-1	Preliminary Analysis	ALL	Partially Satisfied
62-2	Certification of limits	ALL	DATA GAP
62-3	Analytical Method	ALL	DATA GAP
63-2	Color	ALL	41054802
63-3	Physical State	ALL	40958812
63-4	Odor	ALL	40958814
63-5	Melting Point	ALL	41054804
63-6	Boiling Point	ALL	WAIVED
63-7	Density	ALL	40958816
63-8	Solubility	ALL	41155701, 40958818
63-9	Vapor Pressure	ALL	41054805, 40958819
63-10	Dissociation Constant	ALL	WAIVED
63-11	Octanol/Water Partition	ALL	40958820
63-12	pH	ALL	40958821
63-13	Stability	ALL	41155703
63-14	Oxidizing/Reducing Action	ALL	DATA GAP
63-15	Flammability		N/A
63-16	Explodability	ALL	41155703
63-17	Storage stability	ALL	40958822
63-18	Viscosity		N/A
63-19	Miscibility		N/A
63-20	Corrosion characteristics	ALL	DATA GAP

REQUIREMENT		USE PATTERN	CITATION(S)
63-21	Dielectric breakdown volt		N/A
64-1	Submittal of Samples		N/A
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	ALL	41155705
71-1B	Acute Avian Oral - Quail/Duck TEP		N/A
71-2A	Avian Dietary - Quail	ALL	41155706
71-2B	Avian Dietary - Duck	ALL	41155707
71-3	Wild Mammal Toxicity		N/A
71-4A	Avian Reproduction - Quail	A, B, C, D, E, F, J, K	DATA GAP
71-4B	Avian Reproduction - Duck	A, B, C, D, E, F, J, K	DATA GAP
71-5A	Simulated Field Study		RESERVED
71-5B	Actual Field Study		RESERVED
72-1A	Fish Toxicity Bluegill	A, B, C, D, E, F, J, K	41054827
72-1B	Fish Toxicity Bluegill - TEP		N/A
72-1C	Fish Toxicity Rainbow Trout	ALL	00107142, 41054826
72-1D	Fish Toxicity Rainbow Trout-TEP	ALL	41054826
72-2A	Invertebrate Toxicity	ALL	40098001
72-2B	Invertebrate Toxicity - TEP	ALL	40098001
72-3A	Estuarine/Marine Toxicity - Fish	ALL	40098001
72-3B	Estuarine/Marine Toxicity - Mollusk	A, B, C, D, E, F, J, K	40098001
72-3C	Estuarine/Marine Toxicity - Shrimp	A, B, C, D, E, F, J, K	40098001
72-3D	Estuarine/Marine Toxicity Fish-TEP		N/A

REQUIREMENT		USE PATTERN	CITATION(S)
72-3E	Estuarine/Marine Toxicity Mollusk - TEP		N/A
72-3F	Estuarine/Marine Toxicity Shrimp - TEP		N/A
72-4A	Early Life Stage Fish		N/A
72-4B	Life Cycle Invertebrate		N/A
72-5	Life Cycle Fish		N/A
72-6	Aquatic Organism Accumulation		N/A
72-7A	Simulated Field - Aquatic Organisms		N/A
72-7B	Actual Field - Aquatic Organisms		N/A
122-1A	Seed Germination/Seedling Emergence	A, B, C, D, E, F, J, K	41054829, 41564901, PARTIALLY SATISFIED
122-1B	Vegetative Vigor	A, B, C, D, E, F, G, J, K	41440101, SUPPLEMENTAL
122-2	Aquatic Plant Growth	A, B, C, D, E, F, G, J, K	41054829, 41155714, 42882401, 41836101, 42836102, 42836103
123-1A	Seed Germination/Seedling Emergence	A, B, C, D, E, F, G, J, K	DATA GAP
123-1B	Vegetative Vigor	A, B, C, D, E, F, G, J, K	DATA GAP
123-2	Aquatic Plant Growth		RESERVED
124-1	Terrestrial Field		RESERVED
124-2	Aquatic Field		RESERVED
141-1	Honey Bee Acute Contact	A, B, C, D, J, K	00009181
141-2	Honey Bee Residue on Foliage		N/A
141-5	Field Test for Pollinators		N/A

REQUIREMENT		USE PATTERN	CITATION(S)
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	ALL	41054808, 41054808, 41054809, 41155710
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	41054811, 41054812, 41054813, 41155709
81-3	Acute Inhalation Toxicity - Rat	ALL	00127905, 41054814, 41155710, 41750101
81-4	Primary Eye Irritation - Rabbit	ALL	00163578, 41054815, 41054816, 41155711
81-5	Primary Dermal Irritation - Rabbit	ALL	41054817, 41054818, 41155712
81-6	Dermal Sensitization - Guinea Pig	ALL	00150207
81-7	Acute Delayed Neurotoxicity - Hen		N/A
82-1A	90-Day Feeding - Rodent	ALL	00100773, 41064801, 41767901, 41790901
82-1B	90-Day Feeding - Non-rodent		N/A
82-2	21-Day Dermal - Rabbit/Rat	ALL	41231803, 41231804, 41231805
82-3	90-Day Dermal - Rodent		N/A
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	ALL	40958701, 41349101, 41750102
83-1B	Chronic Feeding Toxicity - Non-Rodent	ALL	00083584
83-2A	Oncogenicity - Rat	ALL	42731001
83-2B	Oncogenicity - Mouse	ALL	40958701, 41349101
83-3A	Developmental Toxicity - Rat	ALL	00160685
83-3B	Developmental Toxicity - Rabbit	ALL	41054820, 41064802, 41838301
83-4	2-Generation Reproduction - Rat	ALL	41750103, 41905201

REQUIREMENT		USE PATTERN	CITATION(S)
84-2A	Gene Mutation (Ames Test)	ALL	00100775
84-2B	Structural Chromosomal Aberration	ALL	41054821, 41054822, 41054823, 41054824, 41054825, 41038301
84-4	Other Genotoxic Effects	ALL	41054822, 41054824, 42038301
85-1	General Metabolism	ALL	42155501, 42155502. 42155503, 42723201, 43052201, 43723202, 43723203
85-2	Dermal Penetration	ALL	42651501, 42651502
86-1	Domestic Animal Safety		N/A
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	Foliar Residue Dissipation	A, B, C, D, H, I, J, K	DATA GAP [DCI'S issued September 1992 and October 1995]
132-1B	Soil Residue Dissipation		N/A
133-3	Dermal Passive Dosimetry Exposure	A, B, C, D, H, I, J, K	DATA GAP [DCI's issued September 1992 and October 1995]
133-4	Inhalation Passive Dosimetry Exposure	A, B, C, D, H, J, K, L, M, N, O	DATA GAP [DCI issued October 1995
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	All	00114648
161-2	Photodegradation - Water	A, B, C, D, E, F, G, J	41508607

REQUIREMENT		USE PATTERN	CITATION(S)
161-3	Photodegradation - Soil	A, B, C, J	41508608
161-4	Photodegradation - Air		N/A
162-1	Aerobic Soil Metabolism	A, B, C, D, E, H, I, J, K	41648801
162-2	Anaerobic Soil Metabolism	A, B, C	00114651, 41648802
162-3	Anaerobic Aquatic Metabolism		N/A
162-4	Aerobic Aquatic Metabolism		N/A
163-1	Leaching/Adsorption/ Desorption	A, B, C, D, E, F, G, H, I, J, K	41648803. 41648804, 41648805, 42262602
163-2	Volatility - Lab		RESERVED
163-3	Volatility - Field		RESERVED
164-1	Terrestrial Field Dissipation	A, B, H, I	IN REVIEW
164-2	Aquatic Field Dissipation		RESERVED
164-3	Forest Field Dissipation		RESERVED
164-5	Long Term Soil Dissipation	A, B, C, D, E, J, K	IN REVIEW
165-1	Confined Rotational Crop	A, B, C, D	IN REVIEW
165-2	Field Rotational Crop		RESERVED
165-3	Accumulation - Irrigated Crop		N/A
165-4	Bioaccumulation in Fish	A, B, C, D, E, F, G, J	41155716, 41197602
165-5	Bioaccumulation - Aquatic NonTarget		N/A
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		RESERVED
202-1	Drift Field Evaluation		RESERVED

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	A, B, D, H, K, L	00058377, 00114677, 40259101, 42298301, 42298302
171-4B	Nature of Residue - Livestock	A, B, D, H, L	00057629, DATA GAP
171-4C	Residue Analytical Method - Plants	A, B, D, E, K, L	00010026, 00114642, 00114643, 00114644, OO114654, 00121864, 00123748, 40259001, 41550701, 42155505, 42155506, 42155507, 42155508, 42155509, 42155510, 42218904, 42218905, 42245701, 42271801, 42218901, 42218906, 43406401, DATA GAP
171-4D	Residue Analytical Method - Animal	A, B, D, H, K	00058378, 00114643, 43406401, DATA GAP
171-4E	Storage Stability	A, B, D, E, H, K, L	00121864, 41750107, 42218901, 42444001, 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	A, B, D, H, K	00038919, 00058378, 00114643, DATA GAP
171-4K	Crop Field Trials		
	Root and Tuber Vegetables Group		
	- Horseradish	A, B, D, H, K	00058377

REQUIREMENT	USE PATTERN	CITATION(S)
- Potatoes	A, B, D, H, K	00018299, 00090259, 00114678
- Radish, root	A, B, D, H, K	00121864
- Rutabagas	A, B, D, H, K	PP3E1388
- Sweet potato	A, B, D, H, K	00090259, 00114678, 00114681
- Turnip root	A, B, D, H, K	00090259
- Yams	A, B, D, H, K	00090259, 00114678, 00114681
Leaves of Roots and Tuber Vegetables Groups		
- Radish, tops	A, B, D, H, K	00121864
- Turnip, tops	A, B, D, H, K	00090259
Bulb Vegetables Group		
- Garlic	A, B, D, H, K	00090259, 00130562
- Onions (green and dry bulb)	A, B, D, H, K	00090259, 00114631, 00114681, 42155508
Leafy Vegetables Group (except Brassica)		
- Cress, upland	A, B, D, H, K	00033087, 00090259
- Lettuce	A, B, D, H, K	00033087, 00090259, 42155506
- Parsley	A, B, D, H, K	41550701, DATA GAP
Brassica Leafy Vegetables Group		

REQUIREMENT	USE PATTERN	CITATION(S)
- Broccoli	A, B, D, H, K	00090259, 00114681
- Brussels sprouts	A, B, D, H, K	00090259
- Cabbage	A, B, D, H, K	00090259, 00114681
- Cauliflower	A, B, D, H, K	00090259, 00114681
- Collards	A, B, D, H, K	00090259
- Kale	A, B, D, H, K	00090259
- Mustard greens	A, B, D, H, K	00090259
Legume Vegetables (succulent or dried) Group		
- Beans, succulent and dried	A, B, D, H, K	00017975, 00058377, 00090259, 00114678
- Peas	A, B, D, H, K	00017975, 00058377, 00090259, 00114678
- Soybeans	A, B, D, H, K	00017975, 00058377, 00090259, 00115678
Foliage of Legume Vegetables Group		
- Beans, forage and hay/straw	A, B, D, H, K	0090259, 00114678, Data Gap
- Soybeans, forage and hay	A, B, D, H, K	00058377
Fruiting Vegetables (except cucurbits) Group		
- Eggplant	A, B, D, H, K	00090259, 42155510
- Peppers	A, B, D, H, K	00090259, 00114680, 42155510

REQUIREMENT	USE PATTERN	CITATION(S)
- Pimentos	A, B, D, H, K	00090259, 00114680, 42155510
- Tomatoes	A, B, D, H, K	00090259, 00114679, 00114680, 42218904, 42218905
Cucurbit Vegetables Group		
- Cucumbers	A, B, D, H, K	00090259, 42155507,
- Cantaloups	A, B, D, H, K	00090259, 42218903
- Honeydew melons	A, B, D, H, K	00090259, 42218903
- Squash (summer and winter)	A, B, D, H, K	00090259, 42245701
- Watermelons	A, B, D, H, K	00090259, 42218903
Small Fruits and Berries Group		
- Strawberries	A, B, D, H, K	00090259, 42155509
Cereal Grains Group		
- Corn, field and pop	A, B, D, H, K	00072099
Forage, Fodder, and Straw of Cereal Grains Groups		
- Corn, forage and fodder	A, B, D, H, K	00072099
Miscellaneous Commodities		
- Cottonseed	A, B, D, H, K	00114642, 00114678, 00114681
171-4(l) Magnitude of the Residues in Processed Food/Feed		
- Beans (succulent/dried)	A, B, D, H, K	42218902
- Corn, field	A, B, D, H, K	

REQUIREMENT		USE PATTERN	CITATION(S)
	- Cottonseed	A, B, D, H, K	42218906
	- Potato	A, B, D, H, K	42271801
	- Soybeans	A, B, D, H, K	
	- Tomatoes	A, B, D, H, K	42218905
171-5	Reduction of Residues		N/A
171-6	Proposed Tolerance		N/A
171-7	Support for Tolerance		N/A
171-13	Analtyical 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.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

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

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

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

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

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

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

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

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
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 Citation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (Telephone number: 703-605-6000).

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

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

a. Voluntary Cancellation -

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

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

b. Use Deletion -

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

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

c. Generic Data Exemption -

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

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

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

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

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

Data Exemption cannot be selected as an option for responding to product specific data requirements.

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

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

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

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

Option 1. Developing Data

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

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

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

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

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

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

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

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

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

Option 4. Submitting an Existing Study

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

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

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

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

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

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

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

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

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

Option 5. Upgrading a Study

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

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

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

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

Option 6. Citing Existing Studies

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

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

2. Product Specific Data

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

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

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

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

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

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

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

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

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

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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

a. Low Volume/Minor Use Waiver

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

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

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

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

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

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

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

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

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

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

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

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

b. Request for Waiver of Data

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

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

2. Product Specific Data

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

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

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

and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

DCPA DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 DCPA. 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) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Citation Forms in replying to this DCPA Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for DCPA are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on DCPA 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 DCPA 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 Venus Eagle at (703) 308-8045.

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

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

RE: **DCPA**

DCPA DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 DCPA. 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 3), (4) a list of registrants receiving this DCI (Attachment 5), and (5) the Cost Share and Data Citation Forms in replying to this DCPA Generic Data Call In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for DCPA are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on DCPA are needed. These data are needed to fully complete the reregistration of all eligible DCPA 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 Jill Bloom at (703) 308-8019.

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

Jill Bloom, Chemical Review Manager
Reregistration Branch, II
Special Review and Registration Division (7508C)
Office of Pesticiafde Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: DCPA

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FOR BOTH MUP and EUP products

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

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

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

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum,

or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

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

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

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

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

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

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

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must

be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

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

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

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

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

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

EPA'S BATCHING OF DACTHAL; DCPA; DIMETHYL TETRACHLORO-TEREPHTHALATE; PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

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

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

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

he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5, or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Sixty-two registered products were found which contain DCPA as the active ingredient.

There are only two wettable powder products. One, EPA Reg. # 228-222, will not be batched because it contains 25% AI. The other, EPA Reg. # 4-296, will not be batched because it is a wettable powder product containing 75% AI.

One product, EPA Reg. # 50534-10, will not be batched because of insufficient CSF.

The remaining products have been placed into three Tables.
Table I consisting of three batches in accordance with the active and inert ingredients, type of formulation, and current labeling. Table II consists of unbatched fertilizer products. Table III consists of miscellaneous unbatched products.

TABLE I

Batch 1 identifies concentrated and/or technical products.

Batch 2 identifies those products with low levels of DCPA.

Batch 3 identifies emulsifiable concentrate products.

TABLE II

These fertilizer-containing products are not being batched. Formulations may change, which would also change their acute toxicity. The Agency is developing a policy for the regulation of fertilizers containing pesticides.

TABLE III

Miscellaneous unbatched products.

TABLE I

Batch 1 (Concentrates)

A representative database for these products is summarized here:

Data Required	Toxicity Category	Classification
Acute Oral (§81-1)	IV	A
Acute Dermal (81-2)	III	A
Acute Inhal. (81-3)	IV	A
Eye Irr. (§81-4)	III	A
Dermal Irr. (§81-5)	IV	A
Dermal Sens. (§81-6)	Non-sensitizing	A

* Denotes data review available

EPA Reg. #	% Active Ingredient	Formulation Type
2-296	90.0	G
407-338	100.0	G
677-290	75.3	G
9198-24	75.3	G
11684-2	75.3	G
50534-1	79.0	G
50534-20	79.0	G
50534-28	75.0	G
50534-113*	90.0	G

Batch 2 (low levels of DCPA).

A representative database for these products is summarized here:

Data Required	Toxicity Category	Classification
Acute Oral (§81-1)	IV	G
Acute Dermal (81-2)	IV	G
Acute Inhal. (81-3)	IV	G
Eye Irr. (§81-4)	IV	G
Dermal Irr. (§81-5)	IV	G
Dermal Sens. (§81-6)	Non-sensitizing	G

* Denotes data review available

EPA Reg. #	% Active Ingredient	Formulation Type
4-300	6.7	G
16-42	6.7	G
239-2532*	13.3	G
407-317	5.0	G
407-416	6.7	G
512-237	9.2	G
538-128	5.0	G
538-235	5.0	G
557-1998	5.75	G
572-193	6.4	G
572-237	6.9	G
588-235	5.6	G
769-911	5.6	G
802-441	5.0	G
829-165	5.0	G
961-273	5.0	G
961-278	6.7	G
1386-610	5.0	G
2217-617	2.5	G
7001-275	5.0	G
8590-377	5.0	G
8660-22	7.0	G
8660-33	2.3	G
8660-62	2.5	G
8660-98	5.0	G
9198-1	2.9	G

EPA Reg. #	% Active Ingredient	Formulation Type
10107-82	5.0	G
10107-86	2.5	G
10370-272	3.4	G
32802-14	3.5	G
32802-27	5.6	G
33955-474	2.5	G
50534-3	5.6	G
50534-17	3.4	G

Batch 3 (emulsifiable concentrate products).

There are no toxicity data for these products.

EPA Reg. #	% Active Ingredient	Type of Formulation
1769-246	6.0	EC
50534-187	21.4	EC

TABLE II (Fertilizers; not batched)

Table II identifies products that were not batchable, but were not placed in a "No Batch" group; The products in this category contain significant amounts of fertilizer. Many of these fertilizer components may change from time to time as the registrant sees fit.

Since as much as 96% of these formulations may vary, the Agency does not believe it is possible to batch them. Since the formulation of these products may vary, a set of acute toxicity studies conducted on one of them may not consistently represent that product's acute toxicity potential. Registrants of products in Table II who certify that they do not vary the inert or fertilizer components of their products may request that their products be batched with other similar products. The Agency does not believe that requesting acute data on all fertilizer combinations is sensible. The Agency is in the process of developing a policy that addresses labeling for these products.

No toxicity studies are available for these products.

EPA Reg. #	% Active Ingredient	Formulation Type
238-157	3.9	G
538-87	6.3	G
802-503	4.0	G
802-576	2.6	G
3234-28	3.3	G
7001-270	3.1	G
8378-13	5.0	G
3442-TNE	3.2	G
8660-100	6.7	G
10107-4	2.0	G
11648-2	1.2	G
32802-6	4.7	G
32802-17	6.8	G
42957-83	4.7	G

TABLE III Miscellaneous products not batched, either because of dissimilar concentrations of AI or lack of formulation information.

No toxicity studies are available for these products.

EPA Reg. #	%AI	Type of Formulation
228-222	25.0	WP
4-296	75.0	WP
50534-10	NA	NA

Key

EC = Emulsifiable Concentrate
FC = Flowable Concentrate
G = Granular
WP = Wettable Powder

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

THIS PAGE MUST BE REMOVED PRIOR TO PRINTING AND REPLACED WITH THE REGISTRANT LISTING PRODUCED FROM THE DCI MODULE.

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	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	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, D.C. 20460

Certification of Offer to Cost Share in the Development of Data

Form Approved
OMB No. 2070-0106, 2070-0057
Approval Expires 3-31-99

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

Please fill in blanks below:

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

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 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 firms 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)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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	Date	Typed or Printed Name and Title

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	EPA Reg No./File Symbol	Page of
Applicant's/Registrant's Name & Address	Product	

Ingredient

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					

Signature	Name and Title	Date

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public File Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date			EPA Reg No./File Symbol		Page of
Applicant's/Registrant's Name & Address			Product		
Ingredient					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Signature			Name and Title		Date

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

INSTRUCTIONS FOR DATA MATRIX

INSTRUCTIONS: Identify all data submitted or cited and all submitters from whom permission has been received or to whom offers to pay have been sent by entering sufficient information in the attached matrix (photocopy and attach additional pages as necessary). Complete all columns; omission of essential information will delay approval of the registration/reregistration. On each page enter the date, Applicant's/Registrant's name, EPA Registration Number or application file symbol of the product, ingredient, page number, and total number of pages.

The Data Compensation Form entitled "Certification with Respect to Citation of Data" and the Data Matrix will be publicly available, except for the Guideline Reference Number, Guideline Study Name, and MRID Number columns after the registration/reregistration of this product has been granted or once this form is received in response to a Data-Call-In Notice. However, the information in the Guideline Reference Number, Guideline Study Name, and MRID Number columns is available through the Freedom of Information Act in association with the EPA Registration Number.

Ingredient: Identify the active ingredient(s) in this product for which data are cited. The active ingredient(s) are to be identified by entering the chemical name and the CAS registry number. Begin a new page for each separate active ingredient for which data are cited. If bridging data from a related chemical or representative test compound are cited, enter the identity of that chemical/representative test compound including the EPA Registration Number/File Symbol if appropriate.

If the cite-all method is used for all data supporting this particular ingredient, enter "CITE-ALL" in the Guideline Reference Number column and leave the Guideline Study Name column blank. If the cite-all method is used for a particular Guideline Reference Number enter "CITE-ALL" in the MRID Number column on the line for that Guideline Reference Number. In either case, enter all submitters to whom offers to pay have been sent on subsequent lines. [Note: if the selective method of support is used and written authorization (letter of permission) is provided, the individual Guideline Reference Number, Guideline Study Name, and MRID Number columns must still be completed.] Otherwise:

Guideline Reference Number: Enter on separate lines in numerical order the Guideline Reference Numbers from 40 CFR Part 158 for all studies cited to support the registration/reregistration for this ingredient.

Guideline Study Name: For each Guideline Reference Number cited, enter the corresponding Guideline Study Name.

MRID Number: For each individual study cited in support of a Guideline Reference Number and Guideline Study Name, enter the Master Record Identification (MRID) Number listed in the Pesticide Document Management System (PDMS). Enter only one MRID Number on each line. Note that more than one MRID Number may be required per Guideline Reference Number. Note: Occasionally a study required to maintain a registration/reregistration is not associated with a Guideline Reference Number and Guideline Study Name. In such case, enter the MRID Number(s) for the study(ies).

Submitter: Using the most recent Data Submitters List, identify the Original Data Submitter with their current address for each study cited. The EPA assigned company number or other abbreviation may be used. Clearly explain any variations (alternate addresses, data owners not on the Data Submitters List, etc.) in footnotes to this table.

Status: Enter one of the following codes for each study cited, as appropriate:

OWN:	I am the Original Data Submitter for this study.
EXC:	I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.
PER:	I have obtained the permission of the Original Data Submitter to use this study in support of this application.
OLD:	The study was submitted more than 15 years ago and all periods of compensation have expired.
PL:	The study is in the public literature.
PAY:	I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).
GAP:	This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.
FOR:	I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.

Note: If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

APPENDIX E. List of Available Related Documents

The following is a list of available documents for DCPA that may 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 are available on our website at www.epa.gov/REDs, or contact Connie Childress at (703) 308-8074.

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 DCPA.

The following documents are part of the Administrative Record for DCPA 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

3. Appendix A - Table of Use Patterns Subject to Reregistration